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LEGISLATIVE NOTES

Prepared for the National Advisory Dental Council, June 20-22, and the National Advisory Council on Regional Medical Programs, June 20-21, by Legislative Reference and Liaison Branch, Office of Program Planning, DH, NIH.

June 14, 1966

"The "Legislative Developments" recently distributed to Council members contained an analysis of some of the major legislation introduced in the 89th Congress, Second Session, in the health and related fields. The "Legislative Notes" bring the status of this legislation up to date and include reference to new legislation introduced and Congressional hearings taking place since the issuance of the "Legislative Developments."
COMMUNITY SERVICES ACT OF 1964

The Act was introduced by Senator Fulbright for himself and on behalf of Senator Hill on June 2.

It is designed to offer grants for coordinating existing and new welfare services at the community level by providing matching funds and encouraging their administration as elements of a comprehensive services.

Major Provisions in Brief

Authorizes a program to be administered by the Secretary of HHS providing for:

1. Planning Grants
   Title I authorizes appropriations of $2.5 million to enable grants of up to $50,000 to be made to the States to assist in planning for the development of community service programs and centers.

2. Program Grants
   Title II authorizes appropriations of $40 million for fiscal year 1967, $60 million for fiscal year 1968, and $40 million for fiscal year 1969, to be allotted to the States on the basis of population, extent of need for community service programs, and financial need of the State.

Grants could be made for up to 75% of the administrative and overhead costs of community service programs and 75% of new services such as joint diagnostic and referral services which stem from the development of a program and were not previously available within the community service area.

Each participating State would develop a State plan outlining the development of a statewide system of community service programs based upon a survey of needs and resources and a schedule for implementation.

3. Construction Grants
   Title III authorizes appropriations of $50 million for fiscal year 1967, $75 million for fiscal year 1968, and $100 million for fiscal year 1969, to assist in the cost of construction of community service centers. (Federal share would vary from 1/3 to 2/3 of the cost as determined by a State Coordinating Council.)

Regulations issued by the Secretary of HHS would prescribe the specific types of services required to be provided by a community service center.

Comparable legislation on this subject was introduced in the House May 23:
   H.R. 15282, Congressman Fogarty
   H.R. 15286, Congressman Laird
Library Services and Construction Act
Amendments of 1972

The 1972 extending the Library Services and Construction Act was passed by the House, with Committee amendments, on June 2.

International Education Act of 1966

H.R. 14643, the International Education Act of 1966, amended, was passed by the House by a record vote of 194 to 89 on June 6.

In essence, H.R. 14643 would authorize a domestic program administered by the DHHS of Federal grants designed to strengthen the resources and capabilities of colleges and universities in international studies and research.

Appropriations totaling $140 million are authorized for the first three years—$30 million for fiscal year 1967, $40 million in fiscal year 1968, and $50 million in fiscal year 1969—with such sums as Congress may authorize for the following two years.
The Public Health Service should be the agency to which organizations and individuals throughout the Government turn for advice on all matters related to human health. It should provide professional guidance for the health-related activities of other agencies of the federal government. In short, it should exercise national leadership in health.

Reorganization Plan No. 3 simply provides the Secretary with authority to reorganize. It does not specify what form the reorganization is to take.

Briefly, I propose to put into effect a plan developed by the Surgeon General with the advice of a committee of distinguished citizens chaired by Dr. John J. Corson of Princeton University.

The plan calls for organizing the Public Health Service into eight major components: The Bureaus of Health Services, Health Manpower, and Disease and Injury Prevention and Control, National Institute of Mental Health, and National Institutes of Health, National Library of Medicine, National Center for Health Statistics, and the Office of the Surgeon General.

The Bureau of Health Services will serve as a central resource for improving the quality and accessibility of health care for the American people. It will include all PHS activities concerned with quality standards for health service. It will combine direct medical care programs with those which support and improve personal health services.

The Bureau of Health Manpower will have the primary concern for building an adequate supply of health manpower for the Nation. It will be responsible for projecting manpower needs and developing programs to meet them. It will serve as a central point of information for educators, administrators, and others involved in the training of professional and sub-professional health workers.
The National Institute of Mental Health, as a bureau within the Department of Health, Education, and Welfare, will assume the functions of the existing Mental Health Institute and the Fort Worth and Galveston psychiatric hospitals. It will administer the unified program of research, training, treatment, and mental health services. It will also serve as the principal focus for research and control programs in mental illness and drug addiction. The National Institutes of Health will continue to have a supervisory relationship to its intramural research programs.

The National Institutes of Health will remain a bureau of the Public Health Service, in parallel with the other bureaus, and will continue to serve as the principal medical research arm of the Department. It will be strengthened by the addition of an Environmental Health Sciences Institute.

The National Library of Medicine will retain its existing functions including the programs initiated under the Medical Libraries Assistance Act of 1965. We are considering measures to further strengthen and consolidate the scientific and professional communications functions in the National Library of Medicine.

The National Center for Health Statistics will continue to serve as the principal national source of reliable statistical data on health. I also expect to make further studies of the relationships between the National Center for Health Statistics and other data-gathering units of the Service.

To assure efficient administration for the numerous programs of the Service, we plan to strengthen—and to some extent, reorganize—the Office of the Surgeon General. The proposed changes will be designed to achieve better coordination among the grants programs of the Service, to establish uniform management policies and practices, and to create a central point of contact within the Service for all programs involving other agencies and institutions.

In addition to these organizational measures, I see a great need for improving our capability for planning and coordinating the Department's health programs and for continually reviewing their effectiveness.
The Senate Commerce Committee, in executive session, earlier reported S. 1332, to regulate the transportation, sale, and holding of dogs and cats intended to be used for experimental purposes. June 2.

H.R. 1386 (Tooke) was passed by the House on April 26 and this bill, as ordered reported by the Senate Commerce Committee, contained amendments to include the text of S. 2322 and some of the recommendations, although not all of the Monrorey Amendments designed to make the bill more restrictive on the use of animals in research.

Previously, the Commerce Committee held a one-day hearing, May 27, on the amendments to Chairman Magnuson's bill, S. 2322, as proposed by Senator Monrorey.

Witnesses testifying before the Committee at that time included--in opposition to the amendments: the Director, NIH; Dr. Philip R. Lee, Assistant Secretary for Health and Scientific Affairs, DHHS; Dr. George Irving, Department of Agriculture; Dr. Albert Sabin, professor of research pediatrics, University of Cincinnati; and Dr. John R. Hugness, Dean, School of Medicine, University of Wisconsin. Testifying in support of the amendments were: Senator Clark (Pa.); Dr. Nicholas S. Gimpel, Chief of Surgery, Detroit Metropolitan Hospital; and Dr. Bennett Derby, Head of Neurology, Veterans' Administration Hospital.

In his prepared statement presented to the Committee, Dr. Shannon testified that "...we feel that the theft of dogs and cats and their care and handling by dealers and during transportation can best be handled through a bill along the lines of H.R. 1386...one limited to regulating the transportation and sale of dogs and cats for research purposes. Separate, complementary legislation should be enacted to govern the care and handling of laboratory animals by research and educational facilities. We support S. 3332 for this purpose." (S. 3332, recently introduced by Senator Hill, would have the Secretary of HHS establish national standards for laboratory animal care to be met by all institutions as a condition for receiving Federal support for research involving the use of animals.)

Recent legislation introduced providing "special assistance for the improvement of laboratory animal facilities, and to otherwise assure humane care and treatment of laboratory animals":

H.R. 15129, Congressman Fogarty on May 18
H.R. 15268, Chairman Staggers, House Interstate and Foreign

Commerce Committee on May 25

(Companion bills to S. 3332)
Drug Safety

As part of its oversight operation, the Drug Safetly Subcommittee held a hearing on "Drug Adverse Effects" and continued its work on the issue of drug advertising. The Subcommittee, which met June 7, 1965, in the activities of the Food and Drug Administration in controlling drug advertising, in particular, and certain related areas.

The Subcommittee's focus was on the question of whether the Food and Drug Administration has the responsibility to regulate advertising and promotion of prescription drugs and comparably. The Subcommittee discussed the activities of the Federal Trade Commission with respect to nonprescription drugs.

Commissioner James Goddard, FDA, and Chairman Paul Rand Dixon, FTC, testified for their respective agencies.

A major portion of the Subcommittee's discussion was taken up with the advertising claims made for "Mazarin," an aspirin tablet that the manufacturer alleged would provide up to eight hours of relief, and advertising claims made for Serex, a prescription drug for elderly persons, which the government has charged are false and misleading.

Dr. Goddard testified in his opening statement that "we intend to establish a total system to examine and analyze drug advertising, veterinary as well as human." Further, that in order to achieve a more effective enforcement program, FDA was considering stronger regulations with respect to prescription drug advertisements and was "considering the need for requiring pre-clearance of new ads, after successful criminal or seizure actions and as a part of injunctive relief."

In the second set of hearings, Commissioner Goddard presented a prepared statement detailing the history of FDA's efforts to cope with the development of drug abuse before the passage of the Drug Abuse Control Amendments of 1965 and their subsequent efforts to place the new law into full effect.

In his discussion of LSD, Commissioner Goddard related that on May 18 FDA published in the Federal Register a proposal to control lysergic acid and lysergic acid amide under the new drug control amendments. This proposal was based primarily on the fact that these substances are a starting material in a method of preparing LSD. He stated that "at this time, all objections to this proposal have been received."

The Commissioner stressed that "our programs in the drug abuse control area involve not only coordination with the efforts of other Federal agencies concerned, but also a close working relationship with State and local agencies having responsibilities in this same area... We will be providing States with training for their agents as well as informational and educational materials."
The House Ways and Means Committee held a two-day hearing, June 6-7, on H.R. 8664, Chairman Mills' bill to implement the Agreement on the Importation of Educational, Scientific, and Cultural Materials signed for signature at Lake Success on November 22, 1950 (Florence Agreement); and H.J. Res. 688 (Curtis), to give effect to the Agreement implementing the International Circulation of Visual and Auditory Materials of an Educational, Scientific, and Cultural Character, approved in Beirut in 1949 (Beirut Agreement).

The Florence Agreement is an international agreement which, if implemented by the Congress, would remove duties on imports of educational, scientific, and cultural materials, such as books, maps, and scientific instruments imported by scientific and educational institutions when like instruments and materials are not made in the United States. H.R. 8664 would provide for implementation of this Agreement.

H.J. Res. 688 would implement the Beirut Agreement in comparable manner to provide for duty-free import treatment for visual and auditory materials.

**National Science Policy**

The Senate Government Operations Special Subcommittee on Government Research, Chairman Harris, Oklahoma, held an executive seminar May 20, to receive the views of some of the Nation's scientific leaders regarding the establishment and development of a National Science Policy.

This Special Subcommittee was established last August to study the operations of research and development programs financed by departments and agencies of the Federal Government, including research in such fields as economics and social science, as well as basic science, research, and technology.
The Senate Government Operations Subcommittee on Executive Reorganization, under the temporary chairmanship of senator Kennedy, D. M. has initiated an inquiry on "Federal role for the handicapped" with three day of hearings May 11-13.

This opening phase of a proposed series of hearings was directed to "the organization and coordination of Federal research and regulatory programs on the drug LSD" including the role of public and private agencies, the extent of misuse of LSD, and recommendations of leading experts on the subject of LSD. In addition, representatives of FDA, FBI, and VA, the three Federal agencies most involved in the research, regulation, development, and medical use of LSD, presented testimony to the Subcommittee.

Some of the other areas upon which future hearings will focus are:

- Child Health and Health Personnel
- Programs for Mental Health and Mental Retardation
- Programs for the Aged
- Programs for Disabled and Rehabilitation
- Community Health Programs

Allied Health Professional Personnel Training Act of 1966

The Administration-sponsored bill, H.R. 13196, Allied Health Professional Personnel Training Act of 1966, was order favorably reported to the House (amended) on June 14 by the House Interstate and Foreign Commerce Committee.

The bill would amend the FHE Act to increase the opportunity for training medical technologists and personnel in other allied health professions, improve the educational quality of schools for training such allied health professions personnel, and strengthen and improve the existing student loan programs for medical, dental, pediatrie, pharmacy, optometric, and nursing students.
Sea Grant Colleges

On June 1, the Senate Labor and Public Welfare Special Subcommittee on Sea Grant Colleges under Chairman Pell (R.I.) approved for full Committee consideration, with amendment, the Chairman's bill, S. 2439, authorizing the establishment of programs of education, training, and research in the marine sciences.

The House Merchant Marine and Fisheries Subcommittee on Oceanography held a one-day hearing, June 12, on H.R. 15192, a related bill introduced by Congressman Rogers (Florida).

The major differences between the Senate and House bills are as follows:

1. S. 2439 would amend the National Science Foundation Act of 1950 so as to authorize the NSF to administer the establishment and operation of sea grant colleges and programs.

H.R. 15192 would amend title II of the Merchant Marine Act, 1936, so as to authorize the Board of Regents of the Smithsonian Institution, acting through the Secretary of the Smithsonian, to carry out the policies established by the bill.

2. S. 2439 would authorize appropriations of $10 million for fiscal year 1967, $15 million for fiscal year 1968, and $20 million for fiscal year 1969 with Federal matching funds paying up to 66 2/3% of the total cost, grants and contracts for sea grant colleges and programs.

H.R. 15192 would authorize the Board of Regents to enter into agreements with the Secretary of the Interior with respect to the use, jointly or exclusively, of areas of the submerged lands of the Outer Continental Shelf. There is no provision for funding by direct authorization.

3. S. 2439 would authorize the establishment of a National Advisory Council on Sea Grant Colleges and Programs to be composed of 11 members, appointed by the President, persons prominent in public life or in the fields of education, oceanology, ocean technology, and other field-related to marine resources.

H.R. 15192 carries no such provision.
This policy statement is to be used by those applicants who desire to incorporate systems analysis methodologies into their applications.

The use of systems analysis methodologies in regional medical programs is encouraged, but only to such an extent as it is considered applicable as an essential integral component of the individual program proposed by the applicant. The applicant should emphasize the development of innovative, adequately formulated studies of realistically restricted problems involving the application of "systems" methodologies rather than submit an application dominated by general proposals for the utilization of large scale "systems" approaches for the design of a regional medical program.

The Division of Regional Medical Programs will explore through contracts and selective studies the applicability of systems analysis to the planning and implementation of a regional medical program. One approach to the use of systems analysis in current grant applications, within the framework of this policy, is the incorporation of limited numbers of personnel with such analytic skills into the planning process. These personnel may come from university departments or schools of industrial engineering, schools of public health, commercial systems firms, those with experience in program planning and budgeting, and a variety of other sources. It is expected that from such a beginning, areas worthy of more detailed activity may well become apparent and qualify for subsequent additional grant support.

Applicants are encouraged to direct any questions they may have relative to the use of systems analysis to the Division of Regional Medical Programs.