Kennedy said. He warned against banning inut troublesome questions "for fear of how they ome out."

enate agreed by voice vote to a Helms amendulating that the genetic counseling study shall concern for the essential equality of all human rn and unborn." It also adopted by voice vote a Helms amendment requiring commission ip to be balanced to represent various viewnd it agreed by voice vote to a Richard S. , R-Pa., amendment stressing that commission ere entirely separate from either Congress or the branch, and that its recommendations "cannot g on any department or agency."

passing the bill the Senate agreed to add it as an nt to S 2450, a bill extending funding for comental health centers and biomedical research. e was intended to ensure a House vote on exhe commission, as there was no comparable pending in the House. *(S 2450, story, p. 1731)*

IS

assed by the Senate, S 2579 (Title IV of S 2450):

blished an 11-member President's Commission for ection of Human Subjects of Biomedical and al Research. Five members were to be experienced dical or behavioral research involving human subremainder drawn from other professions including dicine, ethics, theology, science or government. s would be appointed by the president; Senate con was required for the chairman. Representatives of e Defense Department, the CIA, the Veterans Adtion, The National Science Foundation and the Oience and Technology Policy were to serve as ex of-voting advisory members. Members were to serve l four-year terms and were limited to two full terms e. Full-term federal employees were prohibited mbership.

horized the commission for four years. The longer thorized for members of the commission indicated committee expected the commission to be extended r years, according to a Kennedy aide.

ected the commission to finish up unfinished work edecessor.

ected the commission to report every two years to s on the protection of human research subjects in all y funded programs.

ected the commission to conduct special studies on bjects: informed consent in medical practice; the lity of a uniform legal definition of death; ethical, nd legal implications of counseling and other infor programs relating to genetic diseases and condionfidentiality of patient research records and access nts to such records.

ected agencies to furnish the commission with er information it requested. Where the information ed an identifiable individual, the commission was d to protect that individual's privacy and secure his d consent for use of the information. The commisas barred from disclosing classified or similarly ed material.

thorized $6 million a year for commission operations a fiscal 1982. ■

—By Elizabeth Wehr

Senate Action:

New Agencies for Health Care Research Rejected

Persuaded by arguments against an expensive new bureaucracy, the Senate has shot down a proposal to create a National Institutes of Health Care Research to collect health statistics, look at how health care is provided and study new operations and medical machines before they became part of medical practice.

By a 30-48 vote the Senate June 26 rejected a bill (S 2466) to extend existing health statistics and health services research centers at greatly increased funding levels and upgrade them in status to National Institutes of Health. The centers were first authorized in 1974, and extended for one year in 1977. *(1974 Almanac, p. 420; 1977 Almanac, p. 453; Senate vote, Vote 174, Weekly Report p. 1706)*

The bill also would have created a new national institute to evaluate medical technology. Proponents argued that new — and often expensive — procedures such as fetal heartbeat monitoring became established before their usefulness, safety and cost-effectiveness had been determined.

The bill approximately doubled existing spending levels, authorizing $440 million through fiscal 1981. It was reported by the Human Resources Committee May 15 (S Rept 95-839).

Opponent Robert Dole, R-Kan., said that was too much money for a plan that promised "no meaningful improvement" in the "mediocre" performance of existing research facilities (the National Center for Health Services Research and the National Center for Health Statistics). The scheme represented the "beginning of a vast bureaucratic entity," Dole claimed. He also warned that "overregulation in development of medical technology could have a disastrous impact" on medical practice in general.

Siding with Dole against the measure was Henry Bellmon, R-Okla., who said the Carter administration opposed the bill because it would disrupt its recent reorganization involving the existing research facilities. Bellmon praised a "more realistic" pending House bill (HR 12584) that simply continued the health statistics and services units in their present status and provided for special research emphasis on environment-related diseases and conditions. The House bill also provided for a new health technology study unit under the assistant secretary for health of the Department of Health, Education and Welfare (HEW). *(Details, below)*

Bellmon said that in view of high and rising health spending, it was "essential that we resist any major new initiatives which are not clearly essential." However, the $429 million price tag for the House measure was not far below that of the defeated Senate bill.

Sponsor Edward M. Kennedy, D-Mass., said that the important work of the health statistics and health services research units had "never been sufficiently appreciated" within the federal government. These types of research also had suffered from "intense bureaucratic rivalries," leading in some cases to duplicate efforts and in others to wasteful withholding of information, a situation "bordering on administrative chaos," Kennedy said. (At least two other

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Carl Bruce
Perry

HEW entities, the Health Care Financing Administration and the Center for Disease Control, do major statistical and epidemiological studies.)

While the bill did not envision the centralization of all existing health care research efforts into one "super-agency," Kennedy said, upgrading the status of the research units would give "focus, strength and vitality" to their work.

Kennedy said that problems with new health care technologies were of two sorts: some were unavailable to patients for too long, while "others were applied too quickly." Among other things, the proposed new institute could weigh costs of new procedures against their benefits. The Food and Drug Administration would continue to evaluate safety and efficacy of individual drugs and devices, Kennedy said.

The day after Senate action on the bill William D. Hathaway, D-Maine, moved to reconsider the vote. That action left the way open for another vote on the measure, although Kennedy aides said there were no firm plans to bring the bill up again.

House Committee Action

Two emerging issues with important cost implications — environment-related health conditions and proliferating health care technology — required greater federal capacity to "collect and analyze health-related information," the House Commerce Committee said in its May 15 report (H Rept 95-1190) on HR 12584.

The committee's concern for health costs was evident throughout the report. On the one hand, the committee suggested, any apparent savings from watering down statutory controls on pollutants could be gobbled up by increased costs of treating environment-related diseases and conditions. It directed the secretary of HEW to study and report periodically to Congress on the cost of environment-related health conditions, and directed the health statistics center to prepare guidelines for creating a national data base on environmental conditions and public health.

Widespread use of new technologies despite "disturbingly scanty information" about their benefits, risks, cost effectiveness and other factors also aroused committee concern. Indiscriminate use of expensive computerized X-ray machines (CAT or computerized axial tomography scanners) to reassure headache-prone patients that they did not have tumors was cited as a disastrously expensive possibility. At about $230 per head scan, the national bill could approach $2.3 billion — "certainly beyond our means," the committee said. Thus, among other things, there was a need for criteria for selecting appropriate patients for CAT scans, the committee found.

The committee bill authorized $113 million for fiscal 1979 for stepped-up statistical work, health services research and technology assessment. That figure compared with a fiscal 1978 authorization of $62.2 million and a fiscal 1979 budget request of $74 million for statistics and health services research. The bill's three-year total was $429 million. The need for adequate information on which to base health policy decisions justified the jump in spending, the committee said.

In separate views, committee Republicans Samuel L. Devine, Ohio, James M. Collins, Texas, and Dave Stockman, Mich., said the bill was too expensive and that it could lead to federal control over the use of health care technology. The special environmental health costs study was nothing more than "HEW's propaganda response" to public concern about the costs of environmental controls, the Republicans said. Committee Democrat David E. Satterfield, Va., who often votes with Republicans, also criticized the environmental study and said that health technology decisions should only be made by practicing physicians and hospitals.

These were the major provisions of the committee bill:

Health Statistics. The National Center for Health Statistics was designated the lead agency for health information and statistics, with responsibility for standardizing federal health statistics collection by various agencies. The committee authorized $215 million for the agency through fiscal 1981; of that amount, at least $5 million was to be spent for training biostatisticians and epidemiologists. The committee also beefed up the agency's role in an ongoing federal-state health survey, and directed it to focus on data about the costs of health care.

The committee also required the center to establish, within two years of enactment, guidelines for assembling statistical information on "conditions of employment and indoor and outdoor environmental conditions on public health." The purpose of the guidelines was to ensure the availability of such data in usable (comparable) form from all federal sources. The bill provided for protection of medical records, to preserve patient privacy, and of trade secrets. Agencies could withhold data only in cases where the president found that national security was of overriding importance. The center was instructed to ask private health insurers for relevant information.

Environmental Health Costs Study. The secretary of HEW was required to report to Congress within 18 months of enactment and every two years thereafter on the present and future costs of environment-related diseases and disabilities. A second related study was assigned to the U.S. National Committee on Vital and Health Statistics, which was to look into the desirability of establishing a national data base relating to exposure to hazardous substances.

Health Services. The committee boosted the fiscal 1979 authorization for the National Center for Health Services Research to $36 million, from a fiscal 1978 level of $28.6 million. It authorized a total of $129 million for center operations through fiscal 1981, plus an additional $10 million for that period for research training.

Health Care Technology. Conceding that the effort was "controversial and complicated," the committee proposed a new National Center for Health Care Technology in the office of HEW's assistant secretary for health. It authorized $75 million for three years for the office, which would provide grants and contracts for studies on the safety, health and cost effectiveness and social, ethical and economic implications of new medical procedures. The committee stressed that the new center was to be "a research-oriented institution, not a regulatory agency." The bill also established a Health Care Technology Advisory Committee to review grants or contracts over $35,000, and authorized the HEW secretary to support the creation of public or non-profit private technology research centers.

CORRECTION

Page 1706, Vote 174: S 2466 authorized a total of $440 million for fiscal 1979-1981 for the National Institutes of Health Care Research (not $135 million).

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