manufacturers of children's vaccines dropped from seven to two due to a flood of lawsuits filed in response to a network television broadcast claiming that vaccine causes brain injuries. This program has been very successful. However, it has come to our attention that the act requires an amendment which I, and the Senator from Massachusetts and the Senator from Tennessee offer today.

A vaccine becomes part of the compensation program if it is recommended for routine use in children by the Centers for Disease Control. At such time, the Congress must also enact a Federal excise tax on the vaccine (currently at $.75 per antigen in the vaccine). The excise tax revenues are housed in a Federal trust fund, the sole purpose of which is to pay claims and administer this program. The program and the fund is jointly administered by the Department of Health and Human Services (HHS) and the Department of Justice.

HHS publishes a table listing all covered vaccines and events that may be associated with those vaccines as determined by valid scientific studies. Events that are listed on the table, if they occur within the listed time frame, are automatically compensated by the program unless there is demonstration that some other circumstances created the injury. For an event/injury not listed on the table, the claimant must prove causation.

If a vaccine is covered under the Vaccine Injury Compensation program, all claims against it must first be filed and processed through the program. Once a claim is adjudicated (and either an award is made or the claim denied), a claimant can reject the program's determination and opt to file a lawsuit.

Since the benefit of taking a vaccine accrues not only to the recipient but to society as a whole, the Congress decided that it was also society's responsibility to compensate those who are injured by creating a no-fault program that removes the costliness and uncertainty of the tort system. At the time this law was enacted, parameters were established to permit claims for those serious adverse events that were known to be associated with those vaccines that were then available. The statutory proxy for a serious injury is that the residual effect from the injury must be of six months' duration or longer.

Recently, however, a new situation has developed that was not foreseeable at the time of enactment of this law. In October 1999, the CDC's Advisory Committee on Immunization Practices (ACIP), after a review of scientific data from several sources, concluded that intussusception occurs with significantly increased frequency in the first 1–2 weeks after vaccination for rotavirus, particularly after the first dose. Thus, the ACIP withdrew its recommendation for vaccination of infants for rotavirus in the United States.

While most cases of intussusception require only minimal treatment, a few cases require hospitalization and surgery. Under the current law, these cases would not be compensable by the United States Claims Court under the Vaccine Injury Compensation Program, since the statute grants jurisdiction to resolve vaccine cases only in instances in which claimants have suffered the residual effects or complications of a vaccine-related injury for at least six months, or died from the administration of a vaccine.

For this reason, we are offering this bill to amend the law and grant jurisdiction to the Claims Court to resolve compensation cases under the Program in cases in which both hospitalization and surgical intervention were required to correct the ''illness, disability, injury or condition'' caused by the vaccine. Mr. President, this language has been shared with, and is supported by officials at HHS and the American Academy of Pediatrics.

To our knowledge, the amendment would only apply to circumstances under which a vaccine recipient suffered from intussusception as a result of administration of the rotavirus vaccine. The amendment is not intended to expand jurisdiction to other vaccines listed in the Program's Vaccine Injury Table.

We note that this amendment does not address the issue of whether the condition is in fact caused by the vaccine; this is a matter for resolution under other provisions of the no-fault compensation law. Among these are the requirement that the condition either be listed in the Vaccine Injury Table or be established to have been caused in fact by the vaccine. Determinations of this type should only be made after thorough consideration of the scientific evidence by experts in the field; the law commits this issue to the Secretary for consideration in the context of changes to the Vaccine Injury Table through rulemaking, and to the Claims Court for determinations of causation in fact.

Mr. KENNEDY. Mr. President, I join the Senator from Vermont and the Senator from Tennessee in proposing legislation to amend the Vaccine Injury Compensation Program.

This program is an important part of the nation's public health strategy. In order to encourage the development and use of effective vaccines, the program guarantees compensation to the few children who are injured by routine immunization.

Recent evidence suggests that some children may suffer vaccine-related injuries that are not covered under the current criteria used to determine eligibility for compensation. To continue the program's success, Congress must assure that the system is responsive to new developments in medical science. We need to be certain that any child who suffers a severe injury as a result of routine vaccination is eligible for compensation under the program.

My colleague from Vermont has concisely summarized the current status of the program and the importance of amending the statute. Families and physicians need to know that public health procedures are capable of a rapid and appropriate response to scientific developments. It is a privilege to join my colleagues in offering this legislation to improve the Vaccine Injury Compensation Program.

Ms. COLLINS. Mr. President, I ask unanimous consent that the bill be read a third time and passed, the motion to reconsider be laid upon the table, and that statements relating to the bill be printed in the RECORD.

The PRESIDING OFFICER. Without objection, it is so ordered.

The bill (S. 1996) was read the third time and passed, as follows:

S. 1996

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

Section 2111(c)(1)(D) of the Public Health Service Act (42 U.S.C. 300aa–11(c)(1)(D)) is amended by striking ''and'' at the end and inserting ''or (iii) suffered such illness, disability, injury or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention to correct such illness, disability, injury or condition, and''.

CLINICAL RESEARCH ENHANCEMENT ACT OF 1999

Ms. COLLINS. Mr. President, I ask unanimous consent that HELP Committee be discharged from further consideration of S. 1813 and the Senate proceed to its immediate consideration.

The PRESIDING OFFICER. Without objection, it is so ordered. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (S. 1813) to amend the Public Health Service Act to provide additional support for and to expand clinical research programs, and for other purposes.

There being no objection, the Senate proceeded to consider the bill.

Ms. COLLINS. Mr. President, I ask unanimous consent that the bill be read a third time and passed, the motion to reconsider be laid upon the table, and that any statements relating to the bill be printed in the RECORD.

The PRESIDING OFFICER. Without objection, it is so ordered.

The bill (S. 1813) was read the third time and passed, as follows:

S. 1813

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Clinical Research Enhancement Act of 1999''.

SEC. 2. 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 recommended 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.

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.

(12) 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 Act to provide additional support for and to expand clinical research programs.

SEC. 3. 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 provided 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. 4. GENERAL CLINICAL RESEARCH CENTERS.

(a) GRANTS.—Subpart 1 of part B 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 3, 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 individual 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 investigation' 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. 5. 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 authorized 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. 6. 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 services research, or developing new technologies, therapeutic interventions, or clinical trials.''.

SEC. 7. 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 Act.

AMENDING FAIR LABOR STANDARDS ACT OF 1938

Ms. COLLINS. Mr. President, I ask unanimous consent that the Senate proceed to the consideration of H.R. 1693, which is at the desk.

The PRESIDING OFFICER. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (H.R. 1693) to amend the Fair Labor Standards Act of 1938 to clarify the overtime exemption for employees engaged in fire protection activities.

There being no objection, the Senate proceeded to consider the bill.

Ms. COLLINS. Mr. President, I ask unanimous consent the bill be considered read a third time and passed, the motion to reconsider be laid upon the table, and that any statement relating to the bill be printed in the RECORD.

The PRESIDING OFFICER. Without Objection, it is so ordered.

The bill (H.R. 1696) was read the third time and passed.

AMENDING THE PUBLIC HEALTH SERVICE ACT

Ms. COLLINS. MR. President, I ask unanimous consent that the HELP Committee be discharged from further consideration of S. 1488, and that the Senate proceed to its immediate consideration.

The PRESIDING OFFICER. Without objection, it is so ordered. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (S. 1488) 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.

There being no objection, the Senate proceeded to consider the bill.

AMENDMENT NO. 2798

Ms. COLLINS. Mr. President, Senator GORTON has a substitute amendment at the best, and I ask for its consideration.

The PRESIDING OFFICER. The clerk will report the amendment.

The legislative clerk read as follows:

The Senator from Maine [Ms. COLLINS] for Mr. Gorton, proposes an amendment numbered 2798.

(The text of the amendment is printed in today's RECORD under ''Amendments Submitted.'')

Mr. GORTON. I am pleased that the Senate will pass the Cardiac Arrest Survival Act before the end of this session. Each year 250,000 Americans suffer from sudden cardiac arrest. It can claim the life of a promising young athlete, a friend of family member regardless of age or health. Sudden Cardiac Arrest occurs when the heart's electrical impulses become chaotic causing the heart to stop pumping blood. Tragically, 95% of Americans who suffer from sudden cardiac arrest will die.

This bill helps to fight this killer by asking the Secretary of Health and Human Services to develop public access to defibrillation programs for federal buildings. Public access to defibrillation programs include improving access to automated external defibrillators (AEDs), training those likely to use the devices, ensuring proper medical oversight of the program and maintaining the devices according to manufacturer's guidelines. An AED is a small, laptop-sized device that is easy to use and can alalyze the heart rhythms of cardiac arrest victims to determine if a shock is warranted and, if necessary, deliver a lifesaving shock to the heart. The devices are so important because for every minute that passes before a cardiac arrest victim's heart is returned to normal rhythm, his or her chance of survival falls by as much as 10 percent.

This bill also provides important gapfilling Good Samaritan immunity for the few states that have yet to pass AED access laws. It will help ensure that people who respond to an emergency and use an AED to help cardiac arrest victims needn't fear frivolous lawsuits. It also provides reassurance to nonmedical facilities such as adult day care centers, the first aid station in a shopping mall, casinos, fitness clubs, sports stadiums, a health clinic in a business, an airport, ambulance, firetruck or other locations where AEDs may be beneficial that they can make these lifesaving devices available.

I want to thank Senators JEFFORDS and FRIST for their help in moving this bill forward. I am also grateful to the American Heart Association, the American Red Cross and the thirty-three other health organizations that have worked so hard to ensure passage of this bill. This is a good bill, it will help save lives and I look forward to working with my colleagues in the House to ensure that it is signed into law.

Mr. KENNEDY. Mr. President, Senator GORTON and I have worked closely