***In the Senate of the United States,***

*October 26 (legislative day, September 22), 2000.*

*Resolved,* That the bill from the House of Representatives (H.R. 2498) entitled ''An Act to amend the Public Health Service Act to provide for recommendations of the Secretary of Health and Human Services regarding the placement of automatic external defibrillators in Federal buildings in order to improve survival rates of individuals who experience cardiac arrest in such buildings, and to establish protections from civil liability arising from the emergency use of the devices.'', do pass with the following

# AMENDMENT:

Strike out all after the enacting clause and insert:

***SECTION 1. SHORT TITLE; TABLE OF CONTENTS.***

*(a) SHORT TITLE.—This Act may be cited as the ''Public Health Improvement Act''.*

*(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:*

# *TITLE I—EMERGING THREATS TO PUBLIC HEALTH*

### *SEC. 101. SHORT TITLE.*

*This title may be cited as the "Public Health Threats and Emergencies Act".*

### *SEC. 102. AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT.*

*Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by striking section 319 and inserting the following:*

***"SEC. 319. PUBLIC HEALTH EMERGENCIES.***

*"(a) EMERGENCIES.—If the Secretary determines, after consultation with such public health officials as may be necessary, that—*

*"(1) a disease or disorder presents a public health emergency; or*

*"(2) a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists,*

*the Secretary may take such action as may be appropriate to respond to the public health emergency, including making grants and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder as described in paragraphs (1) and (2).*

*"(b) PUBLIC HEALTH EMERGENCY FUND.—*

*"(1) IN GENERAL.—There is established in the Treasury a fund to be designated as the 'Public Health Emergency Fund' to be made available to the Secretary without fiscal year limitation to carry out subsection (a) only if a public health emergency has been declared by the Secretary under such subsection. There is authorized to be appropriated to the Fund such sums as may be necessary.*

*"(2) REPORT.—Not later than 90 days after the end of each fiscal year, the Secretary shall prepare*

*and submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Commerce and the Committee on Appropriations of the House of Representatives a report describing—*

*"(A) the expenditures made from the Public Health Emergency Fund in such fiscal year; and*

*"(B) each public health emergency for which the expenditures were made and the activities undertaken with respect to each emergency which was conducted or supported by expenditures from the Fund.*

*"(c) SUPPLEMENT NOT SUPPLANT.—Funds appropriated under this section shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities under this section.*

***"SEC. 319A. NATIONAL NEEDS TO COMBAT THREATS TO PUBLIC HEALTH.***

*"(a) CAPACITIES.—*

*"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary, and such Administrators, Directors, or Commissioners, as may be appropriate, and in collaboration with State and local health officials, shall establish reasonable capacities that are appropriate for na-*

*tional, State, and local public health systems and the personnel or work forces of such systems. Such capacities shall be revised every 10 years, or more frequently as the Secretary determines to be necessary.*

*"(2) BASIS.—The capacities established under paragraph (1) shall improve, enhance or expand the capacity of national, state and local public health agencies to detect and respond effectively to significant public health threats, including major outbreaks of infectious disease, pathogens resistant to antimicrobial agents and acts of bioterrorism. Such capacities may include the capacity to—*

*"(A) recognize the clinical signs and epidemiological characteristic of significant outbreaks of infectious disease;*

*"(B) identify disease-causing pathogens rapidly and accurately;*

*"(C) develop and implement plans to provide medical care for persons infected with disease-causing agents and to provide preventive care as needed for individuals likely to be exposed to disease-causing agents;*

*"(D) communicate information relevant to significant public health threats rapidly to local,*

*State and national health agencies, and health care providers; or*

*"(E) develop or implement policies to prevent the spread of infectious disease or antimicrobial resistance.*

*"(b) SUPPLEMENT NOT SUPPLANT.—Funds appropriated under this section shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities under this section.*

*"(c) TECHNICAL ASSISTANCE.—The Secretary shall provide technical assistance to the States to assist such States in fulfilling the requirements of this section.*

*"(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $4,000,000 for fiscal year 2001, and such sums as may be necessary for each subsequent fiscal year through 2006.*

***"SEC. 319B. ASSESSMENT OF PUBLIC HEALTH NEEDS.***

*"(a) PROGRAM AUTHORIZED.—Not later than 1 year after the date of enactment of this section and every 10 years thereafter, the Secretary shall award grants to States, or consortia of 2 or more States or political subdivisions of States, to perform, in collaboration with local public health agencies, an evaluation to determine the extent to which the States or local public health agencies can achieve the capacities applicable to State and local public health*

*agencies described in subsection (a) of section 319A. The Secretary shall provide technical assistance to States, or consortia of 2 or more States or political subdivisions of States, in addition to awarding such grants.*

*"(b) PROCEDURE.—*

*"(1) IN GENERAL.—A State, or a consortium of 2 or more States or political subdivisions of States, may contract with an outside entity to perform the evaluation described in subsection (a).*

*"(2) METHODS.—To the extent practicable, the evaluation described in subsection (a) shall be completed by using methods, to be developed by the Secretary in collaboration with State and local health officials, that facilitate the comparison of evaluations conducted by a State to those conducted by other States receiving funds under this section.*

*"(c) REPORT.—Not later than 1 year after the date on which a State, or a consortium of 2 or more States or political subdivisions of States, receives a grant under this subsection, such State, or a consortium of 2 or more States or political subdivisions of States, shall prepare and submit to the Secretary a report describing the results of the evaluation described in subsection (a) with respect to such State, or consortia of 2 or more States or political subdivisions of States.*

*"(d) SUPPLEMENT NOT SUPPLANT.—Funds appropriated under this section shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities under this section.*

*"(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $45,000,000 for fiscal year 2001, and such sums as may be necessary for each subsequent fiscal year through 2003.*

***"SEC. 319C. GRANTS TO IMPROVE STATE AND LOCAL PUBLIC HEALTH AGENCIES.***

*"(a) PROGRAM AUTHORIZED.—The Secretary shall award competitive grants to eligible entities to address core public health capacity needs using the capacities developed under section 319A, with a particular focus on building capacity to identify, detect, monitor, and respond to threats to the public health.*

*"(b) ELIGIBLE ENTITIES.—A State or political subdivision of a State, or a consortium of 2 or more States or political subdivisions of States, that has completed an evaluation under section 319B(a), or an evaluation that is substantially equivalent as determined by the Secretary under section 319B(a), shall be eligible for grants under subsection (a).*

*"(c) USE OF FUNDS.—An eligible entity that receives a grant under subsection (a), may use funds received under such grant to—*

*"(1) train public health personnel;*

*"(2) develop, enhance, coordinate, or improve participation in an electronic network by which disease detection and public health related information can be rapidly shared among national, regional, State, and local public health agencies and health care providers;*

*"(3) develop a plan for responding to public health emergencies, including significant outbreaks of infectious diseases or bioterrorism attacks, which is coordinated with the capacities of applicable national, State, and local health agencies and health care providers; and*

*"(4) enhance laboratory capacity and facilities.*

*"(d) REPORT.—No later than January 1, 2005, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Commerce and the Committee on Appropriations of the House of Representatives a report that describes the activities carried out under sections 319A, 319B, and 319C.*

*"(e) SUPPLEMENT NOT SUPPLANT.—Funds appropriated under this section shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities under this section.*

*"(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $50,000,000 for fiscal year 2001, and such sums as may be necessary for each subsequent fiscal year through 2006.*

***"SEC. 319D. REVITALIZING THE CENTERS FOR DISEASE CONTROL AND PREVENTION.***

*"(a) FINDINGS.—Congress finds that the Centers for Disease Control and Prevention have an essential role in defending against and combatting public health threats of the twenty-first century and requires secure and modern facilities that are sufficient to enable such Centers to conduct this important mission.*

*"(b) AUTHORIZATION OF APPROPRIATIONS.—For the purposes of achieving the mission of the Centers for Disease Control and Prevention described in subsection (a), for constructing new facilities and renovating existing facilities of such Centers, including laboratories, laboratory support buildings, health communication facilities, office buildings and other facilities and infrastructure, for better conducting the capacities described in section 319A, and for supporting related public health activities, there are authorized to be*

*appropriated $180,000,000 for fiscal year 2001, and such sums as may be necessary for each subsequent fiscal year through 2010.*

***"SEC. 319E. COMBATING ANTIMICROBIAL RESISTANCE.***

*"(a) TASK FORCE.—*

*"(1) IN GENERAL.—The Secretary shall establish an Antimicrobial Resistance Task Force to provide advice and recommendations to the Secretary and coordinate Federal programs relating to antimicrobial resistance. The Secretary may appoint or select a committee, or other organization in existence as of the date of enactment of this section, to serve as such a task force, if such committee, or other organization meets the requirements of this section.*

*"(2) MEMBERS OF TASK FORCE.—The task force described in paragraph (1) shall be composed of representatives from such Federal agencies, and shall seek input from public health constituencies, manufacturers, veterinary and medical professional societies and others, as determined to be necessary by the Secretary, to develop and implement a comprehensive plan to address the public health threat of antimicrobial resistance.*

*"(3) AGENDA.—*

*"(A) IN GENERAL.—The task force described in paragraph (1) shall consider factors the Secretary considers appropriate, including—*

*"(i) public health factors contributing to increasing antimicrobial resistance;*

*"(ii) public health needs to detect and monitor antimicrobial resistance;*

*"(iii) detection, prevention, and control strategies for resistant pathogens;*

*"(iv) the need for improved information and data collection;*

*"(v) the assessment of the risk imposed by pathogens presenting a threat to the public health; and*

*"(vi) any other issues which the Secretary determines are relevant to antimicrobial resistance.*

*"(B) DETECTION AND CONTROL.—The Secretary, in consultation with the task force described in paragraph (1) and State and local public health officials, shall—*

*"(i) develop, improve, coordinate or enhance participation in a surveillance plan to detect and monitor emerging antimicrobial resistance; and*

*"(ii) develop, improve, coordinate or enhance participation in an integrated information system to assimilate, analyze, and exchange antimicrobial resistance data between public health departments.*

*"(4) MEETINGS.—The task force described under paragraph (1) shall convene not less than twice a year, or more frequently as the Secretary determines to be appropriate.*

*"(b) RESEARCH AND DEVELOPMENT OF NEW ANTIMICROBIAL DRUGS AND DIAGNOSTICS.—The Secretary and the Director of Agricultural Research Services, consistent with the recommendations of the task force established under subsection (a), shall conduct and support research, investigations, experiments, demonstrations, and studies in the health sciences that are related to—*

*"(1) the development of new therapeutics, including vaccines and antimicrobials, against resistant pathogens;*

*"(2) the development or testing of medical diagnostics to detect pathogens resistant to antimicrobials;*

*"(3) the epidemiology, mechanisms, and pathogenesis of antimicrobial resistance;*

*"(4) the sequencing of the genomes of priority pathogens as determined by the Director of the National Institutes of Health in consultation with the task force established under subsection (a); and*

*"(5) other relevant research areas.*

*"(c) EDUCATION OF MEDICAL AND PUBLIC HEALTH PERSONNEL.—The Secretary, after consultation with the Assistant Secretary for Health, the Surgeon General, the Director of the Centers for Disease Control and Prevention, the Administrator of the Health Resources and Services Administration, the Director of the Agency for Healthcare Research and Quality, members of the task force described in subsection (a), professional organizations and societies, and such other public health officials as may be necessary, shall—*

*"(1) develop and implement educational programs to increase the awareness of the general public with respect to the public health threat of antimicrobial resistance and the appropriate use of antibiotics;*

*"(2) develop and implement educational programs to instruct health care professionals in the prudent use of antibiotics; and*

*"(3) develop and implement programs to train laboratory personnel in the recognition or identification of resistance in pathogens.*

*"(d) GRANTS.—*

*"(1) IN GENERAL.—The Secretary shall award competitive grants to eligible entities to enable such entities to increase the capacity to detect, monitor, and combat antimicrobial resistance.*

*"(2) ELIGIBLE ENTITIES.—Eligible entities for grants under paragraph (1) shall be State or local public health agencies, Indian tribes or tribal organizations, or other public or private nonprofit entities.*

*"(3) USE OF FUNDS.—An eligible entity receiving a grant under paragraph (1) shall use funds from such grant for activities that are consistent with the factors identified by the task force under subsection (a)(3), which may include activities that—*

*"(A) provide training to enable such entity to identify patterns of resistance rapidly and accurately;*

*"(B) develop, improve, coordinate or enhance participation in information systems by which data on resistant infections can be shared rapidly among relevant national, State, and*

*local health agencies and health care providers; and*

*"(C) develop and implement policies to control the spread of antimicrobial resistance.*

*"(e) GRANTS FOR DEMONSTRATION PROGRAMS.—*

*"(1) IN GENERAL.—The Secretary shall award competitive grants to eligible entities to establish demonstration programs to promote judicious use of antimicrobial drugs or control the spread of antimicrobial-resistant pathogens.*

*"(2) ELIGIBLE ENTITIES.—Eligible entities for grants under paragraph (1) may include hospitals, clinics, institutions of long-term care, professional medical societies, or other public or private nonprofit entities.*

*"(3) TECHNICAL ASSISTANCE.—The Secretary shall provide appropriate technical assistance to eligible entities that receive grants under paragraph (1).*

*"(f) SUPPLEMENT NOT SUPPLANT.—Funds appropriated under this section shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities under this section.*

*"(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section,*

*$40,000,000 for fiscal year 2001, and such sums as may be necessary for each subsequent fiscal year through 2006.*

***"SEC. 319F. PUBLIC HEALTH COUNTERMEASURES TO A BIOTERRORIST ATTACK.***

*"(a) WORKING GROUP ON PREPAREDNESS FOR ACTS OF BIOTERRORISM.—The Secretary, in coordination with the Secretary of Defense, shall establish a joint interdepartmental working group on preparedness and readiness for the medical and public health effects of a bioterrorist attack on the civilian population. Such joint working group shall—*

*"(1) coordinate research on pathogens likely to be used in a bioterrorist attack on the civilian population as well as therapies to treat such pathogens;*

*"(2) coordinate research and development into equipment to detect pathogens likely to be used in a bioterrorist attack on the civilian population and protect against infection from such pathogens;*

*"(3) develop shared standards for equipment to detect and to protect against infection from pathogens likely to be used in a bioterrorist attack on the civilian population; and*

*"(4) coordinate the development, maintenance, and procedures for the release of, strategic reserves of vaccines, drugs, and medical supplies which may be*

*needed rapidly after a bioterrorist attack upon the civilian population.*

*"(b) WORKING GROUP ON THE PUBLIC HEALTH AND MEDICAL CONSEQUENCES OF BIOTERRORISM.—*

*"(1) IN GENERAL.—The Secretary, in collaboration with the Director of the Federal Emergency Management Agency, the Attorney General, and the Secretary of Agriculture, shall establish a joint interdepartmental working group to address the public health and medical consequences of a bioterrorist attack on the civilian population.*

*"(2) FUNCTIONS.—Such working group shall—*

*"(A) assess the priorities for and enhance the preparedness of public health institutions, providers of medical care, and other emergency service personnel to detect, diagnose, and respond to a bioterrorist attack; and*

*"(B) in the recognition that medical and public health professionals are likely to provide much of the first response to such an attack, develop, coordinate, enhance, and assure the quality of joint planning and training programs that address the public health and medical consequences of a bioterrorist attack on the civilian population between—*

*"(i) local firefighters, ambulance personnel, police and public security officers, or other emergency response personnel; and*

*"(ii) hospitals, primary care facilities, and public health agencies.*

*"(3) WORKING GROUP MEMBERSHIP.—In establishing such working group, the Secretary shall act through the Assistant Secretary for Health and the Director of the Centers for Disease Control and Prevention.*

*"(4) COORDINATION.—The Secretary shall ensure coordination and communication between the working groups established in this subsection and subsection (a).*

*"(c) GRANTS.—*

*"(1) IN GENERAL.—The Secretary, in coordination with the working group established under subsection (b), shall, on a competitive basis and following scientific or technical review, award grants to or enter into cooperative agreements with eligible entities to enable such entities to increase their capacity to detect, diagnose, and respond to acts of bioterrorism upon the civilian population.*

*"(2) ELIGIBILITY.—To be an eligible entity under this subsection, such entity must be a State, po-*

*litical subdivision of a State, a consortium of 2 or more States or political subdivisions of States, or a hospital, clinic, or primary care facility.*

*"(3) USE OF FUNDS.—An entity that receives a grant under this subsection shall use such funds for activities that are consistent with the priorities identified by the working group under subsection (b), including—*

*"(A) training health care professionals and public health personnel to enhance the ability of such personnel to recognize the symptoms and epidemiological characteristics of exposure to a potential bioweapon;*

*"(B) addressing rapid and accurate identification of potential bioweapons;*

*"(C) coordinating medical care for individuals exposed to bioweapons; and*

*"(D) facilitating and coordinating rapid communication of data generated from a bioterrorist attack between national, State, and local health agencies, and health care providers.*

*"(4) COORDINATION.—The Secretary, in awarding grants under this subsection, shall—*

*"(A) notify the Director of the Office of Justice Programs, and the Director of the National*

*Domestic Preparedness Office annually as to the amount and status of grants awarded under this subsection; and*

*"(B) coordinate grants awarded under this subsection with grants awarded by the Office of Emergency Preparedness and the Centers for Disease Control and Prevention for the purpose of improving the capacity of health care providers and public health agencies to respond to bioterrorist attacks on the civilian population.*

*"(5) ACTIVITIES.—An entity that receives a grant under this subsection shall, to the greatest extent practicable, coordinate activities carried out with such funds with the activities of a local Metropolitan Medical Response System.*

*"(d) FEDERAL ASSISTANCE.—The Secretary shall ensure that the Department of Health and Human Services is able to provide such assistance as may be needed to State and local health agencies to enable such agencies to respond effectively to bioterrorist attacks.*

*"(e) EDUCATION.—The Secretary, in collaboration with members of the working group described in subsection (b), and professional organizations and societies, shall—*

*"(1) develop and implement educational programs to instruct public health officials, medical pro-*

*fessionals, and other personnel working in health care facilities in the recognition and care of victims of a bioterrorist attack; and*

*"(2) develop and implement programs to train laboratory personnel in the recognition and identification of a potential bioweapon.*

*"(f) FUTURE RESOURCE DEVELOPMENT.—The Secretary shall consult with the working group described in subsection (a), to develop priorities for and conduct research, investigations, experiments, demonstrations, and studies in the health sciences related to—*

*"(1) the epidemiology and pathogenesis of potential bioweapons;*

*"(2) the development of new vaccines or other therapeutics against pathogens likely to be used in a bioterrorist attack;*

*"(3) the development of medical diagnostics to detect potential bioweapons; and*

*"(4) other relevant research areas.*

*"(g) GENERAL ACCOUNTING OFFICE REPORT.—Not later than 180 days after the date of enactment of this section, the Comptroller General shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee*

*on Commerce and the Committee on Appropriations of the House of Representatives a report that describes—*

*"(1) Federal activities primarily related to research on, preparedness for, and the management of the public health and medical consequences of a bioterrorist attack against the civilian population;*

*"(2) the coordination of the activities described in paragraph (1);*

*"(3) the amount of Federal funds authorized or appropriated for the activities described in paragraph (1); and*

*"(4) the effectiveness of such efforts in preparing national, State, and local authorities to address the public health and medical consequences of a potential bioterrorist attack against the civilian population.*

*"(h) SUPPLEMENT NOT SUPPLANT.—Funds appropriated under this section shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities under this section.*

*"(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $215,000,000 for fiscal year 2001, and such sums as may be necessary for each subsequent fiscal year through 2006.*

***"SEC. 319G. DEMONSTRATION PROGRAM TO ENHANCE BIOTERRORISM TRAINING, COORDINATION, AND READINESS.***

*"(a) IN GENERAL.—The Secretary shall make grants to not more than three eligible entities to carry out demonstration programs to improve the detection of pathogens likely to be used in a bioterrorist attack, the development of plans and measures to respond to bioterrorist attacks, and the training of personnel involved with the various responsibilities and capabilities needed to respond to acts of bioterrorism upon the civilian population. Such awards shall be made on a competitive basis and pursuant to scientific and technical review.*

*"(b) ELIGIBLE ENTITIES.—Eligible entities for grants under subsection (a) are States, political subdivisions of States, and public or private non-profit organizations.*

*"(c) SPECIFIC CRITERIA.—In making grants under subsection (a), the Secretary shall take into account the following factors:*

*"(1) Whether the eligible entity involved is proximate to, and collaborates with, a major research university with expertise in scientific training, identification of biological agents, medicine, and life sciences.*

*"(2) Whether the entity is proximate to, and collaborates with, a laboratory that has expertise in the identification of biological agents.*

*"(3) Whether the entity demonstrates, in the application for the program, support and participation of State and local governments and research institutions in the conduct of the program.*

*"(4) Whether the entity is proximate to, and collaborates with, or is, an academic medical center that has the capacity to serve an uninsured or underserved population, and is equipped to educate medical personnel.*

*"(5) Such other factors as the Secretary determines to be appropriate.*

*"(d) DURATION OF AWARD.—The period during which payments are made under a grant under subsection (a) may not exceed five years. The provision of such payments shall be subject to annual approval by the Secretary of the payments and subject to the availability of appropriations for the fiscal year involved to make the payments.*

*" (e) SUPPLEMENT NOT SUPPLANT.—Grants under subsection (a) shall be used to supplement, and not supplant, other Federal, State, or local public funds provided for the activities described in such subsection.*

*"(f) GENERAL ACCOUNTING OFFICE REPORT.—Not later than 180 days after the conclusion of the demonstration programs carried out under subsection (a), the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate, and the Committee on Commerce and the Committee on Appropriations of the House of Representatives, a report that describes the ability of grantees under such subsection to detect pathogens likely to be used in a bioterrorist attack, develop plans and measures for dealing with such threats, and train personnel involved with the various responsibilities and capabilities needed to deal with bioterrorist threats.*

*"(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $6,000,000 for fiscal year 2001, and such sums as may be necessary through fiscal year 2006.".*

# *TITLE II—CLINICAL RESEARCH ENHANCEMENT*

***SEC. 201. SHORT TITLE.***

*This title may be cited as the "Clinical Research Enhancement Act of 1999".*

***SEC. 202. FINDINGS AND PURPOSE.***

*(a) FINDINGS.—Congress makes the following findings:*

*(1) Clinical research is critical to the advancement of scientific knowledge and to the development of cures and improved treatment for disease.*

*(2) Tremendous advances in biology are opening doors to new insights into human physiology, pathophysiology and disease, creating extraordinary opportunities for clinical research.*

*(3) Clinical research includes translational research which is an integral part of the research process leading to general human applications. It is the bridge between the laboratory and new methods of diagnosis, treatment, and prevention and is thus essential to progress against cancer and other diseases.*

*(4) The United States will spend more than $1,200,000,000,000 on health care in 1999, but the Federal budget for health research at the National Institutes of Health was $15,600,000,000 only 1 percent of that total.*

*(5) Studies at the Institute of Medicine, the National Research Council, and the National Academy of Sciences have all addressed the current problems in clinical research.*

*(6) The Director of the National Institutes of Health has recognized the current problems in clinical research and appointed a special panel, which rec-*

*ommended expanded support for existing National Institutes of Health clinical research programs and the creation of new initiatives to recruit and retain clinical investigators.*

*(7) The current level of training and support for health professionals in clinical research is fragmented, undervalued, and underfunded.*

*(8) Young investigators are not only apprentices for future positions but a crucial source of energy, enthusiasm, and ideas in the day-to-day research that constitutes the scientific enterprise. Serious questions about the future of life-science research are raised by the following:*

*(A) The number of young investigators applying for grants dropped by 54 percent between 1985 and 1993.*

*(B) The number of physicians applying for first-time National Institutes of Health research project grants fell from 1226 in 1994 to 963 in 1998, a 21 percent reduction.*

*(C) Newly independent life-scientists are expected to raise funds to support their new research programs and a substantial proportion of their own salaries.*

*(9) The following have been cited as reasons for the decline in the number of active clinical researchers, and those choosing this career path:*

*(A) A medical school graduate incurs an average debt of $85,619, as reported in the Medical School Graduation Questionnaire by the Association of American Medical Colleges (AAMC).*

*(B) The prolonged period of clinical training required increases the accumulated debt burden.*

*(C) The decreasing number of mentors and role models.*

*(D) The perceived instability of funding from the National Institutes of Health and other Federal agencies.*

*(E) The almost complete absence of clinical research training in the curriculum of training grant awardees.*

*(F) Academic Medical Centers are experiencing difficulties in maintaining a proper environment for research in a highly competitive health care marketplace, which are compounded by the decreased willingness of third party payers to cover health care costs for patients engaged in research studies and research procedures.*

*(10) In 1960, general clinical research centers were established under the Office of the Director of the National Institutes of Health with an initial appropriation of $3,000,000.*

*(11) Appropriations for general clinical research centers in fiscal year 1999 equaled $200,500,000.*

*(12) Since the late 1960s, spending for general clinical research centers has declined from approximately 3 percent to 1 percent of the National Institutes of Health budget.*

*(13) In fiscal year 1999, there were 77 general clinical research centers in operation, supplying patients in the areas in which such centers operate with access to the most modern clinical research and clinical research facilities and technologies.*

*(b) PURPOSE.—It is the purpose of this title to provide additional support for and to expand clinical research programs.*

***SEC. 203. INCREASING THE INVOLVEMENT OF THE NATIONAL INSTITUTES OF HEALTH IN CLINICAL RESEARCH.***

*Part B of title IV of the Public Health Service Act (42 U.S.C. 284 et seq.) is amended by adding at the end the following:*

***"SEC. 409C. CLINICAL RESEARCH.***

*"(a) IN GENERAL.—The Director of National Institutes of Health shall undertake activities to support and expand the involvement of the National Institutes of Health in clinical research.*

*"(b) REQUIREMENTS.—In carrying out subsection (a), the Director of National Institutes of Health shall—*

*"(1) consider the recommendations of the Division of Research Grants Clinical Research Study Group and other recommendations for enhancing clinical research; and*

*"(2) establish intramural and extramural clinical research fellowship programs directed specifically at medical and dental students and a continuing education clinical research training program at the National Institutes of Health.*

*"(c) SUPPORT FOR THE DIVERSE NEEDS OF CLINICAL RESEARCH.—The Director of National Institutes of Health, in cooperation with the Directors of the Institutes, Centers, and Divisions of the National Institutes of Health, shall support and expand the resources available for the diverse needs of the clinical research community, including inpatient, outpatient, and critical care clinical research.*

*"(d) PEER REVIEW.—The Director of National Institutes of Health shall establish peer review mechanisms to evaluate applications for the awards and fellowships pro-*

*vided for in subsection (b)(2) and section 409D. Such review mechanisms shall include individuals who are exceptionally qualified to appraise the merits of potential clinical research training and research grant proposals.''.*

***SEC. 204. GENERAL CLINICAL RESEARCH CENTERS.***

*(a) GRANTS.—Subpart 1 of part E of title IV of the Public Health Service Act (42 U.S.C. 287 et seq.) is amended by adding at the end the following:*

***''SEC. 481C. GENERAL CLINICAL RESEARCH CENTERS.***

*''(a) GRANTS.—The Director of the National Center for Research Resources shall award grants for the establishment of general clinical research centers to provide the infrastructure for clinical research including clinical research training and career enhancement. Such centers shall support clinical studies and career development in all settings of the hospital or academic medical center involved.*

*''(b) ACTIVITIES.—In carrying out subsection (a), the Director of National Institutes of Health shall expand the activities of the general clinical research centers through the increased use of telecommunications and telemedicine initiatives.*

*''(c) 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.''.*

*(b) ENHANCEMENT AWARDS.—Part B of title IV of the Public Health Service Act (42 U.S.C. 284 et seq.), as amended by section 203, is further amended by adding at the end the following:*

***"SEC. 409D. ENHANCEMENT AWARDS.***

*"(a) MENTORED PATIENT-ORIENTED RESEARCH CAREER DEVELOPMENT AWARDS.—*

*"(1) GRANTS.—*

*"(A) IN GENERAL.—The Director of the National Institutes of Health shall make grants (to be referred to as 'Mentored Patient-Oriented Research Career Development Awards') to support individual careers in clinical research at general clinical research centers or at other institutions that have the infrastructure and resources deemed appropriate for conducting patient-oriented clinical research.*

*"(B) USE.—Grants under subparagraph (A) shall be used to support clinical investigators in the early phases of their independent careers by providing salary and such other support for a period of supervised study.*

*"(2) APPLICATIONS.—An application for a grant under this subsection shall be submitted by an indi-*

*vidual scientist at such time as the Director may require.*

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

*"(b) MID-CAREER INVESTIGATOR AWARDS IN PATIENT-ORIENTED RESEARCH.—*

*"(1) GRANTS.—*

*"(A) IN GENERAL.—The Director of the National Institutes of Health shall make grants (to be referred to as 'Mid-Career Investigator Awards in Patient-Oriented Research') to support individual clinical research projects at general clinical research centers or at other institutions that have the infrastructure and resources deemed appropriate for conducting patient-oriented clinical research.*

*"(B) USE.—Grants under subparagraph (A) shall be used to provide support for mid-career level clinicians to allow such clinicians to devote time to clinical research and to act as mentors for beginning clinical investigators.*

*"(2) APPLICATIONS.—An application for a grant under this subsection shall be submitted by an individual scientist at such time as the Director requires.*

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

*"(c) GRADUATE TRAINING IN CLINICAL INVESTIGATION AWARD.—*

*"(1) IN GENERAL.—The Director of the National Institutes of Health shall make grants (to be referred to as 'Graduate Training in Clinical Investigation Awards') to support individuals pursuing master's or doctoral degrees in clinical investigation.*

*"(2) APPLICATIONS.—An application for a grant under this subsection shall be submitted by an individual scientist at such time as the Director may require.*

*"(3) LIMITATIONS.—Grants under this subsection shall be for terms of 2 years or more and shall provide stipend, tuition, and institutional support for individual advanced degree programs in clinical investigation.*

*"(4) DEFINITION.—As used in this subsection, the term 'advanced degree programs in clinical inves-*

*tigation' means programs that award a master's or Ph.D. degree in clinical investigation after 2 or more years of training in areas such as the following:*

*"(A) Analytical methods, biostatistics, and study design.*

*"(B) Principles of clinical pharmacology and pharmacokinetics.*

*"(C) Clinical epidemiology.*

*"(D) Computer data management and medical informatics.*

*"(E) Ethical and regulatory issues.*

*"(F) Biomedical writing.*

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

*"(d) CLINICAL RESEARCH CURRICULUM AWARDS.—*

*"(1) IN GENERAL.—The Director of the National Institutes of Health shall make grants (to be referred to as 'Clinical Research Curriculum Awards') to institutions for the development and support of programs of core curricula for training clinical investigators, including medical students. Such core curricula may include training in areas such as the following:*

*"(A) Analytical methods, biostatistics, and study design.*

*"(B) Principles of clinical pharmacology and pharmacokinetics.*

*"(C) Clinical epidemiology.*

*"(D) Computer data management and medical informatics.*

*"(E) Ethical and regulatory issues.*

*"(F) Biomedical writing.*

*"(2) APPLICATIONS.—An application for a grant under this subsection shall be submitted by an individual institution or a consortium of institutions at such time as the Director may require. An institution may submit only 1 such application.*

*"(3) LIMITATIONS.—Grants under this subsection shall be for terms of up to 5 years and may be renewable.*

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

***SEC. 205. LOAN REPAYMENT PROGRAM REGARDING CLINICAL RESEARCHERS.***

*Part G of title IV of the Public Health Service Act is amended by inserting after section 487E (42 U.S.C. 288–5) the following:*

***"SEC. 487F. LOAN REPAYMENT PROGRAM REGARDING CLINICAL RESEARCHERS.***

*"(a) IN GENERAL.—The Secretary, acting through the Director of the National Institutes of Health, shall establish a program to enter into contracts with qualified health professionals under which such health professionals agree to conduct clinical research, in consideration of the Federal Government agreeing to repay, for each year of service conducting such research, not more than $35,000 of the principal and interest of the educational loans of such health professionals.*

*"(b) APPLICATION OF PROVISIONS.—The provisions of sections 338B, 338C, and 338E shall, except as inconsistent with subsection (a) of this section, apply to the program established under subsection (a) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III.*

*"(c) FUNDING.—*

*"(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are au-*

*thorized to be appropriated such sums as may be necessary for each fiscal year.*

*"(2) AVAILABILITY.—Amounts appropriated for carrying out this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were made available.".*

***SEC. 206. DEFINITION.***

*Section 409 of the Public Health Service Act (42 U.S.C. 284d) is amended—*

*(1) by striking "For purposes" and inserting "(a) HEALTH SERVICE RESEARCH.—For purposes"; and*

*(2) by adding at the end the following:*

*"(b) CLINICAL RESEARCH.—As used in this title, the term 'clinical research' means patient oriented clinical research conducted with human subjects, or research on the causes and consequences of disease in human populations involving material of human origin (such as tissue specimens and cognitive phenomena) for which an investigator or colleague directly interacts with human subjects in an outpatient or inpatient setting to clarify a problem in human physiology, pathophysiology or disease, or epidemiologic or behavioral studies, outcomes research or health serv-*

*ices research, or developing new technologies, therapeutic interventions, or clinical trials.".*

***SEC. 207. OVERSIGHT BY GENERAL ACCOUNTING OFFICE.***

*Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Congress a reporting describing the extent to which the National Institutes of Health has complied with the amendments made by this title.*

# *TITLE III—RESEARCH LABORATORY INFRASTRUCTURE*

***SEC. 301. SHORT TITLE.***

*This title may be cited as the "Twenty-First Century Research Laboratories Act".*

***SEC. 302. FINDINGS.***

*Congress finds that—*

*(1) the National Institutes of Health is the principal source of Federal funding for medical research at universities and other research institutions in the United States;*

*(2) the National Institutes of Health has received a substantial increase in research funding from Congress for the purpose of expanding the national investment of the United States in behavioral and biomedical research;*

*(3) the infrastructure of our research institutions is central to the continued leadership of the United States in medical research;*

*(4) as Congress increases the investment in cutting-edge basic and clinical research, it is critical that Congress also examine the current quality of the laboratories and buildings where research is being conducted, as well as the quality of laboratory equipment used in research;*

*(5) many of the research facilities and laboratories in the United States are outdated and inadequate;*

*(6) the National Science Foundation found, in a 1998 report on the status of biomedical research facilities, that over 60 percent of research-performing institutions indicated that they had an inadequate amount of medical research space;*

*(7) the National Science Foundation reports that academic institutions have deferred nearly $11,000,000,000 in renovation and construction projects because of a lack of funds; and*

*(8) future increases in Federal funding for the National Institutes of Health must include increased support for the renovation and construction of extramural research facilities in the United States and the*

*purchase of state-of-the-art laboratory instrumentation.*

***SEC. 303. BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES.***

*Section 481A of the Public Health Service Act (42 U.S.C. 287a–2 et seq.) is amended to read as follows:*

***"SEC. 481A. BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES.***

*"(a) MODERNIZATION AND CONSTRUCTION OF FACILITIES.—*

*"(1) IN GENERAL.—The Director of NIH, acting through the Director of the Center, may make grants or contracts to public and nonprofit private entities to expand, remodel, renovate, or alter existing research facilities or construct new research facilities, subject to the provisions of this section.*

*"(2) CONSTRUCTION AND COST OF CONSTRUCTION.—For purposes of this section, the terms 'construction' and 'cost of construction' include the construction of new buildings and the expansion, renovation, remodeling, and alteration of existing buildings, including architects' fees, but do not include the cost of acquisition of land or off-site improvements.*

*"(b) SCIENTIFIC AND TECHNICAL REVIEW BOARDS FOR MERIT-BASED REVIEW OF PROPOSALS.—*

*"(1) IN GENERAL: APPROVAL AS PRECONDITION TO GRANTS.—*

*"(A) ESTABLISHMENT.—There is established within the Center a Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities (referred to in this section as the 'Board').*

*"(B) REQUIREMENT.—The Director of the Center may approve an application for a grant under subsection (a) only if the Board has under paragraph (2) recommended the application for approval.*

*"(2) DUTIES.—*

*"(A) ADVICE.—The Board shall provide advice to the Director of the Center and the advisory council established under section 480 (in this section referred to as the 'Advisory Council') in carrying out this section.*

*"(B) DETERMINATION OF MERIT.—In carrying out subparagraph (A), the Board shall make a determination of the merit of each application submitted for a grant under subsection (a), after consideration of the requirements established in subsection (c), and shall report the results of the determination to the Director of the*

*Center and the Advisory Council. Such determinations shall be conducted in a manner consistent with procedures established under section 492.*

*"(C) AMOUNT.—In carrying out subparagraph (A), the Board shall, in the case of applications recommended for approval, make recommendations to the Director and the Advisory Council on the amount that should be provided under the grant.*

*"(D) ANNUAL REPORT.—In carrying out subparagraph (A), the Board shall prepare an annual report for the Director of the Center and the Advisory Council describing the activities of the Board in the fiscal year for which the report is made. Each such report shall be available to the public, and shall—*

*"(i) summarize and analyze expenditures made under this section;*

*"(ii) provide a summary of the types, numbers, and amounts of applications that were recommended for grants under subsection (a) but that were not approved by the Director of the Center; and*

*"(iii) contain the recommendations of the Board for any changes in the administration of this section.*

*"(3) MEMBERSHIP.—*

*"(A) IN GENERAL.—Subject to subparagraph (B), the Board shall be composed of 15 members to be appointed by the Director of the Center, and such ad-hoc or temporary members as the Director of the Center determines to be appropriate. All members of the Board, including temporary and ad-hoc members, shall be voting members.*

*"(B) LIMITATION.—Not more than 3 individuals who are officers or employees of the Federal Government may serve as members of the Board.*

*"(4) CERTAIN REQUIREMENTS REGARDING MEMBERSHIP.—In selecting individuals for membership on the Board, the Director of the Center shall ensure that the members are individuals who, by virtue of their training or experience, are eminently qualified to perform peer review functions. In selecting such individuals for such membership, the Director of the Center shall ensure that the members of the Board collectively—*

*"(A) are experienced in the planning, construction, financing, and administration of entities that conduct biomedical or behavioral research sciences;*

*"(B) are knowledgeable in making determinations of the need of entities for biomedical or behavioral research facilities, including such facilities for the dentistry, nursing, pharmacy, and allied health professions;*

*"(C) are knowledgeable in evaluating the relative priorities for applications for grants under subsection (a) in view of the overall research needs of the United States; and*

*"(D) are experienced with emerging centers of excellence, as described in subsection (c)(2).*

*"(5) CERTAIN AUTHORITIES.—*

*"(A) WORKSHOPS AND CONFERENCES.—In carrying out paragraph (2), the Board may convene workshops and conferences, and collect data as the Board considers appropriate.*

*"(B) SUBCOMMITTEES.—In carrying out paragraph (2), the Board may establish subcommittees within the Board. Such subcommittees may hold meetings as determined necessary*

*to enable the subcommittee to carry out its duties.*

*"(6) TERMS.—*

*"(A) IN GENERAL.—Except as provided in subparagraph (B), each appointed member of the Board shall hold office for a term of 4 years. Any member appointed to fill a vacancy occurring prior to the expiration of the term for which such member's predecessor was appointed shall be appointed for the remainder of the term of the predecessor.*

*"(B) STAGGERED TERMS.—Members appointed to the Board shall serve staggered terms as specified by the Director of the Center when making the appointments.*

*"(C) REAPPOINTMENT.—No member of the Board shall be eligible for reappointment to the Board until 1 year has elapsed after the end of the most recent term of the member.*

*"(7) COMPENSATION.—Members of the Board who are not officers or employees of the United States shall receive for each day the members are engaged in the performance of the functions of the Board compensation at the same rate received by members of*

*other national advisory councils established under this title.*

*"(c) REQUIREMENTS FOR GRANTS.—*

*"(1) IN GENERAL.—The Director of the Center may make a grant under subsection (a) only if the applicant for the grant meets the following conditions:*

*"(A) The applicant is determined by such Director to be competent to engage in the type of research for which the proposed facility is to be constructed.*

*"(B) The applicant provides assurances satisfactory to the Director that—*

*"(i) for not less than 20 years after completion of the construction involved, the facility will be used for the purposes of the research for which it is to be constructed;*

*"(ii) sufficient funds will be available to meet the non-Federal share of the cost of constructing the facility;*

*"(iii) sufficient funds will be available, when construction is completed, for the effective use of the facility for the research for which it is being constructed; and*

*"(iv) the proposed construction will expand the applicant's capacity for research,*

*or is necessary to improve or maintain the quality of the applicant's research.*

*"(C) The applicant meets reasonable qualifications established by the Director with respect to—*

*"(i) the relative scientific and technical merit of the applications, and the relative effectiveness of the proposed facilities, in expanding the capacity for biomedical or behavioral research and in improving the quality of such research;*

*"(ii) the quality of the research or training, or both, to be carried out in the facilities involved;*

*"(iii) the congruence of the research activities to be carried out within the facility with the research and investigator manpower needs of the United States; and*

*"(iv) the age and condition of existing research facilities.*

*"(D) The applicant has demonstrated a commitment to enhancing and expanding the research productivity of the applicant.*

*"(2) INSTITUTIONS OF EMERGING EXCELLENCE.—From the amount appropriated under sub-*

*section (i) for a fiscal year up to $50,000,000, the Director of the Center shall make available 25 percent of such amount, and from the amount appropriated under such subsection for a fiscal year that is over $50,000,000, the Director of the Center shall make available up to 25 percent of such amount, for grants under subsection (a) to applicants that in addition to meeting the requirements established in paragraph (1), have demonstrated emerging excellence in biomedical or behavioral research, as follows:*

*"(A) The applicant has a plan for research or training advancement and possesses the ability to carry out the plan.*

*"(B) The applicant carries out research and research training programs that have a special relevance to a problem, concern, or unmet health need of the United States.*

*"(C) The applicant has been productive in research or research development and training.*

*"(D) The applicant—*

*"(i) has been designated as a center of excellence under section 739;*

*"(ii) is located in a geographic area whose population includes a significant number of individuals with health status*

*deficit, and the applicant provides health services to such individuals; or*

*"(iii) is located in a geographic area in which a deficit in health care technology, services, or research resources may adversely affect the health status of the population of the area in the future, and the applicant is carrying out activities with respect to protecting the health status of such population.*

*"(d) REQUIREMENT OF APPLICATION.—The Director of the Center may make a grant under subsection (a) only if an application for the grant is submitted to the Director and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Director determines to be necessary to carry out this section.*

*"(e) AMOUNT OF GRANT; PAYMENTS.—*

*"(1) AMOUNT.—The amount of any grant awarded under subsection (a) shall be determined by the Director of the Center, except that such amount shall not exceed—*

*"(A) 50 percent of the necessary cost of the construction of a proposed facility as determined by the Director; or*

*"(B) in the case of a multipurpose facility, 40 percent of that part of the necessary cost of construction that the Director determines to be proportionate to the contemplated use of the facility.*

*"(2) RESERVATION OF AMOUNTS.—On the approval of any application for a grant under subsection (a), the Director of the Center shall reserve, from any appropriation available for such grants, the amount of such grant, and shall pay such amount, in advance or by way of reimbursement, and in such installments consistent with the construction progress, as the Director may determine appropriate. The reservation of any amount by the Director under this paragraph may be amended by the Director, either on the approval of an amendment of the application or on the revision of the estimated cost of construction of the facility.*

*"(3) EXCLUSION OF CERTAIN COSTS.—In determining the amount of any grant under subsection (a), there shall be excluded from the cost of construction an amount equal to the sum of—*

*"(A) the amount of any other Federal grant that the applicant has obtained, or is assured of obtaining, with respect to construction that is to*

*be financed in part by a grant authorized under this section; and*

*"(B) the amount of any non-Federal funds required to be expended as a condition of such other Federal grant.*

*"(4) WAIVER OF LIMITATIONS.—The limitations imposed under paragraph (1) may be waived at the discretion of the Director for applicants meeting the conditions described in subsection (c).*

*"(f) RECAPTURE OF PAYMENTS.—If, not later than 20 years after the completion of construction for which a grant has been awarded under subsection (a)—*

*"(1) the applicant or other owner of the facility shall cease to be a public or non profit private entity; or*

*"(2) the facility shall cease to be used for the research purposes for which it was constructed (unless the Director determines, in accordance with regulations, that there is good cause for releasing the applicant or other owner from obligation to do so);*

*the United States shall be entitled to recover from the applicant or other owner of the facility the amount bearing the same ratio to the current value (as determined by an agreement between the parties or by action brought in the United States District Court for the district in which such facility*

*is situated) of the facility as the amount of the Federal participation bore to the cost of the construction of such facility.*

*"(g) GUIDELINES.—Not later than 6 months after the date of the enactment of this section, the Director of the Center, after consultation with the Advisory Council, shall issue guidelines with respect to grants under subsection (a).*

*"(h) REPORT TO CONGRESS.—The Director of the Center shall prepare and submit to the appropriate committees of Congress a biennial report concerning the status of the biomedical and behavioral research facilities and the availability and condition of technologically sophisticated laboratory equipment in the United States. Such reports shall be developed in concert with the report prepared by the National Science Foundation on the needs of research facilities of universities as required under section 108 of the National Science Foundation Authorization Act for Fiscal Year 1986 (42 U.S.C. 1886).*

*"(i) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $250,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.".*

***SEC. 304. CONSTRUCTION PROGRAM FOR NATIONAL PRIMATE RESEARCH CENTERS.***

*Section 481B(a) of the Public Health Service Act (42 U.S.C. 287a–3(a)) is amended by striking "1994" and all that follows through "$5,000,000" and inserting "2000 through 2002, reserve from the amounts appropriated under section 481A(i) such sums as necessary".*

***SEC. 305. SHARED INSTRUMENTATION GRANT PROGRAM.***

*(a) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $100,000,000 for fiscal year 2000, and such sums as may be necessary for each subsequent fiscal year, to enable the Secretary of Health and Human Services, acting through the Director of the National Center for Research Resources, to provide for the continued operation of the Shared Instrumentation Grant Program (initiated in fiscal year 1992 under the authority of section 479 of the Public Health Service Act (42 U.S.C. 287 et seq.)).*

*(b) REQUIREMENTS FOR GRANTS.—In determining whether to award a grant to an applicant under the program described in subsection (a), the Director of the National Center for Research Resources shall consider—*

*(1) the extent to which an award for the specific instrument involved would meet the scientific needs and enhance the planned research endeavors of the*

*major users by providing an instrument that is unavailable or to which availability is highly limited;*

*(2) with respect to the instrument involved, the availability and commitment of the appropriate technical expertise within the major user group or the applicant institution for use of the instrumentation;*

*(3) the adequacy of the organizational plan for the use of the instrument involved and the internal advisory committee for oversight of the applicant, including sharing arrangements if any;*

*(4) the applicant's commitment for continued support of the utilization and maintenance of the instrument; and*

*(5) the extent to which the specified instrument will be shared and the benefit of the proposed instrument to the overall research community to be served.*

*(c) PEER REVIEW.—In awarding grants under the program described in subsection (a) Director of the National Center for Research Resources shall comply with the peer review requirements in section 492 of the Public Health Service Act (42 U.S.C. 289a).*

# *TITLE IV—CARDIAC ARREST SURVIVAL*

## *Subtitle A—Recommendations for Federal Buildings*

***SEC. 401. SHORT TITLE.***

*This subtitle may be cited as the "Cardiac Arrest Survival Act of 2000".*

***SEC. 402. FINDINGS.***

*Congress makes the following findings:*

*(1) Over 700 lives are lost every day to sudden cardiac arrest in the United States alone.*

*(2) Two out of every three sudden cardiac deaths occur before a victim can reach a hospital.*

*(3) More than 95 percent of these cardiac arrest victims will die, many because of lack of readily available life saving medical equipment.*

*(4) With current medical technology, up to 30 percent of cardiac arrest victims could be saved if victims had access to immediate medical response, including defibrillation and cardiopulmonary resuscitation.*

*(5) Once a victim has suffered a cardiac arrest, every minute that passes before returning the heart to a normal rhythm decreases the chance of survival by 10 percent.*

*(6) Most cardiac arrests are caused by abnormal heart rhythms called ventricular fibrillation. Ventricular fibrillation occurs when the heart's electrical system malfunctions, causing a chaotic rhythm that prevents the heart from pumping oxygen to the victim's brain and body.*

*(7) Communities that have implemented programs ensuring widespread public access to defibrillators, combined with appropriate training, maintenance, and coordination with local emergency medical systems, have dramatically improved the survival rates from cardiac arrest.*

*(8) Automated external defibrillator devices have been demonstrated to be safe and effective, even when used by lay people, since the devices are designed not to allow a user to administer a shock until after the device has analyzed a victim's heart rhythm and determined that an electric shock is required.*

*(9) Increasing public awareness regarding automated external defibrillator devices and encouraging their use in Federal buildings will greatly facilitate their adoption.*

*(10) Limiting the liability of Good Samaritans and acquirers of automated external defibrillator devices in emergency situations may encourage the use*

*of automated external defibrillator devices, and result in saved lives.*

***SEC. 403. RECOMMENDATIONS AND GUIDELINES OF SECRETARY OF HEALTH AND HUMAN SERVICES REGARDING AUTOMATED EXTERNAL DEFIBRILLATORS FOR FEDERAL BUILDINGS.***

*Part B of title II of the Public Health Service Act (42 U.S.C. 238 et seq.) is amended by adding at the end the following:*

*"RECOMMENDATIONS AND GUIDELINES REGARDING AUTOMATED EXTERNAL DEFIBRILLATORS FOR FEDERAL BUILDINGS*

*"SEC. 247. (a) GUIDELINES ON PLACEMENT.—The Secretary shall establish guidelines with respect to placing automated external defibrillator devices in Federal buildings. Such guidelines shall take into account the extent to which such devices may be used by lay persons, the typical number of employees and visitors in the buildings, the extent of the need for security measures regarding the buildings, buildings or portions of buildings in which there are special circumstances such as high electrical voltage or extreme heat or cold, and such other factors as the Secretary determines to be appropriate.*

*"(b) RELATED RECOMMENDATIONS.—The Secretary shall publish in the Federal Register the recommendations of the Secretary on the appropriate implementation of the*

*placement of automated external defibrillator devices under subsection (a), including procedures for the following:*

*"(1) Implementing appropriate training courses in the use of such devices, including the role of cardiopulmonary resuscitation.*

*"(2) Proper maintenance and testing of the devices.*

*"(3) Ensuring coordination with appropriate licensed professionals in the oversight of training of the devices.*

*"(4) Ensuring coordination with local emergency medical systems regarding the placement and incidents of use of the devices.*

*"(c) CONSULTATIONS; CONSIDERATION OF CERTAIN RECOMMENDATIONS.—In carrying out this section, the Secretary shall—*

*"(1) consult with appropriate public and private entities;*

*"(2) consider the recommendations of national and local public-health organizations for improving the survival rates of individuals who experience cardiac arrest in nonhospital settings by minimizing the time elapsing between the onset of cardiac arrest and the initial medical response, including defibrillation as necessary; and*

*"(3) consult with and counsel other Federal agencies where such devices are to be used.*

*"(d) DATE CERTAIN FOR ESTABLISHING GUIDELINES AND RECOMMENDATIONS.—The Secretary shall comply with this section not later than 180 days after the date of the enactment of the Cardiac Arrest Survival Act of 2000.*

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

*"(1) The term 'automated external defibrillator device' has the meaning given such term in section 248.*

*"(2) The term 'Federal building' includes a building or portion of a building leased or rented by a Federal agency, and includes buildings on military installations of the United States.".*

***SEC. 404. GOOD SAMARITAN PROTECTIONS REGARDING EMERGENCY USE OF AUTOMATED EXTERNAL DEFIBRILLATORS.***

*Part B of title II of the Public Health Service Act, as amended by section 403, is amended by adding at the end the following:*

*"LIABILITY REGARDING EMERGENCY USE OF AUTOMATED EXTERNAL DEFIBRILLATORS*

*"SEC. 248. (a) GOOD SAMARITAN PROTECTIONS REGARDING AEDS.—Except as provided in subsection (b), any person who uses or attempts to use an automated external defibrillator device on a victim of a perceived medical*

*emergency is immune from civil liability for any harm resulting from the use or attempted use of such device; and in addition, any person who acquired the device is immune from such liability, if the harm was not due to the failure of such acquirer of the device—*

*"(1) to notify local emergency response personnel or other appropriate entities of the most recent placement of the device within a reasonable period of time after the device was placed;*

*"(2) to properly maintain and test the device; or*

*"(3) to provide appropriate training in the use of the device to an employee or agent of the acquirer when the employee or agent was the person who used the device on the victim, except that such requirement of training does not apply if—*

*"(A) the employee or agent was not an employee or agent who would have been reasonably expected to use the device; or*

*"(B) the period of time elapsing between the engagement of the person as an employee or agent and the occurrence of the harm (or between the acquisition of the device and the occurrence of the harm, in any case in which the device was acquired after such engagement of the person)*

*was not a reasonably sufficient period in which to provide the training.*

*"(b) INAPPLICABILITY OF IMMUNITY.—Immunity under subsection (a) does not apply to a person if—*

*"(1) the harm involved was caused by willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious, flagrant indifference to the rights or safety of the victim who was harmed; or*

*"(2) the person is a licensed or certified health professional who used the automated external defibrillator device while acting within the scope of the license or certification of the professional and within the scope of the employment or agency of the professional; or*

*"(3) the person is a hospital, clinic, or other entity whose purpose is providing health care directly to patients, and the harm was caused by an employee or agent of the entity who used the device while acting within the scope of the employment or agency of the employee or agent; or*

*"(4) the person is an acquirer of the device who leased the device to a health care entity (or who otherwise provided the device to such entity for compensation without selling the device to the entity), and the harm was caused by an employee or agent of the enti-*

*ty who used the device while acting within the scope of the employment or agency of the employee or agent.*

*"(c) RULES OF CONSTRUCTION.—*

*"(1) IN GENERAL.—The following applies with respect to this section:*

*"(A) This section does not establish any cause of action, or require that an automated external defibrillator device be placed at any building or other location.*

*"(B) With respect to a class of persons for which this section provides immunity from civil liability, this section supersedes the law of a State only to the extent that the State has no statute or regulations that provide persons in such class with immunity for civil liability arising from the use by such persons of automated external defibrillator devices in emergency situations (within the meaning of the State law or regulation involved).*

*"(C) This section does not waive any protection from liability for Federal officers or employees under—*

*"(i) section 224; or*

*"(ii) sections 1346(b), 2672, and 2679 of title 28, United States Code, or under al-*

*ternative benefits provided by the United States where the availability of such benefits precludes a remedy under section 1346(b) of title 28.*

*"(2) CIVIL ACTIONS UNDER FEDERAL LAW.—*

*"(A) IN GENERAL.—The applicability of subsections (a) and (b) includes applicability to any action for civil liability described in subsection (a) that arises under Federal law.*

*"(B) FEDERAL AREAS ADOPTING STATE LAW.—If a geographic area is under Federal jurisdiction and is located within a State but out of the jurisdiction of the State, and if, pursuant to Federal law, the law of the State applies in such area regarding matters for which there is no applicable Federal law, then an action for civil liability described in subsection (a) that in such area arises under the law of the State is subject to subsections (a) through (c) in lieu of any related State law that would apply in such area in the absence of this subparagraph.*

*"(d) FEDERAL JURISDICTION.—In any civil action arising under State law, the courts of the State involved have jurisdiction to apply the provisions of this section exclusive of the jurisdiction of the courts of the United States.*

*"(e) DEFINITIONS.—*

*"(1) PERCEIVED MEDICAL EMERGENCY.—For purposes of this section, the term 'perceived medical emergency' means circumstances in which the behavior of an individual leads a reasonable person to believe that the individual is experiencing a life-threatening medical condition that requires an immediate medical response regarding the heart or other cardiopulmonary functioning of the individual.*

*"(2) OTHER DEFINITIONS.—For purposes of this section:*

*"(A) The term 'automated external defibrillator device' means a defibrillator device that—*

*"(i) is commercially distributed in accordance with the Federal Food, Drug, and Cosmetic Act;*

*"(ii) is capable of recognizing the presence or absence of ventricular fibrillation, and is capable of determining without intervention by the user of the device whether defibrillation should be performed;*

*"(iii) upon determining that defibrillation should be performed, is able to*

*deliver an electrical shock to an individual; and*

*"(iv) in the case of a defibrillator device that may be operated in either an automated or a manual mode, is set to operate in the automated mode.*

*"(B)(i) The term 'harm' includes physical, nonphysical, economic, and noneconomic losses.*

*"(ii) The term 'economic loss' means any pecuniary loss resulting from harm (including the loss of earnings or other benefits related to employment, medical expense loss, replacement services loss, loss due to death, burial costs, and loss of business or employment opportunities) to the extent recovery for such loss is allowed under applicable State law.*

*"(iii) The term 'noneconomic losses' means losses for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation and all other nonpecuniary losses of any kind or nature.".*

# *Subtitle B—Rural Access to Emergency Devices*

***SEC. 411. SHORT TITLE.***

*This subtitle may be cited as the "Rural Access to Emergency Devices Act" or the "Rural AED Act".*

***SEC. 412. FINDINGS.***

*Congress makes the following findings:*

*(1) Heart disease is the leading cause of death in the United States.*

*(2) The American Heart Association estimates that 250,000 Americans die from sudden cardiac arrest each year.*

*(3) A cardiac arrest victim's chance of survival drops 10 percent for every minute that passes before his or her heart is returned to normal rhythm.*

*(4) Because most cardiac arrest victims are initially in ventricular fibrillation, and the only treatment for ventricular fibrillation is defibrillation, prompt access to defibrillation to return the heart to normal rhythm is essential.*

*(5) Lifesaving technology, the automated external defibrillator, has been developed to allow trained lay rescuers to respond to cardiac arrest by using this simple device to shock the heart into normal rhythm.*

*(6) Those people who are likely to be first on the scene of a cardiac arrest situation in many communities, particularly smaller and rural communities, lack sufficient numbers of automated external defibrillators to respond to cardiac arrest in a timely manner.*

*(7) The American Heart Association estimates that more than 50,000 deaths could be prevented each year if defibrillators were more widely available to designated responders.*

*(8) Legislation should be enacted to encourage greater public access to automated external defibrillators in communities across the United States.*

***SEC. 413. GRANTS.***

*(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Rural Health Outreach Office of the Health Resources and Services Administration, shall award grants to community partnerships that meet the requirements of subsection (b) to enable such partnerships to purchase equipment and provide training as provided for in subsection (c).*

*(b) COMMUNITY PARTNERSHIPS.—A community partnership meets the requirements of this subsection if such partnership—*

*(1) is composed of local emergency response entities such as community training facilities, local emergency responders, fire and rescue departments, police, community hospitals, and local non-profit entities and for-profit entities concerned about cardiac arrest survival rates;*

*(2) evaluates the local community emergency response times to assess whether they meet the standards established by national public health organizations such as the American Heart Association and the American Red Cross; and*

*(3) submits to the Secretary of Health and Human Services an application at such time, in such manner, and containing such information as the Secretary may require.*

*(c) USE OF FUNDS.—Amounts provided under a grant under this section shall be used—*

*(1) to purchase automated external defibrillators that have been approved, or cleared for marketing, by the Food and Drug Administration; and*

*(2) to provide defibrillator and basic life support training in automated external defibrillator usage through the American Heart Association, the American Red Cross, or other nationally recognized training courses.*

*(d) REPORT.—Not later than 4 years after the date of enactment of this Act, the Secretary of Health and Human Services shall prepare and submit to the appropriate committees of Congress a report containing data relating to whether the increased availability of defibrillators has affected survival rates in the communities in which grantees under this section operated. The procedures under which the Secretary obtains data and prepares the report under this subsection shall not impose an undue burden on program participants under this section.*

*(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $25,000,000 for fiscal years 2001 through 2003 to carry out this section.*

# *TITLE V—LUPUS RESEARCH AND CARE*

***SEC. 501. SHORT TITLE.***

*This title may be cited as the "Lupus Research and Care Amendments of 2000".*

***SEC. 502. FINDINGS.***

*The Congress finds that—*

*(1) lupus is a serious, complex, inflammatory, autoimmune disease of particular concern to women;*

*(2) lupus affects women nine times more often than men;*

*(3) there are three main types of lupus: systemic lupus, a serious form of the disease that affects many parts of the body; discoid lupus, a form of the disease that affects mainly the skin; and drug-induced lupus caused by certain medications;*

*(4) lupus can be fatal if not detected and treated early;*

*(5) the disease can simultaneously affect various areas of the body, such as the skin, joints, kidneys, and brain, and can be difficult to diagnose because the symptoms of lupus are similar to those of many other diseases;*

*(6) lupus disproportionately affects African-American women, as the prevalence of the disease among such women is three times the prevalence among white women, and an estimated 1 in 250 African-American women between the ages of 15 and 65 develops the disease;*

*(7) it has been estimated that between 1,400,000 and 2,000,000 Americans have been diagnosed with the disease, and that many more have undiagnosed cases;*

*(8) current treatments for the disease can be effective, but may lead to damaging side effects;*

*(9) many victims of the disease suffer debilitating pain and fatigue, making it difficult to maintain employment and lead normal lives; and*

*(10) in fiscal year 1996, the amount allocated by the National Institutes of Health for research on lupus was $33,000,000, which is less than one-half of 1 percent of the budget for such Institutes.*

## *Subtitle A—Research on Lupus*

***SEC. 511. EXPANSION AND INTENSIFICATION OF ACTIVITIES.***

*Subpart 4 of part C of title IV of the Public Health Service Act (42 U.S.C. 285d et seq.) is amended by inserting after section 441 the following:*

*"LUPUS*

*"SEC. 441A. (a) IN GENERAL.—The Director of the Institute shall expand and intensify research and related activities of the Institute with respect to lupus.*

*"(b) COORDINATION WITH OTHER INSTITUTES.—The Director of the Institute shall coordinate the activities of the Director under subsection (a) with similar activities conducted by the other national research institutes and agencies of the National Institutes of Health to the extent that such Institutes and agencies have responsibilities that are related to lupus.*

*"(c) PROGRAMS FOR LUPUS.—In carrying out subsection (a), the Director of the Institute shall conduct or*

*support research to expand the understanding of the causes of, and to find a cure for, lupus. Activities under such subsection shall include conducting and supporting the following:*

*"(1) Research to determine the reasons underlying the elevated prevalence of lupus in women, including African-American women.*

*"(2) Basic research concerning the etiology and causes of the disease.*

*"(3) Epidemiological studies to address the frequency and natural history of the disease and the differences among the sexes and among racial and ethnic groups with respect to the disease.*

*"(4) The development of improved diagnostic techniques.*

*"(5) Clinical research for the development and evaluation of new treatments, including new biological agents.*

*"(6) Information and education programs for health care professionals and the public.*

*"(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 of the fiscal years 2001 through 2003.".*

## *Subtitle B—Delivery of Services Regarding Lupus*

***SEC. 521. ESTABLISHMENT OF PROGRAM OF GRANTS.***

*(a) IN GENERAL.—The Secretary of Health and Human Services shall in accordance with this subtitle make grants to provide for projects for the establishment, operation, and coordination of effective and cost-efficient systems for the delivery of essential services to individuals with lupus and their families.*

*(b) RECIPIENTS OF GRANTS.—A grant under subsection (a) may be made to an entity only if the entity is a public or nonprofit private entity, which may include a State or local government; a public or nonprofit private hospital, community-based organization, hospice, ambulatory care facility, community health center, migrant health center, or homeless health center; or other appropriate public or nonprofit private entity.*

*(c) CERTAIN ACTIVITIES.—To the extent practicable and appropriate, the Secretary shall ensure that projects under subsection (a) provide services for the diagnosis and disease management of lupus. Activities that the Secretary may authorize for such projects may also include the following:*

*(1) Delivering or enhancing outpatient, ambulatory, and home-based health and support services, in-*

*cluding case management and comprehensive treatment services, for individuals with lupus; and delivering or enhancing support services for their families.*

*(2) Delivering or enhancing inpatient care management services that prevent unnecessary hospitalization or that expedite discharge, as medically appropriate, from inpatient facilities of individuals with lupus.*

*(3) Improving the quality, availability, and organization of health care and support services (including transportation services, attendant care, homemaker services, day or respite care, and providing counseling on financial assistance and insurance) for individuals with lupus and support services for their families.*

*(d) INTEGRATION WITH OTHER PROGRAMS.—To the extent practicable and appropriate, the Secretary shall integrate the program under this subtitle with other grant programs carried out by the Secretary, including the program under section 330 of the Public Health Service Act.*

***SEC. 522. CERTAIN REQUIREMENTS.***

*A grant may be made under section 521 only if the applicant involved makes the following agreements:*

*(1) Not more than 5 percent of the grant will be used for administration, accounting, reporting, and program oversight functions.*

*(2) The grant will be used to supplement and not supplant funds from other sources related to the treatment of lupus.*

*(3) The applicant will abide by any limitations deemed appropriate by the Secretary on any charges to individuals receiving services pursuant to the grant. As deemed appropriate by the Secretary, such limitations on charges may vary based on the financial circumstances of the individual receiving services.*

*(4) The grant will not be expended to make payment for services authorized under section 521(a) to the extent that payment has been made, or can reasonably be expected to be made, with respect to such services—*

*(A) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or*

*(B) by an entity that provides health services on a prepaid basis.*

*(5) The applicant will, at each site at which the applicant provides services under section 521(a), post a conspicuous notice informing individuals who re-*

*ceive the services of any Federal policies that apply to the applicant with respect to the imposition of charges on such individuals.*

***SEC. 523. TECHNICAL ASSISTANCE.***

*The Secretary may provide technical assistance to assist entities in complying with the requirements of this subtitle in order to make such entities eligible to receive grants under section 521.*

***SEC. 524. DEFINITIONS.***

*For purposes of this subtitle:*

*(1) OFFICIAL POVERTY LINE.—The term "official poverty line" means the poverty line established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981.*

*(2) SECRETARYThe term "Secretary" means the Secretary of Health and Human Services.*

***SEC. 525. AUTHORIZATION OF APPROPRIATIONS.***

*For the purpose of carrying out this subtitle, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2003.*

# *TITLE VI—PROSTATE CANCER RESEARCH AND PREVENTION*

***SEC. 601. SHORT TITLE.***

*This title may be cited as the "Prostate Cancer Research and Prevention Act".*

***SEC. 602. AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT.***

*(a) PREVENTIVE HEALTH MEASURES.—Section 317D of the Public Health Service Act (42 U.S.C. 247b–5) is amended—*

*(1) by striking subsection (a) and inserting the following:*

*"(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States and local health departments for the purpose of enabling such States and departments to carry out programs that may include the following:*

*"(1) To identify factors that influence the attitudes or levels of awareness of men and health care practitioners regarding screening for prostate cancer.*

*"(2) To evaluate, in consultation with the Agency for Health Care Policy and Research and the National Institutes of Health, the effectiveness of screening strategies for prostate cancer.*

*"(3) To identify, in consultation with the Agency for Health Care Policy and Research, issues related to the quality of life for men after prostrate cancer screening and followup.*

*"(4) To develop and disseminate public information and education programs for prostate cancer, including appropriate messages about the risks and benefits of prostate cancer screening for the general public, health care providers, policy makers and other appropriate individuals.*

*"(5) To improve surveillance for prostate cancer.*

*"(6) To address the needs of underserved and minority populations regarding prostate cancer.*

*"(7) Upon a determination by the Secretary, who shall take into consideration recommendations by the United States Preventive Services Task Force and shall seek input, where appropriate, from professional societies and other private and public entities, that there is sufficient consensus on the effectiveness of prostate cancer screening—*

*"(A) to screen men for prostate cancer as a preventive health measure;*

*"(B) to provide appropriate referrals for the medical treatment of men who have been screened under subparagraph (A) and to ensure,*

*to the extent practicable, the provision of appropriate followup services and support services such as case management;*

*"(C) to establish mechanisms through which State and local health departments can monitor the quality of screening procedures for prostate cancer, including the interpretation of such procedures; and*

*"(D) to improve, in consultation with the Health Resources and Services Administration, the education, training, and skills of health practitioners (including appropriate allied health professionals) in the detection and control of prostate cancer.*

*"(8) To evaluate activities conducted under paragraphs (1) through (7) through appropriate surveillance or program monitoring activities."; and*

*(2) in subsection (l)(1), by striking "1998" and inserting "2004".*

*(b) NATIONAL INSTITUTES OF HEALTH.—Section 417B(c) of the Public Health Service Act (42 U.S.C. 286a–8(c)) is amended by striking "and 1996" and inserting "through 2004".*

# *TITLE VII—ORGAN PROCUREMENT AND DONATION*

***SEC. 701. ORGAN PROCUREMENT ORGANIZATION CERTIFICATION.***

*(a) SHORT TITLE.—This section may be cited as the "Organ Procurement Organization Certification Act of 2000".*

*(b) FINDINGS.—Congress makes the following findings:*

*(1) Organ procurement organizations play an important role in the effort to increase organ donation in the United States.*

*(2) The current process for the certification and recertification of organ procurement organizations conducted by the Department of Health and Human Services has created a level of uncertainty that is interfering with the effectiveness of organ procurement organizations in raising the level of organ donation.*

*(3) The General Accounting Office, the Institute of Medicine, and the Harvard School of Public Health have identified substantial limitations in the organ procurement organization certification and recertification process and have recommended changes in that process.*

*(4) The limitations in the recertification process include:*

*(A) An exclusive reliance on population-based measures of performance that do not account for the potential in the population for organ donation and do not permit consideration of other outcome and process standards that would more accurately reflect the relative capability and performance of each organ procurement organization.*

*(B) A lack of due process to appeal to the Secretary of Health and Human Services for recertification on either substantive or procedural grounds.*

*(5) The Secretary of Health and Human Services has the authority under section 1138(b)(1)(A)(i) of the Social Security Act (42 U.S.C. 1320b–8(b)(1)(A)(i)) to extend the period for recertification of an organ procurement organization from 2 to 4 years on the basis of its past practices in order to avoid the inappropriate disruption of the nation's organ system.*

*(6) The Secretary of Health and Human Services can use the extended period described in paragraph (5) for recertification of all organ procurement organizations to—*

*(A) develop improved performance measures that would reflect organ donor potential and interim outcomes, and to test these measures to ensure that they accurately measure performance differences among the organ procurement organizations; and*

*(B) improve the overall certification process by incorporating process as well as outcome performance measures, and developing equitable processes for appeals.*

*(c) CERTIFICATION AND RECERTIFICATION OF ORGAN PROCUREMENT ORGANIZATIONS.—Section 371(b)(1) of the Public Health Service Act (42 U.S.C. 273(b)(1)) is amended—*

*(1) by redesignating subparagraphs (D) through (G) as subparagraphs (E) through (H), respectively;*

*(2) by realigning the margin of subparagraph (F) (as so redesignated) so as to align with subparagraph (E) (as so redesignated); and*

*(3) by inserting after subparagraph (C) the following:*

*"(D) notwithstanding any other provision of law, has met the other requirements of this section and has been certified or recertified by the Secretary within the previous 4-year period as meeting the per-*

*formance standards to be a qualified organ procurement organization through a process that either—*

*"(i) granted certification or recertification within such 4-year period with such certification or recertification in effect as of January 1, 2000, and remaining in effect through the earlier of—*

*"(I) January 1, 2002; or*

*"(II) the completion of recertification under the requirements of clause (ii); or*

*"(ii) is defined through regulations that are promulgated by the Secretary by not later than January 1, 2002, that—*

*"(I) require recertifications of qualified organ procurement organizations not more frequently than once every 4 years;*

*"(II) rely on outcome and process performance measures that are based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of qualified organ procurement organizations;*

*"(III) use multiple outcome measures as part of the certification process; and*

*"(IV) provide for a qualified organ procurement organization to appeal a decer-*

*tification to the Secretary on substantive and procedural grounds;''.*

***SEC. 702. DESIGNATION OF GIVE THANKS, GIVE LIFE DAY.***

*(a) FINDINGS.—Congress finds that—*

*(1) traditionally, Thanksgiving is a time for families to take time out of their busy lives to come together and to give thanks for the many blessings in their lives;*

*(2) approximately 21,000 men, women, and children in the United States are given the gift of life each year through transplantation surgery, made possible by the generosity of organ and tissue donations;*

*(3) more than 66,000 Americans are awaiting their chance to prolong their lives by finding a matching donor;*

*(4) nearly 5,000 of these patients each year (or 13 patients each day) die while waiting for a donated heart, liver, kidney, or other organ;*

*(5) nationwide there are up to 15,000 potential donors annually, but families' consent to donation is received for less than 6,000;*

*(6) the need for organ donations greatly exceeds the supply available;*

*(7) designation as an organ donor on a driver's license or voter's registration is a valuable step, but does not ensure donation when an occasion arises;*

*(8) the demand for transplantation will likely increase in the coming years due to the growing safety of transplantation surgery due to improvements in technology and drug developments, prolonged life expectancy, and increased prevalence of diseases that may lead to organ damage and failure, including hypertension, alcoholism, and hepatitis C infection;*

*(9) the need for a more diverse donor pool, including a variety of racial and ethnic minorities, will continue to grow in the coming years;*

*(10) the final decision on whether a potential donor can share the gift of life usually is made by surviving family members regardless of the patient's initial intent;*

*(11) many Americans have indicated a willingness to donate their organs and tissues but have not discussed this critical matter with the family members who are most likely to make the decision, if the occasion arises, as to whether that person will be an organ and tissue donor;*

*(12) some family members may be reluctant to give consent to donate their deceased loved one's or-*

*gans and tissues at a very difficult and emotional time if that person has not clearly expressed a desire or willingness to do so;*

*(13) the vast majority of Americans are likely to spend part of Thanksgiving Day with some of those family members who would be approached to make such a decision; and*

*(14) it is fitting for families to spend a portion of that day discussing how they might give life to others on a day devoted to giving thanks for their own blessings.*

*(b) DESIGNATION.—November 23, 2000, Thanksgiving Day, is hereby designated as a day to "Give Thanks, Give Life" and to discuss organ and tissue donation with other family members so that informed decisions can be made if the occasion to donate arises.*

# *TITLE VIII—ALZHEIMER'S CLINICAL RESEARCH AND TRAINING*

## *SEC. 801. ALZHEIMER'S CLINICAL RESEARCH AND TRAINING AWARDS.*

*Subpart 5 of part C of title IV of the Public Health Service Act (42 U.S.C. 285e et seq.) is amended—*

*(1) by redesignating section 445I as section 445J; and*

*(2) by inserting after section 445H the following:*

***"SEC. 445I. ALZHEIMER'S CLINICAL RESEARCH AND TRAINING AWARDS.***

*"(a) IN GENERAL.—The Director of the Institute is authorized to establish and maintain a program to enhance and promote the translation of new scientific knowledge into clinical practice related to the diagnosis, care and treatment of individuals with Alzheimer's disease.*

*"(b) SUPPORT OF PROMISING CLINICIANS.—In order to foster the application of the most current developments in the etiology, pathogenesis, diagnosis, prevention and treatment of Alzheimer's disease, amounts made available under this section shall be directed to the support of promising clinicians through awards for research, study, and practice at centers of excellence in Alzheimer's disease research and treatment.*

*"(c) EXCELLENCE IN CERTAIN FIELDS.—Research shall be carried out under awards made under subsection (b) in environments of demonstrated excellence in neuroscience, neurobiology, geriatric medicine, and psychiatry and shall foster innovation and integration of such disciplines or other environments determined suitable by the Director of the Institute.*

*"(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized*

*to be appropriated $2,250,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2002 through 2005.".*

# *TITLE IX—SEXUALLY TRANSMITTED DISEASE CLINICAL RESEARCH AND TRAINING*

### *SEC. 901. SEXUALLY TRANSMITTED DISEASE CLINICAL RESEARCH AND TRAINING AWARDS.*

*Subpart 6 of part C of title IV of the Public Health Service Act (42 U.S.C. 285f et seq.) is amended by adding at the end the following:*

### *"SEC. 447B. SEXUALLY TRANSMITTED DISEASE CLINICAL RESEARCH AND TRAINING AWARDS.*

*"(a) IN GENERAL.—The Director of the Institute is authorized to establish and maintain a program to enhance and promote the translation of new scientific knowledge into clinical practice related to the diagnosis, care and treatment of individuals with sexually transmitted diseases.*

*"(b) SUPPORT OF PROMISING CLINICIANS.—In order to foster the application of the most current developments in the etiology, pathogenesis, diagnosis, prevention and treatment of sexually transmitted diseases, amounts made available under this section shall be directed to the support of promising clinicians through awards for research, study,*

*and practice at centers of excellence in sexually transmitted disease research and treatment.*

*"(c) EXCELLENCE IN CERTAIN FIELDS.—Research shall be carried out under awards made under subsection (b) in environments of demonstrated excellence in the etiology and pathogenesis of sexually transmitted diseases and shall foster innovation and integration of such disciplines or other environments determined suitable by the Director of the Institute.*

*"(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $2,250,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2002 through 2005.".*

# *TITLE X—MISCELLANEOUS PROVISION*

***SEC. 1001. TECHNICAL CORRECTION TO THE CHILDREN'S HEALTH ACT OF 2000.***

*(a) IN GENERAL.—Section 2701 of the Children's Health Act of 2000 is amended by striking "part 45 of title 46" and inserting "part 46 of title 45".*

*(b) EFFECTIVE DATE.—The amendment made by subsection (a) takes effect on the date of enactment of the Children's Health Act of 2000.*

Attest:

*Secretary.*

106TH CONGRESS
2D SESSION

# H. R. 2498

## AMENDMENT