immunization and it reduces the adverse effect of the tort system on vaccine supply and cost. Prior to enactment, the number of U.S. 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 (or vaccine component) at a rate sufficient to cover the costs of the program. 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 filed and (and either the claim or injury) are established to permit claims for 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 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, the Centers for Disease Control’s (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. Thereafter, the ACIP voted to recommend 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 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 of the Claims Court or 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 that vaccine causes brain injuries. 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 provides 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 success of the program, Congress must assure that the system is responsive to new developments in medical science.

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. 96) was read the third time and passed, as follows:

S. 96
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 230a(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 resulting 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 then read as follows:

A bill (S. 1813) to amend the Public Health Service Act to provide additional support 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. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

Section 230a(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 resulting 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 then read as follows:

A bill (S. 1813) to amend the Public Health Service Act to provide additional support 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:
November 19, 1999
CONGRESSIONAL RECORD—SENATE S. 1813
Be it enacted by the Senate and House of Representa-
tives of the United States of America in Congress assem-bled,

SECTION 1. SHORT TITLE.
This Act may be cited as the “Clinical Re-
search Enhancement Act of 1999”.

SEC. 2. FINDINGS AND PURPOSE.
(a) FINDINGS.—Congress makes the fol-
lowing findings:
(1) Clinical research is critical to the ad-
vancement of scientific knowledge and to
the development of cures and improved treat-
ment 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 re-
search process leading to general human ap-
plications. It is the bridge between the lab-
oratory and new methods of diagnosis, treat-
ment, 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 on health care in 1999, but the
Federal budget for health research at the
National Institutes of Health was
$15,600,000,001 only 1 percent of that total.
(5) Studies by 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 prob-
lems in clinical research and appointed a
special panel, which recommended expanded
support for access to the most mod-
ern clinical research and clinical research fa-
cilities and technologies.
(b) PURPOSE.—It is the purpose of this Act
to provide additional support for and to ex-
and 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. 496C. CLINICAL RESEARCH.
“(a) IN GENERAL.—The Director of Na-
tional Institutes of Health shall undertake ac-
tivities to support and expand the increased
use of clinical research at general clinical
research centers.
“(b) REQUIREMENTS.—In carrying out sub-
section (a), the Director of National Insti-
tutes of Health shall—
“(1) consider the recommendations of the Di-
vision of Research Grants Clinical Re-
search Study Group and other recommenda-
tions for enhancing clinical research; and
“(2) establish intramural and extramural
clinical research programs directed
specificially at medical and dental stu-
dents and a continuing education clinical re-
search training program at the National In-
stitutes of Health.
“(c) SUPPORT FOR DIVERSE NEEDS OF
CLINICAL RESEARCH.—The Director of Na-
tional 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 re-
sources available for the diverse needs of
the clinical research community, including inpa-
tient, outpatient, and critical care clinical
research.
“(d) PEER REVIEW.—The Director of Na-
tional Institutes of Health shall establish
peer review mechanisms to evaluate appli-
cations for the awards and fellowships provided
in subsection (b)(2) and section 490d. Such
review mechanisms shall include indi-
viduals who are exceptionally qualified to
appraise the merits of potential clinical re-
search training and research grant pro-
posals.”.

SEC. 4. GENERAL CLINICAL RESEARCH CENTERS.
(a) GRANTS.—Subpart I of part B of title IV
of the Public Health Service Act (42 U.S.C. 286 et seq.) is amended by adding at the end the following:

SEC. 496C. GENERAL CLINICAL RESEARCH CEN-
TERS.
“(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 infras-
structure for clinical research including clini-
cal research training and career enhance-
mant. Such centers shall support clinical
studies and career development in all set-
tings of the hospital or academic medical
center involved.
“(b) ACTIVITIES.—In carrying out sub-
section (a), the Director of National Insti-
tutes 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. 496D. ENHANCEMENT AWARDS.
(a) PATIENT-ORIENTED RESEARCH CAREER DEVELOPMENT AWARDS.—
“(1) GRANTS.—
“(a) IN GENERAL.—The Director of the Na-
tional Institutes of Health shall make grants
to support mid-career investigators in
clinical research and clinical research fa-
cilities.
“(b) USE.—Grants under subparagraph (A)
shall be used to support clinical investiga-
tors in the early phases of their independent
career providing support for a period as
other for a period of supervised study.
“(c) AUTHORIZATION OF APPROPRIATIONS.—
For the purpose of carrying out this subsec-
tion, 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 Na-
tional Institutes of Health shall make grants
to support mid-career investigators in
clinical research and clinical research fa-
cilities.
“(b) USE.—Grants under subparagraph (A)
shall be used to support mid-career level
clinicians to allow such clinicians
to devote time to clinical research and to act
as mentors for beginning clinical investiga-
tors.
“(c) AUTHORIZATION OF APPROPRIATIONS.—
For the purpose of carrying out this subsec-
tion, there are authorized to be appropriated such
sums as may be necessary for each fiscal year.
“(d) GRADUATE TRAINING IN CLINICAL INVEST-
IGATION AWARD.—
“(1) IN GENERAL.—The Director of the Na-
tional 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) USE.—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 individuals engaged in NIH intramural research. 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) APPLICATION OF PROVISIONS.—The provisions of sections 338B, 338C, and 338E shall, except as inconsistent with subsection (a) of this section, be applicable to the grants 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. 286a) 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 12 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 bill has been referred to the Committee on Health, Education, Labor and Pensions.

The PRESIDENT. Without objection, it is so ordered.

The legislative clerk read as follows:

AMENDING THE PUBLIC HEALTH SERVICE ACT

Ms. COLLINS. Mr. President, I ask unanimous consent that the Senate proceed to the 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 an 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.

AMENDING THE PUBLIC HEALTH SERVICE ACT