may require the disclosure of such personal data.

"(c) The Commission shall not disclose any information collected or maintained by it pursuant to this title which is properly classified or is protected from unauthorized disclosure by statute.

"DEFINITIONS

"SEC. 1808. (a) As used in this title, the terms 'department or agency' and 'department and agency' mean each authority of the Government of the United States, whether or not it is within or subject to review by another department or agency, but does not include—

"(1) the Congress;

"(2) the courts of the United States;

"(3) the governments of the territories or possessions of the United States; and

"(4) the government of the District of Columbia.

"(b) As used in this title, the term 'protection of human subjects' includes, among other things, protection of their health and safety and protection of their privacy.

"AUTHORIZATIONS FOR APPROPRIATIONS

"SEC. 1809. For the purpose of carrying out the provisions of this title, there are authorized to be appropriated $6,000,000 for the fiscal year ending September 30, 1979 and for each of the next three fiscal years thereafter.".

SEC. 403. (a) Part A of title II of the National Research Act (42 U.S.C. 289l–1) is amended by adding at the end thereof the following new section:

"FOLLOWUP OF WORK OF THE COMMISSION BY THE PRESIDENT'S COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

"SEC. 206. The President's Commission for the Protection of Human Subjects of Biomedical and Behavioral Research shall complete any of the duties of the Commission set forth in section 202 that remain unfinished when the Commission ceases to exist and, where appropriate, conduct additional studies and investigations on any of the matters set forth in section 202 with respect to any and all departments and agencies of the Government of the United States (but excluding the Congress, the courts of the United States, the governments of the territories or possessions of the United States and the government of the District of Columbia) whether or not such departments and agencies are subject to review by another department or agency.".

(b) Part A of title II of the National Research Act (42 U.S.C. 289l–1) is repealed except for section 206 added by subsection (a).

(c) Sections 211 and 213 of the National Research Act are repealed.

(d) Subsection (f) of section 217 of the Public Health Service Act (42 U.S.C. 218(f)) is repealed.

Mr. KENNEDY. Mr. President, I move to reconsider the vote by which the bill was passed.

Mr. SCHWEIKER. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

PRESIDENT'S COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH ACT OF 1978

The Senate continued with the consideration of S. 2579.

The PRESIDING OFFICER. The question recurs on S. 2579.

Mr. KENNEDY. Mr. President, I ask unanimous consent to further defer action on that one and I move to call up S. 2466.

The PRESIDING OFFICER. Is there objection? The Chair hears none, and it is so ordered.

NATIONAL INSTITUTES OF HEALTH CARE RESEARCH ACT OF 1978

Mr. KENNEDY. Mr. President, I move that the Senate proceed to the consideration of S. 2466.

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

The legislative clerk read as follows:

Calendar 970, S. 2466, a bill to amend the Public Health Service Act to establish the National Institutes of Health Care Research; to extend and revise the assistance programs for health services research and health statistics, to establish the National Center for the Evaluation of Medical Technology, and for other purposes.

The motion was agreed to and the Senate proceeded to consider the bill which had been reported from the Committee on Human Resources with an amendment to strike all after the enacting clause and insert the following:

SHORT TITLE; REFERENCE TO ACT

SECTION 1. (a) This Act may be cited as the "National Institutes of Health Care Research Act of 1978".

(b) Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Public Health Service Act.

SEC. 101. Section 304 and the heading thereto are amended to read as follows:

"NATIONAL INSTITUTES OF HEALTH CARE RESEARCH

"SEC. 304. (a) The Secretary shall establish, in the Department of Health, Education, and Welfare, the National Institutes of Health Care Research (hereinafter in this section referred to as the "Institutes"). The Institutes shall be headed by a Director appointed by the President, by and with the advice and consent of the Senate. The Director, with the approval of the Secretary, may appoint a Deputy Director and may employ and prescribe the functions of such officers and employees as are necessary to administer the activities to be carried out through the Institutes.

"(b)(1) The Secretary, acting through the Institutes, shall conduct and support research, demonstrations, evaluations, and statistical and epidemiological activities for the purpose of improving the effectiveness, efficiency, and quality of health services in the United States.

"(2) In carrying out paragraph (1), the Secretary, acting through the Institutes, shall give appropriate emphasis to research, demonstrations, evaluations, and statistical and epidemiological activities respecting—

"(A) the accessibility, acceptability, planning, organization, distribution, utilization, and financing of systems for the delivery of health care,

"(B) alternative methods for measuring and evaluating the quality of systems for the delivery of health care,

"(C) the collection, analysis, and dissemination of health related statistics,

"(D) alternative methods to improve and promote health statistical and epidemiological activities,

"(E) the safety, efficacy, effectiveness, cost effectiveness, and social, economic, and ethical impacts of medical technologies,

"(F) alternative methods for disseminating knowledge concerning health and health related activities, and

"(G) the prevention of illness, disability, and premature deaths in the United States.

"(3) The Secretary, acting through the Institutes, shall (through National Research Service Awards) undertake and support manpower training programs to provide for an expanded and continuing supply of individuals qualified to perform the research, evaluation, and demonstration projects as set forth in sections 305, 306, and 305A.

"(4) The Secretary, acting through the Institutes, shall supervise the administration and operation of the National Institute for Health Policy Research, the National Institute for Health Statistics and Epidemiology, and the National Center for the Evaluation of Medical Technology in order to assure that (A) the programs carried out through each such Institute and Center receive appropriate and equitable support, and (B) there is cooperation among the Institutes and the Center in the implementation of such programs.

"(c) To implement subsection (b), the Secretary may, in addition to any other authority which under other provisions of this Act or any other law may be used by him to implement such subsection, do the following:

"(1) utilize personnel and equipment, facilities, and other physical resources of the Department of Health, Education, and Welfare, permit appropriate (as determined by the Secretary) entities and individuals to utilize the physical resources of such Department, provide technical assistance and advice, make grants to public and nonprofit entities and individuals, and, when appropriate, enter into contracts with public and private entities and individuals;

"(2) secure, from time to time and for such periods as the Secretary deems advisable, the assistance and advice of experts and consultants from the United States or abroad. In addition, the Director of the National Institute for Health Policy Research and the Director of the National Institute for Statistics and Epidemiology, in order to assist each of them in carrying out the functions set forth in sections 305 and 306, respectively, and without regard to any other provision of this Act, are each authorized to obtain the services of not more than fifteen experts or consultants who have appropriate scientific or professional qualifications; and

"(3) acquire, construct, improve, repair, operate, and maintain laboratory, research, and other necessary facilities and equipment, and such other real or personal property (including patents) as the Secretary deems necessary; and acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise, through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia.

"(d) The Secretary shall coordinate all research, evaluation, demonstration, and statistical and epidemiological activities referred to in subsection (b) undertaken and supported through units of the Department of Health, Education, and Welfare. Such coordination shall be carried out through the Institutes.

"(e) The Director of the Institutes shall submit a report to the Secretary for simultaneous transmittal, not later than October 30 of each year, to the President and to the Committee on Human Resources of the Senate and the Committee on Interstate and Foreign Commerce of the House of Representatives setting forth the program accomplishments of the Institutes in the preceding fiscal year and the objectives and priorities for the current fiscal year.".

SEC. 102. (a) The heading for section 305 is amended to read as follows:

"NATIONAL INSTITUTE FOR HEALTH POLICY RESEARCH".

(b) Section 305(a) is amended to read as follows:

"(a) There is established in the National Institutes of Health Care Research the National Institute for Health Policy Research (hereinafter in this section referred to as the 'Institute') which shall be under the direction of a Director who shall be appointed by the Secretary and supervised by the Director of the National Institutes of Health Care Research.".

(c) Section 305(b) is amended by—

(1) striking "304(a)" and inserting in lieu thereof "304(b)";

(2) Striking "Center" and inserting in lieu thereof "Institute";

(3) striking "may undertake" and inserting in lieu thereof "shall undertake";

(4) striking "and" after "evaluation," and inserting in lieu thereof "and/or";

(5) striking "technology," in paragraph (1);

(6) striking "and" after "manpower;" in paragraph (2);

(7) striking the period in paragraph (3) and inserting in lieu therof ", and"; and

(8) adding at the end thereof the following new paragraph:

"(4) the uses of computer science in health services delivery and medical information system.".

(d) Section 305(c) is amended by striking "Center" and inserting in lieu thereof "Institute".

(e) Sections 305(d)(1) and 305(d)(2)(A) are amended by inserting ", acting through the Institute," after "Secretary" each place it occurs.

(f) Subsection (e) of section 305 is amended by striking "304(h)" and inserting in lieu thereof "304(c)".

SEC. 103. (a) The heading to section 306 is amended to read as follows:

"NATIONAL INSTITUTE FOR HEALTH STATISTICS AND EPIDEMIOLOGY".

(b) Section 306(a) is amended to read as follows:

"(a) There is established in the National Institutes of Health Care Research the National Institute for Health Statistics and Epidemiology (hereinafter in this section referred to as the 'Institute') which shall be under the direction of a Director who shall be appointed by the Secretary and supervised by the Director of the National Institutes of Health Care Research.".

(c) Section 306(b) is amended by—

(1) striking "304(a)" and inserting in lieu thereof "304(b)";

(2) striking "Center" and inserting in lieu thereof "Institute";

(3) striking "may" and inserting in lieu thereof "shall";

(4) striking "and" after "dissolution" in paragraph (1)(H);

(5) inserting "or both" after "contract" in paragraph (2);

(6) striking "and" after "demonstration." in paragraph (2) and inserting in lieu thereof "and/or"; and

(7) adding at the end thereof the following new paragraph:

"(3) undertake and support (by grant or contract or both) epidemiological research, demonstrations, and evaluations on the matters referred to in paragraph (1).".

(d) Section 306(c) is amended by—

(1) striking "Center" and inserting in lieu thereof "Institute";

(2) inserting "and epidemiological" after "statistical" each place it occurs; and

(3) striking "Labor and Public Welfare" and inserting in lieu thereof "Human Resources".

(e) Section 306(d) is amended by striking "Center" and inserting in lieu thereof "Institute".

(f) Section 306(e) is amended by—

(1) inserting ", through the Institute," after "Secretary";

(2) inserting "to be known as the Cooperative Health Statistics System" after "levels" in paragraph (1);

(3) striking "such cooperative system" each place it occurs and inserting in lieu thereof "such System";

(4) inserting "or both" after "contract" in paragraph (3).

(g) The first sentence of section 306(f) is amended by inserting ", through the Institute," after "Secretary".

(h) Section 306(g) is amended by inserting ", through the Institute," after "health data, the Secretary".

(i) Section 306(i)(1) is amended by striking "United States".

(j) Section 306 is amended by adding at the end thereof the following new subsection:

"(j) In carrying out the requirements of sections 304(d) and paragraph (2) of subsection (e), the Secretary, acting through the Institute, shall coordinate health statistical and epidemiological activities of the Department of Health, Education, and Welfare by—

"(1) developing in consultation with the National Committee on Vital and Health Statistics, promulgating by regulation, and maintaining the minimum sets of data needed on a continuing basis to fulfill the collection requirements of subsection (b)(1),

"(2) after consultation with the National Committee on Vital and Health Statistics, establishing, by regulation, standards to assure the quality of health statistical and epidemiological data collection, processing, and analysis,

"(3) reviewing periodically all existing health statistical data collections of the Department that were previously approved pursuant to the Federal Reports Act of 1942 to determine whether such collections conform with the minimum sets of data and the standards promulgated pursuant to paragraphs (1) and (2). If any such collections are found not to be in conformance, the Secretary shall take the necessary action to assure that any future collections (effective ninety days after the review) are in conformance,

"(4) reviewing all proposed health statistical data collections of the Department that require approval pursuant to the Federal Reports Act of 1942 to determine whether such proposed collections conform with the minimum sets of data and the standards promulgated pursuant to paragraphs (1) and (2). If any such proposed collections are found not to be in conformance, the Secretary shall take the necessary action to bring them into conformance before such proposed collections are initiated.".

SEC. 104. Title III is amended by adding after section 306 the following new heading and section:

"NATIONAL CENTER FOR THE EVALUATION OF MEDICAL TECHNOLOGY

"SEC. 306A. (a) There is established in the National Institutes of Health Care Research the National Center for the Evaluation of Medical Technology (hereinafter in this section referred to as the 'Center') which shall be under the direction of a Director who shall be appointed by the Secretary and supervised by the Director of the National Institutes of Health Care Research.

"(b) The Secretary, acting through the Center, shall—

"(1) establish, in consultation with the Council for the Evaluation of Medical Technology, priorities for research, demonstrations, and evaluations of medical technologies as prescribed by paragraph (2)(A). In establishing such priorities, particular emphasis should be placed on—

"(A) the actual or potential risks and the actual or potential benefits to patients associated with the use of the medical technology,

"(B) per use and/or aggregate cost of the medical technology,

"(C) the rate of utilization of the medical technology, and

"(D) the stage of development of the medical technology; and

"(2) undertake and support (by grant or contract or both) research, demonstrations, and evaluations concerning—

"(A) the safety, efficacy, effectiveness, cost effectiveness, and social, ethical, and economic impact of particular medical technologies;

"(B) the factors that affect the utilization of medical technologies throughout the United States;

"(C) alternative methods for disseminating information on medical technologies to health professionals;

"(D) alternative methods for measuring the quality of health services; and

"(E) the effectiveness, administration, and enforcement of quality assurance programs.

"(c) To assist in carrying out this section, the Secretary, acting through the Center, shall cooperate and consult with the National Institutes of Health, the Veterans' Administration and any other interested Federal departments or agencies and with State and local health departments and agencies.

"(d)(1) The Secretary, acting through the Center, shall, by grants or contracts, or both, assist public and/or private nonprofit entities in meeting the costs of planning and establishing new centers, and operating existing and new centers for multidisciplinary research, evaluations, and demonstrations respecting the matters referred to in paragraph (2) of subsection (b). To the extent practicable, the Secretary shall take such actions, in accordance with the requirements of this subsection and section 308, to assure that three such centers shall be operational by September 1, 1981.

"(2)(A) No grant or contract may be made under this subsection for planning and establishing a center unless the Secretary, acting through the Center, determines that when it is operational it will meet the requirements listed in subparagraph (B), and no payment shall be made under a grant or contract for operation of a center unless the center meets such requirements.

"(B) Each center shall meet the following requirements:

"(i) there shall be a full-time director of the center who possesses a demonstrated capacity for sustained productivity and leadership in research, demonstrations, and evaluations respecting the matters referred to in paragraph (2) of subsection (b), and there shall be such additional professional staff as may be appropriate;

"(ii) the staff of the center shall have expertise in the various disciplines needed to conduct multidisciplinary research, evaluations and demonstrations respecting the matters referred to in paragraph (2) of subsection (b);

"(iii) the center shall be located within an established academic or research institution with departments and resources appropriate to the programs of the center; and

"(iv) each center shall meet such additional requirements as the Secretary may by regulation prescribe.

"(e) (1) There is established in the Center a National Council for the Evaluation of Medical Technology (hereinafter in this subsection referred to as the 'Council') to be composed as follows:

"(A) The Surgeon General, the Director of the National Institutes of Health, the Chief Medical Director of the Veterans' Administration, the Assistant Secretary of Defense

for Health Affairs, the Chairman of the National Professional Standards Review Council (or their designees), and three other employees of the Department of Health, Education, and Welfare (or their designees) appointed by the Secretary, shall be ex officio members of the Council.

"(B) Eighteen members appointed by the Secretary. Six of the appointed members shall be selected from among leading medical or scientific authorities; two of the appointed members shall be practicing physicians; two of the appointed members shall be practicing hospital administrators; two of the appointed members shall be selected from members of the general public who are leaders in the field of economics; two of the appointed members shall be selected from members of the general public who are leaders in the field of law; and four of the appointed members shall be selected from outstanding members of the general public who, based on their interests, disciplines, and/or expertise, would be appropriate members of the Council.

"(2)(A) Each appointed member of the Council shall be appointed for a term of four years, except that—

"(i) any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term; and

"(ii) of the members first appointed after the effective date of this section, five shall be appointed for a term of four years, five shall be appointed for a term of three years, five shall be appointed for a term of two years, and three shall be appointed for a term of one year, as designated by the Secretary at the time of appointment.

Appointed members may serve after the expiration of their terms until their successors have taken office.

"(B) A vacancy in the Council shall not affect its activities, and twelve members of the Council shall constitute a quorum.

"(C) Members of the Council who are not officers or employees of the United States shall receive for each day they are engaged in the performance of the functions of the Council compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule, including traveltime; and all members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

"(3) The Council shall annually elect one of its appointed members to serve as Chairman until the next election.

"(4) The Director of the Center shall (1) designate a member of the staff of the Center to act as Executive Secretary of the Council, and (2) make available to the Council such staff, information, and other assistance as it may require to carry out its functions.

"(5) The Council shall meet at the call of the Chairman, but not less often than four times a year.

"(6) The Council is authorized to—

"(A) advise, consult with, and make recommendations to the Secretary, the Director of the National Institutes of Health Care Research, and the Director of the Center with respect to carrying out the provisions of this section;

"(B) after consultation with appropriate public and private entities, advise the Secretary concerning the safety, efficacy, effectiveness, cost effectiveness, and the social and economic impact of particular medical technologies;

"(C) after consultation with appropriate public and private entities, develop, when appropriate and to the extent practicable, exemplary standards, norms, and criteria concerning the utilization of particular medical technologies;

"(D) publish, make available and disseminate, through the National Library of Medicine, promptly in understandable form and as widely as possible, but, at a minimum, to each of the National Institutes of Health, to the Food and Drug Administration, to the Indian Health Service, and the Bureau of Medical Services of the United States Public Health Services, to all health systems agencies, to all Professional Standards Review Organizations, to all medical schools, professional associations, State and local departments of public health, and to the Department of Medicine and Surgery of the Veterans' Administration and the Assistant Secretary of Defense for Health Affairs, the standards, norms, and criteria developed pursuant to paragraph (C); and

"(E) review and approve any grant that the Center proposes to make and any contract the Center proposes to enter pursuant to this section if such grant or contract is in an amount exceeding $35,000 of direct costs.

"(f) For purposes of this section, medical technology means any discrete and identifiable medical or surgical regimen or modality used to diagnose or treat illness, prevent disease, support life, or maintain patient well-being.".

SEC. 105. (a) The heading to section 308 is amended by striking "304, 305, 306, AND 307" and inserting in lieu thereof "304, 305, 306, 306A, AND 307,".

(b) Section 308(a)(1) is repealed.

(c) Section 308(a)(2) is amended by (1) redesignating it as section 308(a) (1), and (3) striking "the National Center for Health Services Research and the National Center for Health Statistics" and inserting in lieu thereof "the National Institutes of Health Care Research".

(d) Section 308(a)(3) is redesignated as section 308(a)(2).

(e) Section 308(b)(1) is amended by inserting "306A," after "306".

(f) Section 308(d) is amended by (1) inserting "306A," before "or 307" and (2) by inserting "or epidemiological" after "statistical" in paragraph (1).

(g) Section 308(e) is amended by inserting "306A," after "306" each place it occurs.

(h) Section 308(f) is amended by striking "or 306" and inserting in lieu thereof "306, or 306A".

(i) Section 306(g)(2) is amended by striking "and 306" and inserting in lieu thereof "306, and 306A".

(j) Section 308(h)(1) is amended by striking "or 306" each place it occurs and inserting in lieu thereof "306 or 306A".

(k) Section 308(i)(1) is amended to read as follows:

"(i)(1) For health services research, evaluation, and demonstration activities undertaken or supported under section 304 or 305, there are authorized to be appropriated $40,000,000 for the fiscal year ending September 30, 1979; $45,000,000 for the fiscal year ending September 30, 1980; and $50,000,000 for the fiscal year ending September 30, 1981. Of the funds appropriated under this paragraph for any fiscal year, at least 15 per centum of such funds or $6,000,000, whichever is less, shall be available only for health services research, evaluation, and demonstration activities directly undertaken by the National Institute for Health Policy Research and a least 5 per centum of such funds or $1,00,000, whichever is less, shall be available only for dissemination activities directly undertaken by the Center.".

(l) Section 308(i)(2) is amended to read as follows:

"(i)(2) For health statistical and epidemiological activities undertaken or supported under section 304 or 305, there are authorized to be appropriated $60,000,000 for the fiscal year ending September 30, 1979, $65,000,000 for the fiscal year ending September 30, 1980, and $70,000,000 for the fiscal year ending September 30, 1981. Of the funds appropriated under this paragraph for any fiscal year commencing after September 30, 1978, at least 15 per centum of such funds shall be available only for health statistical and epidemiological activities directly undertaken by the National Institute for Health Statistics and Epidemiology.".

(m) Section 308(i) is amended by adding at the end thereof the following new paragraph:

"(3) For medical technology research, evaluation, and demonstration activities undertaken or supported under section 304 or 306A, there are authorized to be appropriated $25,000,000 for the fiscal year ending September 30, 1979, $35,000,000 for the fiscal year ending September 30, 1980, and $50,000,000 for the fiscal year ending September 30, 1981. Of the funds appropriated under this paragraph for any fiscal year commencing after September 30, 1980, at least 15 per centum of such funds shall be available only for medical technology research, evaluation, and demonstration activities directly undertaken by the National Center for the Evaluation of Medical Technology.".

SEC. 106. (a) Section 472(a)(3)(A) is amended by—

(1) striking "and" after "private institutions," in clause (iii);

(2) redesignating clause (iv) as clause (vii); and

(3) inserting after clause (iii) the following:

"(iv) research at the National Institutes of Health Care Research,

"(v) training at the National Institutes of Health Care Research to undertake such research,

"(vi) research on the matters set forth in section 304(b)(2) at public institutions and at nonprofit private institutions, and".

(b) The last sentence of section 472(a)(3) is amended by inserting ", National Institutes of Health Care Research," after "National Institutes of Health".

SEC. 107. Part K of title III is repealed in its entirety.

SEC. 108. Title IV is amended by adding at the end thereof the following new section:

"SEC. 477. The Director of the National Institutes of Health shall make available annually to the National Center for the Evaluation of Medical Technology and the Council for the Evaluation of Medical Technology a list of all technologies (as defined in section 306A(g)) of which he is aware that are under development and that appear likely to be used in medical practice in the near future.".

SEC. 109. The Secretary, acting through the National Institute for Health Policy Research, shall arrange for the conduct of a study to evaluate the impact upon the utilization of health services by and the health status of members of the United Mine Workers and their dependents as a result of changes in the United Mine Workers' collective-bargaining agreements of March 1978, that require copayments for health services. Such study and a report thereon shall be completed and submitted to the Secretary, the Committee on Human Resources, the Committee on Appropriations, and the Committee on Finance of the Senate, and the Committee on Ways and Means, the Committee on Appropriations, and the Committee on Interstate and Foreign Commerce of the House of Representatives no later than thirty months after the date of enactment of this section. Not more than $1,000,000 of the sums authorized to be appropriated for health services research,

...evaluation and dissemination activities by section 308(d)(1) of the Public Health Service Act as amended by section 105 of this Act shall be made available for such study.

SEC. 110. (a) The Secretary, acting through the National Institutes for Health Care Research, in cooperation with the Secretary of Labor and the Administrator of the Environmental Protection Agency, shall develop a plan for the collection and coordination of statistical and epidemiological data on the effects of the environment on health. Such plan shall include, but not be limited to, a review of the data now available on health effects, deficiencies in such data, and methods by which existing data deficiencies can be corrected. The plan shall be submitted to Congress not later than October 1, 1979.

(b) In carrying out the provisions of subsection (a), the Secretary, the Secretary of Labor, and the Administrator of the Environmental Protection Agency shall consult with the Committee on Human Resources and other appropriate committees of the Senate and the Committee on Interstate and Foreign Commerce and other appropriate committees of the House of Representatives.

Mr. KENNEDY. Mr. President, I would like to make a few comments on S. 2466, the National Institutes of Health Care Research Act of 1978, as the Senate moves to consider this legislation. I introduced S. 2466 on January 30, 1978 with the cosponsorship of Senators SCHWEIKER, WILLIAMS, and JAVITS. The purpose of this proposed legislation is to give focus, strength, and vitality to a series of research and statistical activities aimed at improving the quality, efficiency, and effectiveness of health services in the United States. I urge my colleagues to give favorable consideration to this proposal.

Americans have an abiding faith that new knowledge can improve their lives. I share this belief. I am proud that our country has had the wisdom to invest generously over the last 30 years in biomedical and behavorial research aimed at the conquest of disease. Hard as it is to believe now, there was a time when these research areas were neglected and undeveloped. It took a combination of unstinting public funding and careful institution building to bring them to the point they are today. That national effort is now paying generous dividends.

This history of Federal involvement in the biomedical and behavioral research offers important lessons for the Congress and the American people. For despite our Nation's commitment to health research, some areas of health related inquiry are still neglected. These activities include:

First. Health services research and development.

Second. Health statistics.

Third. Epidemiology.

Fourth. Technology evaluation.

These research activities have made major contributions to our understanding of health care trends in the Nation. They have provided a factual backdrop for many important decisions in the health field in the areas of cost containment, quality of care, the distribution of health services, and the control of toxic substances. They have done so despite inadequate funding. In addition, where funds are available for such research activities, they are often fragmented haphazardly among uncoordinated and competitive programs. As a result, valuable opportunities to effect improvements in the Nation's health care system and the health of Americans have been lost.

The committee believes that we cannot expect research investments to pay off unless we provide the disciplines involved with the necessary support. The committee feels that the research activities described above need better funding. But just as much as more money, they need a defined institutional home and a more hospitable organizational climate.

Since they are related but distinct disciplines, these research activities need to be coordinated, but at the same time given enough room to follow separate leads. They must have public accountability. They need policy guidance. But they must be insulated from ever-fluctuating political pressure. Otherwise, they will not be able to pursue excellence in their respective fields.

For the traditional biomedical sciences, the NIH fulfills these institutional requirements. It is time, Mr. President, that we provided the same advantages to health services research and the other, related health science disciplines which we have traditionally neglected in this country.

It is for this purpose, Mr. President, that the Committee on Human Resources has reported S. 2466, the National Institutes of Health Care Research Act of 1978, to the Senate floor. This bill would provide an institutional home for health care research and related activities, an advantage which the biomedical sciences have enjoyed for decades. It would provide increased authority and direction for the Department to draw together scattered programs in the areas of statistics and health services research. It would provide moderate increases in funding for these activities. It would give HEW money and authority to expand and systemize its work in the area of evaluating health technologies. And it would provide an institutional umbrella which could be expanded to include other research missions as appropriate. These could include, for example, selected areas related to disease prevention and control.

Specifically, the bill would accomplish the following:

First. It would create a National Institutes of Health Care Research modeled upon and parallel to the National Institutes of Health. This umbrella organization would provide overall policy guidance and coordination for its component institutions.

Second. It would create a National Center for the Evaluation of Medical Technologies, a new agency located in the National Institutes of Health Care Research. The purpose of this new Center would be to assess the cost and effectiveness of medical practices and procedures.

Third. It would expand, redirect and rename the National Center for Health Statistics. This agency would take on important new functions in the conduct of epidemiologic research and in the coordination of health statistics work. It would become a component institute of the National Institutes of Health Care Research.

Fourth. Finally, S. 2466 would expand, redirect and rename the National Center for Health Services Research. This agency would also become a component institute of the National Institutes of Health Care Research.

Under the new law, the NIHCR would be charged with the responsibility of supporting research, demonstrations, evaluations, and statistical and epidemiological activities which examine—

First. The accessibility, acceptability, planning, organization, distribution, utilization and financing of systems for the the delivery of health care;

Second. Alternative methods for measuring and evaluating the quality of systems for the delivery of health care;

Third. The collection, analysis, and dissemination of health-related statistics;

Fourth. Alternative methods to improve and promote health statistical and epidemiological activities;

Fifth. The safety, efficacy, effectiveness, cost effectiveness, and social, economic, and ethical impacts of medical technologies; and

Sixth. Alternative methods for disseminating knowledge concerning health and health related activities.

The committee is aware of the concerns expressed in some quarters that the strong coordinating mandate of the proposed NIHCR will interfere with the ability of various programs in the Department to perform their missions effectively. The committee recognizes that multiple PHS and HCFA agencies have ongoing and important activities in the gathering of health statistics, the conduct of epidemiology, the evaluation of clinical procedures and the conduct of health services research. It is not the committee's intent to centralize all these functions in one agency, or to frustrate the mission-oriented work of the various agencies.

However, the committee also feels strongly that some agency in the Department must be given responsibility for making certain that the activities of these various bureaucratic entities are molded, to the maximum extent practical, into a coordinated and comprehensive plan for health research and development. The current situation, bordering on administrative chaos, cannot be permitted to persist. It wastes the scarce resources of research disciplines which have been historically underfunded and neglected. It creates a situation in which research and data which are potentially useful to many Department agencies cannot serve multiple purposes. It further discredits research activities which, though very important, have never been sufficiently appreciated within the Federal Government.

The balance between central planning and agency freedom is difficult to set in any substantive area. In the past, because of lack of administrative interest and intense bureaucratic rivalries, the pendulum in the research areas we are dis-

quality has swung dramatically toward deinstitutionalization. The committee feels that strong corrective measures are in order.

Mr. President, let me comment now on some of the specific provisions of S. 2466.

The proposed legislation would establish a National Institute for Health Policy Research whose functions would incorporate and expand current activities at the National Center for Health Services Research. The legislation would authorize an increase in appropriations for health services research, from $28.6 million in 1978 to $40 million in 1979, $45 million in 1980, and $50 million in 1981.

The new National Institute for Health Policy Research would be required specifically to undertake and support research, evaluation, and/or demonstration projects which examine—

First. The accessibility, acceptability, planning, organization, distribution, utilization, quality, and financing of health services and systems;

Second. The supply and distribution, education and training, quality, utilization, organization, and costs of health manpower;

Third. The design, construction, utilization, organization, and cost of facilities and equipment; and

Fourth. The use of computer science in health services delivery and medical information systems.

This last directive grows out of a comprehensive Office of Technology Assessment study which illustrated the pressing need for work on medical information systems, particularly as they employ computer technologies.

The committee believes that despite the many accomplishments of the National Center for Health Services Research since 1974, the need for reform in the National Center's mandate and functioning is clear. The National Center has had a number of problems during these years of accomplishment, but it is not clear that these problems reflect exclusively a failing of the Center. And in no way do these difficulties imply that health services research is anything less than vital and indispensable. The committee believes that the creation of a National Institute for Health Policy Research would lay the necessary institutional groundwork for a revitalized and strengthened health services research facility.

By transforming the National Center for Health Services Research into the National Institute for Health Policy Research, the committee has been guided by the following objectives and intentions:

First, health services research must be regarded as a research discipline, not simply a short-term aid to policy formation.

Second, health services research must be protected to the extent possible from political pressures so that excellent research may be conducted and so that talented personnel may be recruited.

Third, health services research must remain relevant to policy needs—thus the Institute for "Health Policy Research"—but the time frame for its accomplishments must be reasonable.

The committee also proposes to establish as a component part of the National Institutes of Health Care Research a National Institute for Health Statistics and Epidemiology which would incorporate the mission of the National Center for Health Statistics and add two crucial new functions to the Center's activities. The new National Institute will continue the Center's excellent and widely respected health surveys and monitoring activities which have provided detailed information on such crucial matters as the prevalence and incidence of various diseases in the Nation, infant mortality rates, the frequency of visits to physician offices, utilization of hospital beds, and the levels of expenditures for various health services.

The committee has mandated for the new National Institute two additional functions which the Center never fully addressed or implemented. First, it will become by law the Secretary's instrument for coordinating health data collection in the Department of Health, Education, and Welfare and for eliminating overlap, duplication and lack of standardization in data gathering. Second, the National Institute will assume major new responsibilities intended by the committee to strengthen the Nation's capability to perform epidemiological work.

The need for improved coordination of the Department's health statistical activities has long been recognized by both the administration and the Congress. The Center, under its mandate to establish the cooperative health statistical system, has made progress recently in achieving coordination of data gathering activities within the Public Health Service. However, progress has been slow and the committee has noted the substantial and persistent problems which have impeded cooperation between the Health Care Financing Adminsitration and the Public Health Service. There is evident a pressing need to revise authorities which permit the same data to be gathered twice, which allow agencies to refuse to share data, and which provide individual agencies with an opportunity to define unique standards for data collection, with the result that statistics are frequently not comparable from one agency to another.

With regard to the National Institute's new epidemiological responsibilities, the committee proposes that the Institute undertaken an expanded program of intramural and extramural epidemiology and data analysis. The committee believes that the National Institute could make a major contribution in explaining trends in the health status of the population (for example, the cause of the dramatic recent decline in deaths from heart disease), and in perfecting the methodology of statistical work in epidemiology. Currently, the National Center for Health Statistics funds original research at a level of less than $300,000 out of a budget of $36 million.

Consistent with this expanded mandate, the legislation provides the National Institute for Health Statistics and Epidemiology with an authorization of $60 million for fiscal year 1979, $65 million for fiscal year 1980, and $70 million for fiscal year 1981. It should be noted that the committee has increased authorizations at these levels for the additional reason of permitting the National Institute to expand substantially the cooperative health statistics system. Such authorizations should permit the National Institute to arrange for three components of the system to be in place in all 50 States by the end of 1979. By 1983, if the sums suggested become available, the cooperative health statistics system should be fully installed throughout the United States.

The legislation proposes to establish a new agency, the National Center for the Evaluation of Medical Technology, which would be a component part of the National Institutes of Health Care Research. The new National Center would be charged with the responsibility of supporting evaluations of new and existing medical technologies. The committee believes that such evaluations are absolutely critical if the cost of medical care is to be reduced and quality of care is to be improved. Currently no Federal agency has clear responsibility for this task.

The Nation has witnessed in recent years an unprecedented explosion in our understanding of biology and of disease. The research community is often criticized for failing to transfer this new knowledge rapidly enough from bench to bedside, from laboratory abstraction to practical application. This is a problem of "technology transfer" with which the Congress and this committee has been especially concerned recently.

This alleged lag in the translation of knowledge from bench to bedside is one part of the technology transfer problem. There is another side to the problem, a dimension which also has its roots in the productivity of the research establishment. While some new medical technologies lag in their translation from bench to bedside, others are applied too quickly. With the quickening pace of biomedical research, there has been a proliferation in the number and kinds of health practices and procedures to which patients are subjected. Some of these new technologies and practices have found their way into widespread use before their efficacy and safety have been established by thorough scientific testing.

It has been estimated by some experts that as much as one-half of the annual increase in the cost of a day of hospital care can be attributed to the use of more technology in medical practice. This estimate would mean that between 1966 and 1976 expenditures for medical technology added $8 to $12 billion to the Nation's hospital bill, which totaled $55 billion in 1977. At subcommittee hearings last summer, testimony was presented on the cost and effectiveness of surgery for coronary artery disease. Each such operation costs from $10,000 to $12,500, and national expenditures for coronary artery surgery alone have approached $1 billion a year. This new surgical procedure was in widespread use before any comprehensive studies had been done to establish its

efficiency and effectiveness. The result has been a growing consensus that it is overutilized, with substantial adverse consequences for the health of some patients and the costs of medical care generally.

For these several reasons, the committee proposes to establish a National Center for the Evaluation of Medical Technology. Specifically, the National Center would be required to undertake and support research, demonstrations, and evaluations concerning—

First, the safety, efficacy, effectiveness, cost effectiveness, and social, ethical, and economic impact of particular medical technologies;

Second, the factors that affect the utilization of medical technologies throughout the United States;

Third, alternative methods for disseminating information on medical technologies to health professionals;

Fourth, alternative methods for measuring the quality of health services; and

Fifth, the effectiveness, administration, and enforcement of quality assurance programs.

The committee sees a number of special roles for the National Center which are not and cannot be fulfilled by other agencies. First, the committee hopes the Center will provide valuable assistance to the Department in setting priorities for the study of medical practice and procedures. This priority setting process must take into account multiple views and perspectives including those of clinicians, scientists, Federal regulatory decisionmakers, hospital administrators and others. The proposed membership of the Council is carefully designed to provide the necessary input for this Department-wide function. No other agency currently has this capacity.

Second, the Center's mandate permits it to study some medical practices and procedures for which no governmental agency currently has special responsibility. Examples of these are surgical procedures and regimens which involve drugs, devices and procedures in a coordinated protocol. It is expected that the Food and Drug Administration would continue to be chiefly responsible in the Federal Government for collecting and evaluating information on the safety and efficacy of individual drugs and devices.

Third, the National Center would be the only Federal agency with the talents and the mandate to consider the costs of procedures and practices, as well as their safety and efficiency, in formulating model norms and standards.

Finally, with the creation of the National Center for the Evaluation of Medical Technologies, the Department would at last have a single agency with responsibility for surveying all on-going evaluations of medical technologies, for recommending where important gaps exist, and for providing early warning when important new practices and procedures are coming into use without appropriate testing for safety, cost and efficacy.

In order to undertake these important and unique activities, the committee has provided the National Center for the Evaluation of Medical Technologies with an authorization of $25 million for fiscal year 1979, $35 million for fiscal year 1980, and $50 million for fiscal year 1981.

Mr. President, I think the various provisions of S. 2466, taken together, will go a long way toward revitalizing and strengthening a series of research disciplines which hold major promise for improving the efficiency, effectiveness and quality of our Nation's health care services. I am pleased to convey again the unanimous opinion of the Committee on Human Resources that the legislation deserves favorable consideration from the Senate.

Again, Mr. President, I wish to express my appreciation to the members of the committee, and to my colleague and principal minority sponsor of this legislation, the Senator from Pennsylvania (Mr. SCHWEIKER).

The PRESIDING OFFICER. The Senator from Pennsylvania.

Mr. SCHWEIKER. Mr. President, I rise in support of S. 2466, the National Institutes of Health Care Research Act. This legislation will reorganize health services research, health statistics, and epidemiological activities within the Department of Health, Education, and Welfare and create a new National Center for the Evaluation of Medical Technologies.

The Subcommittee on Health and Scientific Research, of which I am the ranking Republican member, has conducted a series of hearings on federally supported research activities over the past year. In the course of these hearings, it has become clear that not enough research in the area of health services delivery is now being done. I have concluded that the current governmental research entities in many cases could not, and in other instances, would not, give this area the priority it deserves.

I want to stress that this bill does not envision the centralization of the functions of all existing Public Health Service and Health Care Financing Administration efforts into one superagency. I recognize that the Center for Disease Control has developed expertise in the field of epidemiology related to the control of infectious disease and the investigation of disease incidence and outbreaks, for example, and should retain its capabilities in such areas, and that the National Institutes of Health should continue its important epidemiological work in the disease-oriented institutes. The mandate in this bill is for clearer coordination, not the elimination of functions performed well and with great expertise by responsible existing agencies.

I do not in any way wish to suggest that the research currently being conducted is undesirable or unnecessary, but I am convinced that greater attention to health services research, epidemiological studies, and the assessment of medical technologies is warranted. In addition, current statistical activities supported by various agencies within HEW have at times proved to be less useful than they could have been, due to problems of coordination and comparability of data. Perhaps as much as $200 million could be saved if statistical and data gathering activities could be effectively coordinated and duplication eliminated, according to one estimate.

I hope that the bill before us today will go a long way toward improving statistical and epidemiological activities by strengthening the mandate of the present National Cancer for Health Statistics, forming a National Institute of Health Statistics and Epidemiology. This Institute, along with the National Institute for Health Policy Research (which will succeed the present National Center for Health Services Research) and the Center for the Evaluation of Medical Technology, will comprise the National Institutes for Health Care Research, according to the terms of S. 2466.

It is not my intention in supporting a new National Center for the Evaluation of Medical Technologies to create a Federal agency which will regulate medical technology or medical practice. Rather, I seek to establish a national center to serve as a focal point for medical technology assessment activities, to evaluate appropriate technologies for safety and effectiveness and share the result of these evaluations with the appropriate public and private entities.

The Center will be advised in the discharge of its functions by a National Council for the Evaluation of Medical Technologies. I believe it is critical that representatives of the private health care community be involved in the Council's work, and I am pleased that the bill as reported by the committee specifically provides for representation on the Council of leading medical and scientific authorities, practicing hospital administrators and practicing physicians.

One other aspect of the bill which I would like to highlight is the provision I introduced to require the Institute for Health Policy Research to conduct a study of the impact of the new United Mine Workers' collective-bargaining agreement, which requires copayment for health services, upon the utilization of health services and the health status of the mine workers and their families. It has been suggested by a number of very distinguished health experts that copayment would reduce utilization without adversely affecting health status. The new agreement ratified by the mine workers provides a unique opportunity for study which should not be lost. I am glad that my colleagues in the committee have agreed to this provision and concur with the need for the study. I think the results will be very useful as we continue to search for ways to control costs while assuring quality health care.

I believe S. 2466 will represent a positive step toward better performance and better coordination of federally supported health services research, technology assessment, and statistic collection and evaluation efforts and I urge my colleagues in the Senate to join me in support of this important legislation.

Mr. President, I yield myself 3 additional minutes.

Mr. President, I think it is important to point out that the United Mine Workers agreement gives us the opportunity to study and to put to rest the argument

once and for all about what copayment does. We all have opinions. We have all seen projections, but we have a prime case here that we can study to see what exactly the introduction of copayments in the mine workers health plan does in terms of holding down costs or not the same quantity or quality of health status, delivering health services at the same rate as before, or not delivering the same quantity or quality of health services to the mine worker families as before.

We have a unique experiment going on in this country. We ought to evaluate it and interpret what it means for our future health programs. I think that is a reasonable and a very pragmatic way to get some insight and to also utilize that insight for health economies in the future.

Here is another point I would like to make: As confusing as it may sound, we are actually just shifting three basic entities from the present setup into the National Institutes of Health Care Research. So we are not creating three new entities, and I think it is important to say that but we are taking three present entities and transferring them to a National Institutes of Health Care Research.

For example, the National Center for Health Statistics becomes the National Institute for Health Statistics and Epidemiology. That is an old center that becomes a new institute.

The National Center for Health Services Research becomes the National Institute of Health Policy Research, again an old agency with a new name and purpose.

Third, within the Office of the Assistant Secretary for Health there is now an Office for Evaluation of Medical Technology. That is now in existence. Under the proposed bill we are setting that up as a National Center for Evaluation of Medical Technology.

So all these three centers and offices currently exist. We are simply putting them into a National Institute of Health Care Research framework where they will not be kicked around or be stepchildren, as they have been before; where they will not be so subject to political influence; and wherever duplicate assessments of information or technologies are proposed that fact can be quickly ascertained and the duplication eliminated with one overall administrator who will be looking at the whole picture of HEW research and data gathering in the fields. This was not true before. I think it is going to lead to more efficient collection, and assessment of our statistics, epidemiological data, and health services research, as well as assessments of medical technologies.

The PRESIDING OFFICER. Who yields time?

Mr. SCHWEIKER. How much time does the Senator from Kansas wish?

Mr. DOLE. Fifteen minutes.

Mr. SCHWEIKER. Mr. President, I yield 15 minutes to the Senator from Kansas.

The PRESIDING OFFICER. The Senator from Kansas is recognized for 15 minutes.

Mr. DOLE. Mr. President, I wish to speak on S. 2466, which has not been passed and which I think perhaps needs some attention.

In an effort to improve health care research programs, the present bill proposes replacement of an existing agency in HEW with a new and expanded agency. By providing the new bureaucracy with a spanking new name, "The National Institute of Health Care Research," and by upgrading two of the three component agencies from "centers" to "institutes," we are led to believe in the committee report that new life and vitality will be instilled in the two older agencies. While such a "public relations" ploy may serve as a temporary palliative, I am not hopeful that any meaningful improvement in performance will result from passage of the present legislation.

The committee report sheds remarkably little light on why an institute of health care research is needed at this time. Instead of pinpointing the specific accomplishments of the old centers or the bold new initiatives to be assigned to the new institutes, we are given lame excuses as to why the previous performance of the centers has been so mediocre. Consider for example the following statement in the report:

> But just as much as more money, they (the institutes) need a defined institutional home and a more hospitable organizational climate . . . they must have public accountability. They need policy guidance. But they must be insulated from ever fluctuating political pressure. Otherwise, they will not be able to pursue excellence in their respective fields.

These vague generalizations and "good words" hardly provide the basis for the tremendous increase in funds authorized in the bill. Relative to present funding levels, a 100-percent increase is requested, bringing the total outlay to $125 million. If past experience is a reliable guide, I predict that this will mark the beginning of a vast bureaucratic entity.

Perhaps my strongest objection to the bill is that it will worsen the problem of overlapping authority which are rampant in HEW. To illustrate the duplication of effort, consider the fact that the center for disease control, the NIH, and the Health Care Financing Administration all have significant programs devoted to health care statistics. Yet, we are asked to increase funding substantially for still another bureaucracy so that the various programs in HEW can be better coordinated. I suggest that a more efficient and much less costly approach would be to coordinate this work through administrative means within the Office of the Assistant Secretary for Health.

In addition to the elevation of two centers to the status of institute, the bill creates an entirely new agency, the National Center for the Evaluation of Medical Technology. Amongst several other responsibilities, the center is required to support research concerning safety, efficacy, effectiveness, cost effectiveness, and social ethical, and economic impact of particular medical technologies. In addition to advising the various research and health-care delivery agencies, the center is charged the task of issuing standards—which, we are told, are not regulations—for the use of medical technologies.

It is certainly premature to reach any final conclusions about the relationship between technology and rising health care costs. Conventional wisdom of many health care professions indicates that technology is an important factor in determining health care costs and therefore should be monitored closely. What does concern me is that in our desire to hold down health care costs we not abandon our attempts to improve the health care system through vigorous research and development of medical technology.

I would also caution the committee that over-regulation of the development of medical technology could have a disastrous impact on the entire climate for innovation in the medical sciences. I suggest we pay close attention to advice offered by the eminent scientist, Edward David, who served as the President's science advisor in the last administration and now is the director of research at Exxon. Dr. David observed that "technology assessment can easily become technology arrestment," depending on the point of view of the persons conducting the assessment. If the present bill is enacted, we may soon find bureaucrats demanding that the laboratory scientist submit an "impact statement" before being given permission to initiate a scientific investigation. Only in totalitarian states is there a precedent for this kind of interference with generation of knowledge.

In evaluating the merits of the present bill, I urge the Members of the Senate to consider carefully the comments of Joseph Kraft which appeared in the Washington Post yesterday. Commenting on the passage of proposition 13 in California, Mr. Kraft noted:

> In fact almost all recent legislation—whether in health, housing, urban affairs, race, welfare, poverty, education, or communication—has been initiated and designed and lobbied and administered by the government professionals rather than by the private interests.

According to Mr. Kraft, the passage of proposition 13 indicates that the voters no longer support policies contrived exclusively by Government. With this in mind, I question whether there exists a constituency in the private sector that supports the present legislation.

In fact, I wonder if anybody supports the present legislation, if the administration supports the present legislation.

Recently, I have observed statements attempting to interpret the meaning of the passage in California of Proposition 13. We have been suggesting more effective ways to cut the fraud and fat and waste in public programs, and we understand it is not going to be easy to do that. Many of us have long been advocates of this kind of fiscal responsibility.

It seems to me, and perhaps I do not fully understand the proposed legislation, we are being asked to create a new agency and spend more money in the hope of solving a problem. I doubt the wisdom of the proposed approach. Earlier we cited what happens in cancer research,

where billions of dollars have been spent in the past 7 years. Perhaps the results are there, but for some reason we have not been informed of the results.

With respect to the present bill, it seems to me that all we are doing is expanding a bureaucracy where there is very little justification.

Finally, this bill has been well stated by the manager of the bill.

The National Center for Health Services Research will become the National Institute for Health Policy Research.

The National Center for Health Statistics to become National Institute for Health Statistics and Epidemiology.

To establish a new National Center for the evaluation of Medical Technology.

We are going to increase funding from $66 million to $125 million for fiscal year 1979.

It seems to me we now have in HEW some agencies that already carry out these activities. Maybe not. Maybe the Senator from Kansas does not fully understand the purpose of the bill.

I just cannot quite comprehend how we can create another bureaucracy within HEW, which is already overrun with bureaucracy and bureaucratic redtape, with a $182 billion total budget, and Secretary Califano himself said there was probably $7 billion in waste and fraud in HEW. How many more dollars do we have to send to HEW. When is a bargain no longer a bargain. Is this bill a bargain?

Let me give an illustration.

The Center for Disease Control, the NIH, and the Health Care financing Administration all have significant programs devoted to health care statistics, which is the mission of the new Institute for Health Statistics. The NIH, the Center for Disease Control, and the Food and Drug Administration all have statutory authority for monitoring medical technology, as will the new Institute for the Evaluation of Medical Technology.

So it seems to me that all we are doing is upgrading and adding more names, calling them institutes, and increasing funding and saying that this is a solution.

In the report, the committee acknowledges that the missions of the two Centers "have been repeatedly frustrated—primarily by the nature of the bureaucracy."

The committee also admits "that the Department relies heavily on personal ties between key administrators * * *" Also the committee continues to see evidence of destructive competition and poor coordination in the areas of health services research and health statistics.

Having said that, I fail to understand how the committee reaches the conclusion "that placing the two existing Centers in NIHCR will promote the long-term development of these two Centers * * *" This is another example of "shuffling and expanding the bureaucracy that the Senator from Kansas fails to understand.

The authority to issue standards for medical technology to the new Center for the Evaluation of Medical Technology may well result in overregulation of the development of useful medical technology. We are involved in overregulation all across America today. We must consider what regulation costs the American taxpayer and of what we are deprived as a result of overregulation.

The PRESIDING OFFICER. The Senator's 15 minutes have expired.

Mr. DOLE. May I have 5 additional minutes?

Mr. SCHWEIKER. I yield 5 additional minutes to the Senator.

Mr. DOLE. Mr. President, the report states that "the committee is aware of the concerns expressed by certain groups that the Center for the Evaluation of Medical Technology may become a regulatory agency * * *"

I said repeat what Dr. David said:

Technology assessment can easily become technology arrestment.

I would hope that is not the case. I appreciate the comments made by the distinguished Senator from Pennsylvania in suggesting that this is clearly not the case. By my evaluation of the bill is that I am not certain. I do not see how we are streamlining or increasing the responsiveness government. By putting in money, creating a new agency, and doubling the funding, what will we accomplish?

Maybe there is something of value in this bill that has missed the attention of the Senator from Kansas. But I would hope those who vote for this bill might look at it very carefully and then make the determination of whether or not it should be approved.

Mr. President, I yield back the remainder of my time.

The PRESIDING OFFICER. Who yields time?

Mr. KENNEDY. Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. On whose time?

Mr. KENNEDY. On our time.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. SCHWEIKER. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

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

AMENDMENT NO. 3006, AS MODIFIED

(Purpose: To assure health care needs for low income and minority persons)

Mr. SCHWEIKER. Mr. President, I call up amendment No. 3006, sponsored by my distinguished colleague from Pennsylvania (Mr. HEINZ), and ask that it be stated.

The PRESIDING OFFICER. The amendment will be stated.

The legislative clerk read as follows:

The Senator from Pennsylvania (Mr. SCHWEIKER), on behalf of Mr. HEINZ, proposes an amendment numbered 3006:

On page 24, line 7, strike "and".

On page 24, insert the following between lines 7 and 8: "(G) the special health needs of low income and minority individuals to insure that these needs are assessed not less than annually,".

On page 24, line 8, strike out "(G)" and substitute "(H)".

Mr. SCHWEIKER. Mr. President, I ask unanimous consent to send to the desk a modification of the amendment offered by Senator HEINZ, as a substitute.

The PRESIDING OFFICER. The modified amendment will be stated.

The legislative clerk read as follows:

On page 24, line 7, strike "and".

On page 24, insert the following between lines 7 and 8:

"(G) the health problems of low-income and minority groups and the elderly to insure that these problems are assessed on a regular, periodic basis.".

On page 24, line 8, strike out "(G)" and substitute "(H)".

Mr. SCHWEIKER. Mr. President, I understand that this amendment by my colleague from Pennsylvania, Senator HEINZ, as modified, is acceptable to the distinguished floor manager of the bill, and I urge its adoption. The adoption of this amendment certainly will strengthen and enhance the bill now before the Senate.

Mr. President, I ask unanimous consent to have printed in the RECORD a statement by Senator HEINZ which discusses the amendment in detail.

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

STATEMENT BY SENATOR HEINZ

Amendment No. 3006 proposed to S. 2486, the National Institutes of Health Care Research Act of 1978, is an important modification to a significant bill. S. 2486 would establish in the Department of Health, Education, and Welfare a National Institutes of Health Care Research. The Institutes would be responsible for conducting and supporting research, demonstrations, evaluations and statistical and epidemiological activities in order to improve the effectiveness, efficiency, and quality of health services in this country.

S. 2486 would also change the name of the National Center for Health Services Research to the National Institute for Health Policy Research, and this institute would become a component of the National Institutes of Health Care Research. Further, the National Center for Health Statistics would be renamed the National Institute for Health Statistics and Epidemiology and would also become a part of the National Institutes of Health Care Research. A new National Center for the Evaluation of Medical Technology would be established within the National Institutes of Health Care Research to assess the cost and effectiveness of medical practice and procedures. Finally, S. 2486 would provide authorizations of appropriations for the activities of the National Institutes of Health Care Research for 2 years.

I believe that it is essential for the new institutes to place emphasis on the severe problems in delivery of health services experienced by low-income and minority groups in this Nation. My amendment would insure that such a focus is established and reported on a regular, periodic basis.

Of special significance is a report published last September by the Department of Health, Education and Welfare which brought to our attention the massive need for attention to the health of the disadvantaged population in the United States. The report revealed the following disturbing facts:

Although the life expectancy gap between whites and minorities has decreased since 1900, minorities today have a life expectancy that is 6 years less than that of whites;

Geographically, the lowest life expectancy rate is found in the South, which has the highest percentage of low income and minority population;

The mortality rate of minorities is 60 percent higher than that of whites, and the mortality rate of minority males in 1970 was equal to that of white males in 1935;

Infant mortality rates for blacks and native Americans were significantly higher than for whites. During the period after birth—postnatal—mortality rates were twice as high for native Americans as for all races, and more than twice as high for blacks and native Americans as for whites;

Residents of poverty areas experienced a 50 percent greater infant mortality rate than those residents in nonpoverty areas;

A mother who happens to be black or Hispanic or native American has a four times greater chance of dying in childbirth than a white mother;

The prevalence of hypertension was approximately 66 percent greater for blacks than for whites; and this difference increases as age increases; and

Low income and minority persons visit the doctor less and have more severe problems than whites.

The list goes on and on and by all indices, disparity is greater for low-income and minority persons. Whether for number of days of disability, length of hospital stay, or nonaging institutional care, the message is the same. From a health standpoint, low-income and minority persons are worse off.

The evidence is overwhelming. We must take care, therefore, to insure that when this Congress moves to create a comprehensive approach to conducting research, demonstrations, evaluations, and statistical and epidemiological activities to improve the effectiveness, efficiency, and quality of health services in America, those most vulnerable should be given high-priority attention.

It is for this reason that I offer my amendment: to insure that the special health problems of low-income and minority groups are not submerged or subordinated, but instead are highlighted and addressed by the National Institutes of Health Care Research.

I urge my colleagues to give favorable consideration to this amendment and to the bill.

Mr. SCHWEIKER. Mr. President, I yield back the remainder of my time on this amendment.

Mr. KENNEDY. Mr. President, I have no objection to the amendment. As I understand, it includes the health problems of low-income minority groups as well as the elderly. That certainly will be a subject of concern before this institute.

I urge the Senate to accept the amendment.

The PRESIDING OFFICER. The question is on agreeing to the amendment, as modified.

The amendment, as modified, was agreed to.

Mr. KENNEDY. Mr. President, I ask unanimous consent that it be in order to ask for the yeas and nays on S. 2579 and S. 2466 at the appropriate time, after third reading.

The PRESIDING OFFICER. With a single show of hands on both?

Mr. KENNEDY. With a single show of hands.

The PRESIDING OFFICER. Is there a sufficient second? There is a sufficient second.

The yeas and nays are ordered on both bills.

Who yields time?

Mr. KENNEDY. Mr. President, I suggest the absence of a quorum, on my time.

The PRESIDING OFFICER. The clerk will call the roll.

The second assistant legislative clerk proceeded to call the roll.

Mr. KENNEDY. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

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

Mr. KENNEDY. Mr. President, I ask for a third reading on S. 2466.

The PRESIDING OFFICER. The bill is open to further amendment. If there be no further amendment, the question is on agreeing to the committee amendments in the nature of a substitute.

The committee amendments in the nature of a substitute were agreed to.

The bill was ordered to be engrossed for a third reading and was read the third time.

Mr. WILLIAMS. Mr. President, I am pleased to join with Senator KENNEDY and other members of the Committee on Human Resources in recommending passage of S. 2466, the National Institutes of Health Care Research Act of 1978.

Over the past year, oversight hearings reviewing federally supported research efforts have indicated that a number of research and related activities, which are needed to improve our Nation's health care delivery system, are being neglected. These include collection and analysis of health statistics, epidemiological research, health services research, and evaluation of medical technologies.

S. 2466 responds to the need by giving these activities a new institutional home within the Department of Health, Education, and Welfare and higher authorized levels of funding. Specifically, the bill would establish a seventh agency in the Public Health Service named the National Institutes of Health Care Research. Expiring authorities for the National Center for Health Statistics and the National Center for Health Services Research would be revised by renaming the Centers and granting them institute status. In addition, a new National Center would be created for the evaluation of medical technologies. This new Center and the two institutes would be grouped together in the new National Institutes of Health Care Research. And, perhaps most important from an institutional perspective, the new institutes would be parallel in structure to the National Institutes of Health.

It is widely recognized that we have invested much more as a Nation in biomedical research than we have on translating biomedical research findings into practical applications. S. 2466 has been designed to remedy this situation.

The overall intent of the legislation is to give new visibility, direction, and prestige to health statistics and epidemiology, health services research, and evaluation of medical technologies.

The provisions of S. 2466 would give us a base upon which to develop all of the elements necessary to our Nation's health research capacity and to improve the quality, efficiency, and effectiveness of health services for all Americans.

Mr. DOMENICI. Mr. President, I must reluctantly oppose S. 2466, the National Institute of Health Care Research Act. I share many of the concerns of my colleagues regarding the need for sound research and evaluation of health practices and new technology. Certainly, research and statistics are essential for policy discussions and for responsible allocation of scarce health resources. This need is becoming even more critical as new technology drives up spiraling health care costs and raises disturbing ethical questions about "who shall live." Choices will have to be made which will require highly reliable research concerning those alternatives which are most cost-effective in promoting the health of all citizens.

Thus, Mr. President, although I support the objectives of this legislation, I feel that it is premature at this time. It is my understanding that the administration does not support S. 2466 in its present form. Dr. Richmond, Assistant Secretary for Health, has outlined a comprehensive program to strengthen health care research which should achieve the objectives contained in S. 2466. The following is a list of some of the new initiatives announced by Dr. Richmond:

The National Center for Health Statistics (NCHS) and the National Center for Health Services Research (NCHSR) will be moved into the office of the Assistant Secretary. This will provide for program coordination and reduce the problem of fragmentation which has characterized health care research in the past.

The Assistant Secretary proposes to establish a PHS Committee for coordination of health statistics systems chaired by the Director of NCHS.

A health data advisory committee will be established.

Finally, a new Office of Health Technology will be established to develop and initiate a strategy for evaluating health technology in the Office of the Assistant Secretary for Health.

Mr. President, considerable progress has already made in improving health statistics, epidemiology, and health technology assessment research. For example, new techniques have been developed for mapping infant mortality and a national death index is being established which can be used to greatly improve mortality studies, especially mortality related to environmental factors. In addition, the Assistant Secretary has announced an expanded technology research program for fiscal year 1979 including some transfer of funds from existing programs to strengthen this effort.

In view of the reorganization currently underway, Mr. President, it would appear to be premature and disruptive to carry out a major restructuring of NCHS and NCHSR at this time. We should give the Secretary time to evaluate these new initiatives and determine if a new institute is really necessary. If the proposed reorganization is not effective in improving the coordination and quality of health care research, a more drastic reorga-

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...IONAL INSTITUTES OF HEALTH CARE RESEARCH ACT OF 1978

The PRESIDING OFFICER. Pursuant to a previous order, the Senate will now proceed to vote on S. 2466, as amended. The yeas and nays have previously been ordered, and the clerk will call the roll. Senators are reminded that this will be a 10-minute vote.

The legislative clerk called the roll.

Mr. CRANSTON. I announce that the Senator from Minnesota (Mr. ANDERSON), the Senator from Indiana (Mr. BAYH), the Senator from Iowa (Mr. CLARK), the Senator from Mississippi (Mr. EASTLAND), the Senator from Alaska (Mr. GRAVEL), the Senator from Maine (Mr. HATHAWAY), the Senator from Arkansas (Mr. HODGES), the Senator from Minnesota (Mrs. HUMPHREY), the Senator from Hawaii (Mr. INOUYE), the Senator from Louisiana (Mr. LONG), the Senator from Mississippi (Mr. STENNIS), the Senator from Tennessee (Mr. SASSER), and the Senator from Colorado (Mr. HASKELL) are necessarily absent.

I further announce that the Senator from South Dakota (Mr. McGOVERN) is absent on official business.

I further announce that, if present and voting, the Senator from Iowa (Mr. CLARK) and the Senator from Minnesota (Mrs. HUMPHREY) would each vote "yea."

Mr. STEVENS. I announce that the Senator from Tennessee (Mr. BAKER), the Senator from Massachusetts (Mr. BROOKE), the Senator from Utah (Mr. GARN), the Senator from New York (Mr. JAVITS), the Senator from Nevada (Mr. LAXALT), the Senator from Illinois (Mr. PERCY), the Senator from South Carolina (Mr. THURMOND), and the Senator from Connecticut (Mr. WEICKER) are necessarily absent.

I further announce that, if present and voting, the Senator from South Carolina (Mr. THURMOND) would vote "nay."

The result was announced—yeas 30, nays 48, as follows:

[Rollcall Vote No. 174 Leg.]

YEAS—30

Abourezk	Jackson	Moynihan
Bentsen	Johnston	Pell
Case	Kennedy	Riegle
Chafee	Leahy	Sarbanes
Church	Magnuson	Schweiker
Cranston	Mathias	Sparkman
Culver	Matsunaga	Stafford
Durkin	McIntyre	Stevenson
Eagleton	Melcher	Stone
Heinz	Metzenbaum	Williams

NAYS—48

Allen	Glenn	Muskie
Bartlett	Goldwater	Nelson
Bellmon	Griffin	Nunn
Biden	Hansen	Packwood
Bumpers	Hart	Pearson
Burdick	Hatch	Proxmire
Byrd, Harry F., Jr.	Hatfield, Mark O.	Randolph
Byrd, Robert C.	Hatfield, Paul G.	Ribicoff
Cannon	Hayakawa	Roth
Chiles	Helms	Schmitt
Curtis	Hollings	Scott
Danforth	Huddleston	Stevens
DeConcini	Lugar	Talmadge
Dole	McClure	Tower
Domenici	Morgan	Wallop
Ford		Young
		Zorinsky

NOT VOTING—22

Anderson	Bayh	Clark
Baker	Brooke	Eastland
Garn	Inouye	Percy
Gravel	Javits	Thurmond
Haskell	Laxalt	Weicker
Hathaway	Long	
Hodges	McGovern	
Humphrey	Sarbanes	

So the bill (S. 2466) was not passed.

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CON

NATIONAL INSTITUTES OF HEALTH CARE RESEARCH ACT OF 1978

Mr. HATHAWAY. Mr. President, I move to reconsider the vote by which S. 2466 failed of passage.

Mr. DOLE. Mr. President, will the Senator yield?

Mr. HATHAWAY. The Senator from Colorado has the floor.

Mr. DOLE. For a parliamentary inquiry?

Mr. HASKELL. I yield for a parliamentary inquiry.

Mr. DOLE. On the motion just made by the distinguished Senator from Maine, is my understanding correct that this goes on the calendar, to be called up at some later time, and the effect is to keep the bill alive, and perhaps we can work out some accommodation with the distinguished Senator from Massachusetts? Will that be the purpose?

The PRESIDING OFFICER. The Senator is correct.

Mr. DOLE. And any time it is brought up, it would be subject to a vote on reconsideration, or a tabling motion?

The PRESIDING OFFICER. The first motion would be a motion to proceed to the motion to reconsider. If that is

9891

1

9902

MOTIONS REGARDING S. 2466

Mr. HATHAWAY. Mr. President, I enter a motion to reconsider third reading of S. 2466, and I enter a motion to reconsider third reading of S. 2466, and I enter a motion to reconsider the vote by which the committee substitute amendment, as amended, to S. 2466 was agreed to. This has been cleared with Senator DOLE.

Mr. FORD. Mr. President, a parliamentary inquiry. What is happening down front? May we have an explanation?

The PRESIDING OFFICER. Who yields time for the parliamentary inquiry?

Mr. FORD. Is this the bill that was defeated the other day by a large vote, and now we are going back to reconsider that vote? There was an 18-vote difference. Is that what is happening down front?

Mr. HATHAWAY. Yes.

Mr. FORD. I object, Mr. President, to interjecting this unanimous-consent request into the proceeding at this time.

Mr. HATHAWAY. This is not a unanimous-consent request.

The PRESIDING OFFICER. The Senator has a right to enter the motions.

2

1. Amended
S. 2466 does not connect my objection to the creation of overlapping authorities ~~as~~ ~~to~~ that portion creating the National Center for the evaluation of medical Technology appears to duplicate funded authorities of this nature in the NIH.

2. Review of the authorities of the several Institutes of the NIH clearly indicates the ability and the appropriations for evaluation of medical Technology envisioned as the responsibility of the proposed new National Center

For instances the mandate of the NHBLI provides for
"research into the development trial and evaluation of techniques drugs and devices used in ... prevention of heart blood vessel lung and blood diseases"

clearly NHBLI could undertake and has undertaken with consent of its advisory council the review of efficacy of coronary bypass surgery which is repeatedly cited as an example for the need for the New center (How long, how much people.)

3. If the center is created should we not ~~[illegible]~~ reduce the NIH budget by a corresponding amount? — Should we not alter the authorities of the several Institutes lest we generate internal infighting over which organization has jurisdiction over ~~such~~ an evaluation of a technology such as coronary bypass?

What does

4. ~~would~~ will not leaving the authority with NIH and ~~assume that~~ its ~~expen~~ ~~this~~ world famous access to experts ~~will~~ not add value judgments inherent to assessment judgments ~~or attempt~~ or enable the setting of regulatory standards?

5. If, as the proponents of this bill indicate the center "would have no regulatory authority and its findings would have no direct impact on any existing federal programs" why is not the authority provided to PHS-NIH not sufficient

6. Proponents indicate that several HGW subunits "conduct some research on medical services and procedures" I am advised ~~that~~ some amounts to one hundred million dollars ~~in~~ in NIH's annual inventory for the purpose of evaluating safety & efficacy these funds ~~#~~ have been ~~advised~~ expended ~~on eval~~ such evaluations as: the widely publized diabetic retinopathy trials studies on oral anti-diabetic agents, breast cancer screening and many other technologies

7. Even the fetal monitoring example cited as a need for the center was clinically tested under grant no. "Steps" necessary to coordinate NIH studies ~~as noted~~ obviously require no new legislative authority but ~~bill passage~~ creation of the new center as noted will clash with many existing legislative authorities

Fetal monitoring

Hasselmeyer

Health Services Research

8. Further the proponents indicate "the proposed center w/d undertake studies of new and existing medical practices and procedures to improve understanding of their efficacy and safety. Does not FDA have the responsibility to monitor efficacy and safety of

Sec P. 33 of Rogers report

8. clear confusion amongst agencies now — as to what responsibility goes where. cite call to HSA, HRA + NIA.

Heart — Clinical Apps. + Prevention Program + Clinical

1 Multiple risk factor Intervention Trial — Hypertension, cigarettes, + Lipids

2. Aspirin myocardial Infarction study

3 Beta blocker heart trial

4. Coronary drug project — drugs weren't useful in population study, — clofibrate.

8.

Cardiology Branch
Dr. Michael Mock

Coronary by-pass surgery
how many died - infarction after 4-5 yrs
Pf safety + efficacy
is negative
Cost payment is obvious

later know
whether any
difference between
those medicinal-
treated + those
surgically treated
W/ know cost
effective