The original documents are located in Box 37, folder "Transition Reports (1977) - Health, Education and Welfare (2)" of the John Marsh Files at the Gerald R. Ford Presidential Library.

PUBLIC HEALTH SERVICE

PHS

PHS TRANSITION PAPERS

The following papers briefly highlight significant policy issues which will surface during early 1977.

In addition, a copy of the Forward Plan for Health 1978-82 is attached. This document is produced annually by the Assistant Secretary as a part of the planning process. It contains an analysis and discussion of the major health issues facing the Nation.

ISSUE: National Influenza Immunization Program (NIIP)

BACKGROUND: A number of issues remain to be addressed in the implementation of the NIIP. They include:

Short Term

Low Participation by Citizens in Black and Other Ethnic Minority Communities

There is a continuing concern over reports of low citizen participation, especially among Blacks in large urban areas and other ethnic minority communities. This citizen dissonance may be due, in part to (a) low traditional turnout in poverty areas, (b) media focus on controversial aspects of NIIP, (c) media exploitation of unfounded vaccine-related deaths, (d) absence to date of swine-like or other flu outbreaks, (e) general mistrust of programs having big-government connotations, and (f) lack of readily available material and information on which to base an affirmative decision.

Steps Being Considered to Resolve This Issue

Immediate development and distribution of mass media information with special focus on ethnic minority communities. A more aggressive stepped-up approach at the National level will also be made to take advantage of the support that Black and other ethnic minority leaders are willing to give in support of the immunization program. In addition, efforts are being made to stimulate State and local health departments as well as voluntary agencies to conduct intensive public education and public awareness activities to counter fears of illness and death due to the vaccine that has been generated through the media.

Vaccine for Healthy Children

On November 15, 1976, following completion of field trials and data analysis, the Public Health Service announced its policy on inoculation of normal, healthy children between ages 3 and 18. While a safe and effective vaccine exists, from a practical standpoint, the manufacturers can not supply sufficient quantities of the kind of monovalent swine flu vaccine (split-virus) required by healthy children. Three of four manufacturers have formally indicated that they cannot produce additional flu vaccine this year. A potentially serious short-fall, therefore, exists since currently there is enough vaccine for four million children--one-tenth the number of children in that age group.

Steps Being Considered to Resolve This Issue

Since attempts to stimulate further split-virus vaccine production do not appear to be imminently fruitful, efforts are being aimed at distributing the available split-virus vaccine to inner city

neighborhood health clinics and other urban sites for children whose living conditions may make them more susceptible to influenza infection and serious complications because of crowded conditions and inadequate existing medical services.

Non-Official Americans Overseas

A policy and plan for the immunization of 1,250,000 American citizens working and residing overseas in a non-governmental capacity has not been approved. In late September an interdepartmental consensus proposal was drafted and forwarded to the White House for consideration and decision. In early November, it was referred back to the Department level for resolution by the Secretaries of HEW, Defense, and State.

Steps Being Considered to Resolve This Issue

Submission of the interdepartmental consensus proposal to the Secretaries of HEW, Defense, and State which recommends that American corporations and voluntary agencies located in host countries be permitted to utilize normal Customs Clearance procedures to import swine flu vaccine.

Program Evaluation

There are five major areas of evaluation of NIIP:

1. Surveillance
2. Assessment of vaccine delivery and distribution
3. Epidemiological evaluation of vaccine efficacy
4. Program costs
5. Special issues as to information dissemination, public attitudes, and characteristics of participants and non-participants

Steps Being Considered to Resolve This Issue

Augment current CDC activities of program evaluation.

Long Term

Implications for Future Immunization Programs

Efforts to clearly document various aspects of NIIP are needed so as to prevent a repetition of problems. Additionally, P.L. 93-380 calls for a study of personal liability and calls for provisions that the Secretary provide the Congress with reports on litigation and settlement by August 1977 and semi-annually thereafter.

Steps Being Considered to Resolve This Issue

Data are being compiled for quarterly reports to Congress on the administration of the swine flu program including vaccine supply, the number of persons inoculated, amount of funds expended by States, and the epidemiology of influenza in the United States. Data are being compiled to meet the requirements of a report to Congress on the conduct and settlement of litigation activities specifying the number, value, nature and status of all claims made. Finally, a study of the scope and extent of liability in immunization programs is being examined from the standpoint of alternative approaches to providing protection against such liability.

ISSUE: Immunization Policy

BACKGROUND: The now well-established role of the Federal Government in national immunization efforts includes direct support of routine vaccination programs in State and local health departments through project grants. In this regard, support takes the form of providing vaccines used routinely in childhood immunization and purchased under Federal contract and of supporting staff to coordinate and promote relevant vaccination programs. Indirect Federal responsibilities involve surveillance of vaccine-preventable diseases, of vaccine use, and of adverse reactions to vaccination.

In recent years the rate of immunization has been waning. This is particularly so in some urban and rural areas where the traditionally underserved and hard-to-reach groups show evidence of rates of immunization in preschool and childhood groups which are far below what is generally accepted to preclude outbreaks. The reasons for the decline in rates of immunization in childhood are not fully known. Thought to be contributing are the growing lack of personal motivation as program successes have removed the threat of infectious diseases and the mounting concern over the almost negligible but acknowledged inherent risk of serious adverse reactions from some of the commonly used vaccines. This latter issue has been recently dramatized by litigation of liability for paralysis associated with oral polio vaccine and for central nervous system reactions to live measles vaccine. The National Influenze Immunization Program against swine influenza has further dramatized the liability issues associated with communitywide use of vaccines and has begun to establish the use of individualized disclosure documents and consent-obtaining procedures in public immunization programs.

Future immunization policy should take cognizance of the Federal responsibility to assure uniform and high levels of protection against the infectious diseases for which effective immunizing agents are available. It should address more completely the waning public motivation for vaccination, particularly in the traditionally hard-to-reach populations. The policy should acknowledge the inherent risk of vaccines in regular use in preventive medical practice and provide solutions to problems of vaccine-associated disability for those injured as a result of taking federally-licensed and recommended vaccines which provide both personal and community protection.

POSSIBLE ACTION/DISCUSSION: Recently a National Conference on Immunization Policy was held and a set of recommendations with respect to this issue are now being developed. New legislation and resources may be required to implement these policy recommendations.

ISSUE: Implementation of new legislation on health information, health promotion, and the prevention of illness.

BACKGROUND: Legislation was enacted on June 23, 1976 (the "National Consumer Health Information and Health Promotion Act of 1976," P.L. 94-317, which specifies additional legislative authorities for the Department in the areas of health information, the prevention of illness, and health promotion. In addition to the ongoing activities of Departmental agencies which are related to the dissemination of health information, and prevention and health promotion, the Congress called for expanded coordination, including the development of national goals and strategies for health information and health promotion, prevention health services, and education in the appropriate use of health care. The $4 million supplemental budget request will be used to support additional work, including grants and contracts, by all six Agencies of the Public Health Service, the Regional Offices, the Office of Education, other DHEW Agencies, as well as joint efforts with USDA, EPA and other Federal Agencies, and with the private sector. The principal objective of these activities will not be the transmission of units of information per se, but transmission of information that reflects the state of our knowledge in a culturally appropriate way to help people change their individual and social behavior in order to improve their health. The primary focus for the expenditure of funds early in the implementation of this authority will be: research and evaluation, including state-of-the-art assessments of health education and health promotion activities, and the identification, through existing research programs, of the environmental, social and behavioral factors which affect health and which may be amenable to prevention or health promotion activities.

POTENTIAL DECISIONS OR ISSUES: A number of policy issues will have to be resolved as the PHS implements this new authority.

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ISSUE: Strengthening the Nation's ability to deliver health care to children and mothers.

BACKGROUND: It has been estimated that between four and ten million children in the United States are not enrolled in a health care system in either private or public sectors.* As many as half a million women receive totally inadequate prenatal and postnatal health care. For reasons of poverty, ineligibility for health programs which use means tests to determine eligibility, and residence in underserved areas, children and mothers often receive inadequate health care or care on an emergency basis only. Though progress has been made in the past decade in reaching children previously underserved, poor and minority children continue to have fewer physician visits than middle class children and to suffer disproportionately from ill health. Each year millions of children suffer needlessly from the effects of preventable or correctable illnesses and birth defects as a result of inadequate child and maternal health care.

A PHS initiative is being proposed to assure all children and mothers continuous and comprehensive health care. Those now outside the system will be identified and the system expanded to provide for their care.

Within this objective the following goals have been identified:

1. Create capacity and participation at State and local levels assuring access to comprehensive health care for children and mothers,

2. Develop necessary data base to achieve the above goal, and

3. Assure development of adequate resources to provide more effective and efficient health care for children and mothers.

POSSIBLE DECISIONS/ACTIONS: A proposal with options is now in the final stages of development. Recommendations including legislative and cost implications will be available shortly.

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*Estimates vary from Brookings figure of 4 million children to OCHA's figure of 10 million, based on analyses of provider availability and practice constraints.

ISSUE: Adolescent Pregnancy and Childbearing

BACKGROUND: In the United States in 1974 there were about 10 million women age 15-19. An estimated 4.3 million of these women were sexually active and about 4 million were at risk of unintended pregnancy. An additional 400 to 600 thousand women age 13 and 14 were also at risk of unintended pregnancy. In 1974 there were 247,000 births to adolescents age 17 and under. There were 30,000 births to women under 15 years old.

In the age group 15-19 an estimated one million unintended pregnancies occurred 2/3 of which were concieved out of wedlock. Only 27% of sexually active teenage females reported always using some form of contraception; over one-half reported they did not use contraception the last time they had intercourse; and 9 out of 10 young teenagers who requested family planning clinic services reported having had intercourse without contraceptive protection for a year or more prior to their enrollment in the family planning program.

Early childbearing severely limits opportunities available to young women since young mothers lack skills, tend to drop out of school, and have a greater risk of being dependent on welfare.

Maternal deaths are higher for women under age 19, they have more low weight babies, and death rates in the first year for babies born to the group are higher. Marriages of women in this age group tend to be less stable and they on the average have more children.

The reasons why some of these women do not use contraception include ignorance of their use and inaccessability of suitable and acceptable services.

Federal action to alleviate this problem is now underway including the following:

1. Expanding and strengthening subsidized family planning services for teenagers including specialized services organized especially for teenagers. Teenagers desire pregnancy testing services, responsive appointment schedules, convenient hours, convenient locations, and simple admission procedures. For continued clinic use they cite as important staff attitude, clinicians attitude and clinic efficiency. Clinic services should include outreach for teenagers, education and counselling at clinic sessions and responsive follow-up.

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2. Expanding one network of preventive family planning programs directed toward teenagers and school health services and free clinics. These programs should include realistic sex education that offers teenagers honest and pertinent information about fertility regulation and where they can obtain the service.

3. Providing adequate pregnancy counselling and equal access to adequate prenatal, obstetrical and pediatric care for those who desire to carry their pregnancies to term as well as access to legal abortion for those who wish to terminate their pregnancies.

4. Expanding of biomedical research to discover new, safe and effective techniques of fertility regulation better suited for use by young men and women.

POSSIBLE ACTIONS/DECISIONS: Need to develop a Department-wide coordinated program to provide additional support for the activities required to reduce adolescent pregnancies.

ISSUE: Abortion

BACKGROUND: Section 209 of P.L. 94-439 - the HEW-Labor Appropriation Act for 1977 stated that none of the funds contained in this Act shall be used to perform abortions except when the life of the mother would be endangered if the fetus were carried to term.

On October 1, 1976, Judge John Dooling of the U.S. District Court for the Eastern District of New York issued a temporary restraining order forbidding the Secretary of DHEW to refuse "to pay federal matching funds (at the proportionate levels they were being paid before the Hyde amendment was enacted on September 30, 1976) for abortions provided to women eligible for Medicaid."

Judge John F. Dooling further issued a preliminary injunction on October 22 and ordered DHEW to continue making federal reimbursements for abortion services nationwide, pending the final outcome of the litigation. He also instructed DHEW to inform its regional offices of his order, with instructions that they notify State Medicaid agencies which, in turn, are to notify abortion providers. The notice, specified by the court, reads as follows:

> The Department of Health, Education, and Welfare will provide reimbursement for all abortions provided to Medicaid-eligible women by certified Medicaid providers on the same basis as the Department pays reimbursement for pregnancy and childbirth-related services.

This notice was sent to DHEW Regional Directors and appropriate officials of the Bureau of Medical Services and the Bureau of Community Health Services on November 3, 1976.

In his October 22 order, Judge Dooling had allowed Rep. Henry J. Hyde (R-Ill.), Sens, James L. Buckley (C/R-N.Y.) and Jesse A. Helms (R-N.C.) to act as "intervenors" (not as members of Congress but as private citizens) and in the case on the side of the government and, in that capacity, they had applied to the Supreme Court for a stay, which, in effect, would have invalidated Judge Dooling's order. DHEW and the Solicitor General, on the other hand, while continuing to argue in support of the Hyde amendment, opposed a stay. In a memorandum to the Supreme Court, the Solicitor General, Robert H. Bork, noted that the intervenors "fail to suggest any irreparable injury that they will suffer from the denial of a stay, and we can find none." He added:

> Although the Secretary of DHEW has estimated that, during the current fiscal year, an obligation of between $22 and $27 million

may therefore be incurred by the Federal Government, in contravention of the clear commend of Congress, we do not believe that this possible monetary loss, although significant, constitutes an irreparable injury sufficient to warrant issuance of a stay pending appeal, especially since this loss may be offset at least partially by the saving of monies that would otherwise have been expended for childbirth and post-natal care if women were to carry unwanted pregnancies to term. On November 8, the U. S. Supreme Court refused to stay the Federal District Court Order.

In the meantime, DHEW had asked Judge Dooling to modify his October 22 order so that, if and when higher courts overruled his judgement, the department would be able to recoup Medicaid payments made to providers of abortion services in the interim period.

Judge Dooling did not modify his ruling and stated that even if DHEW were eventually to win the case, "the payments (made in the interim) will not have been illegal. They will be payments lawfully made under court order for lawful services acutally rendered."

POSSIBLE ACTIONS/DECISION: The issue awaits court action, and lead responsibility within the Department is with the Office of the General Counsel.

ISSUE: The National Institutes of Health Guidelines on Recombinant Deoxyribonucleic Acid (DNA) Research.

BACKGROUND: After extensive scientific and public review, the National Institutes of Health, on June 23, released guidelines that established strict conditions for recombinant DNA research. The guidelines were published in the Federal Register on July 7 for public comment. Further, the NIH undertook to prepare and filed a draft environmental impact statement in the Federal Register on September 9 for public comment.

The NIH, in August, also published a volume containing the transcript of an NIH public hearing held on the proposed guidelines as well as the correspondence received by the Director, NIH on this matter and relevant meetings held prior to the release of the guidelines in June.

Further, in a letter to President Ford this summer, Senators Kennedy and Javits recommended executive action to extend the scope of the NIH guidelines to the rest of the public and private sectors. In response, President Ford recommended the creation of an interagency committee to review these and other important policy matters pertaining to this research. The Senate Health Subcommittee, under the chairmanship of Senator Kennedy, conducted oversight hearings on September 22 that focused on the need to extend the NIH guidelines to the public and private sectors with a mechanism to ensure compliance. Dr. Donald Frederickson, Director, NIH, testified for the Administration and agreed that an interagency committee would review these matters and come forth with appropriate recommendations. A memorandum was sent by the President on September 22 to all government department and agency heads requesting their cooperation in the formation of an interagency committee. Following that memorandum, Secretary of Health, Education, and Welfare, David Mathews sent a letter to agency heads requesting that they nominate representatives to serve on this committee. The committee held its first meeting on November 4. At Secretary Mathews' request, Dr. Donald Frederickson is serving as chairman.

The mandate of the interagency committee is to review the nature and scope of Federal and private sector activities relating to recombinant DNA research, and to determine the applicability of the NIH guidelines to govern this research in the public and private sectors. Further, the committee will recommend whether legislative or executive action is necessary to ensure compliance to standards. Contacts have been made and are being pursued to determine the scope of this activity and the application of NIH guidelines to private industry.

POSSIBLE ACTIONS/DECISIONS: The interagency committee will review the nature and scope of Federal and private sector activities relating to recombinant DNA research and will determine the applicability of NIH guidelines to govern research in the public and private sectors. Within the next three to four months, the committee is expected to have recommendations for the President regarding legislative or executive actions necessary to ensure compliance with the standards set for this research.

ISSUE: The Complex Regulation of Federal Research

BACKGROUND: The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was mandated by Title II of P.L. 93-348 to make recommendations to the Secretary of HEW on a variety of issues related to the Protection of Human Subjects. In the statute particular emphasis was directed at formulating means for protecting those with diminuition in their capacity to provide informed consent, specifically, prisoners, children, and the institutionalized mentally infirm. In addition, the statute required that the Commisssion address the propriety of psychosurgery, fetal research and develop methods for protecting subjects of research when the regulations developed by DHEW were inapplicable (i.e., when no Departmental funds were involved). The law requires the Secretary to publish Commission recommendations in the Federal Register, evaluate public comments, and then publish regulations which incorporate the recommendations of the Commission (or explain why the recommendations are not incorporated in the regulations).

The Commission has submitted to the Secretary recommendations with respect to fetal research and these have now been published as rulemaking in the Federal Register. Among the requirements for full implementation of these regulations, is the establishment of an Ethical Advisory Board. This Board has not yet been created; steps within the Department leading to the establishment of the Board are underway.

The Commission has also submitted recommendations with respect to prison research and the Department is currently drafting regulations with regard to this subject group.

The National Commission is also required to report on the maintenance of confidentiality with respect to research designs, hypotheses, and protocols contained in research grant applications and contract proposals, the opening or closing to the public of Initial Review Groups and Councils when reviewing such applications or proposals, and the release to the public of preliminary research data.

The other elements of the Commission's charge are rapidly approaching completion and should be presented to the Secretary before April 1977. However, the recent Congress extended the life of the Commission by one year, from April 30, 1977, to April 30, 1978. No additional responsibilities were placed upon the Commission and it is not clear what the Congress expects the Commission to accomplish during this extension period. During the closing days of the 94th Congress, the Senate passed and the House sent to Committee, a statute to make the Commission a permanent body and elevate it to a Presidential Commission.

Each of these sets of recommendations will eventually be reduced to regulation form. Each will have a significant effect on the way that the PHS pursues its statutory research mission. Taken altogether, these regulations will have a profound effect on the function, the cost, and the nature of research conducted, supported, or regulated by the Secretary of HEW.

The regulations generated by the National Commission for the Protection of Human Subjects are not the only regulatory activity which is modifying and transforming the procedures according to which research is carried out in this country.

The Food and Drug Administration has already issued regulations governing investigational drugs and has issued sweeping proposed rulemaking concerning investigational medical devices. It is proposing to issue regulations concerning good laboratory practices and the testing of vaccines. Each of these sets of regulations will have significant impact on the conduct of research in this country.

Other agencies have also issued regulations which, directly or indirectly, exert influence on the way that research is carried out in the U.S. The Environmental Protection Agency has sweeping authority to regulate research that may affect the environment. Already it has required the National Institutes of Health to issue an environmental impact statement regarding recombinant DNA research, and such statements may be required for other types of research in the future. It is likely that legislation similar to the Clean Air Act will be passed with further possible research impacts.

The Department of Agriculture promulgates regulations governing the care and transportation of animals, including animals utilized for research purposes. The Department of Transportation has published regulations governing the transportation of hazardous substances, including radioactive and etiological agents. The list of regulations which direct, constrain, restrict, or prohibit the conduct of research is growing. (See also, for example, Toxic Substances and Recombinant DNA Research.)

POSSIBLE ACTION/DECISIONS: It is imperative that a comprehensive evaluation of the increasingly complex impact of such regulations on research conducted, supported, or regulated by the Secretary of HEW, as well as research conducted or supported by other Federal agencies, be made, in order that Congressional mandates for performing research not be inadvertently impeded by mandates for other programs.

ISSUE: The implementation of the Health Professions Educational Assistance Act of 1976 (P.L. 94-484).

BACKGROUND: P.L. 94-484, enacted October 12, 1976, affects the entire spectrum of health manpower education and training. It authorizes modification and continuation of current manpower programs in fiscal year 1977 and new and modified programs in fiscal year 1978. It carries a total authorization level in excess of $2 billion.

The Public Health Service must simultaneously (1) operate a grant cycle for 41 separate health manpower programs, (2) implement, including the promulgation of 30 sets of regulations, 25 major programs, and (3) recentralize personnel and functions from 10 HEW Regional Offices.

The timing for implementing these factors of the law is critical, since they impinge on the planning and budgeting of every medical and dental school in the country, assistance to over 20,000 needy students, and the securing of medical manpower to serve in rural and urban health manpower shortage areas throughout the country.

POSSIBLE DECISIONS/ACTION: A number of policy issues must be resolved as the PHS implements this legislation.

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ISSUE: Federal Role in the Credentialing of Health Manpower

BACKGROUND: In 1971, pursuant to a Congressional mandate, DHEW prepared the Report on Licensure and Related Health Personnel Credentialing that addressed recommendations to States and professional organizations concerning health manpower licensure and certification. The 1971 Licensure Report also called for DHEW to support a number of studies to determine the most appropriate alternatives for credentialing health manpower. In 1975, PHS established the Subcommittee on Health Manpower Credentialing under the aegis of the Health Manpower Coordinating Committee to review these studies and make additional recommendation if needed.

After intensive review of DHEW research efforts, as well as those conducted by States and professional organizations, the Subcommittee prepared a draft report, A Proposal for Credentialing Health Manpower, which contained seven far-reaching recommendations for improving health manpower licensure and certification. However, before formal PHS or Departmental action was taken on the report, it was submitted to State agencies and professional organizations for comment. The report was widely distributed during the summer with a deadline for comments by October 31, 1976. Approximately 500 responses have been received and analyzed by the Subcommittee.

The report is presently being revised to address the major issues raised by the respondents. This revision should be completed during December 1976.

Major recommendations in the draft report pertain to the development of a national (non-Federal) certification council to enhance health manpower certification, development of uniform standards for licensure and certification, and possible linkage of uniform licensure and certification standards to Federal reimbursement for health care. In addition, other recommendations call for improvement of present State licensure procedures, more research related to proficiency examinations, and more attention focused on continued competency matters.

POSSIBLE ACTIONS/DECISIONS: The report is being revised based on public comment and decisions will be required as to its acceptance. The report will become the general blue-print for future DHEW credentialing activities over the next several years.

It should be noted that the draft report has engendered considerable interest and controversy among State agencies, professional organizations. and health personnel. Therefore, the decisions on the report will have a significant impact on the professional community.

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ISSUE: Graduate Medical Education National Advisory Committee

BACKGROUND: There is general public and professional agreement that there is an imbalance of physicians among the various medical and surgical specialties. The current output of graduate medical education training programs neither reflects a cohesive physician manpower strategy nor is it derived from any agreed upon national goals for specialty manpower requirements. To address these problems, the Secretary has established the Graduate Medical Education National Advisory Committee using existing authority under Section 222 of the Public Health Service Act as amended, 42 USC 217a. The purpose of GMENAC is to analyze the distribution among specialties of physicians and residents and to evaluate alternative approaches to ensure an appropriate balance. Also of special importance to the Committee will be health care financing and reimbursement issues which heavily affect the support of, and scope of, graduate medical education and factors which must be given careful consideration in the design of national health insurance options.

Rational, dependable goals and policies for specialty physician manpower production will require a substantial improvement in manpower data, analytic methodologies, and understanding of the dynamics and content of specialty practice. Because of this, GMENAC's accomplishments and contributions must be seen as both short and long range. During its initial 2 year phase, it is anticipated that the Committee will provide the following: a description of the current supply of physicians by specialty, nationally and with regional variations; a description of physician specialty requirements using various assumptions; a characterization of the current graduate medical education pipeline; a first approximation of a more appropriate specialty education production mix; the identification of research issues that must be addressed to improve our understanding and ability to refine graduate medical education goals in the future; and provide recommendations for action to the Secretary based upon its findings.

It should also be noted that Congress accepted GMENAC, in concept, and rejected a more direct regulatory approach to solving the problem of specialty maldistribution. For this reason, the work of GMENAC is much more critical in providing the setting of additional congressional legislation in this area.

POSSIBLE ACTION/DECISION: GMENAC will be providing a major report to the Secretary embodying its findings and recommendations 18 months after it convenes. Additionally, a status report will be provided no later than December 15 in each year of the Committee's existence. At present, the appointment of members to the Committee is pending.

ISSUE: Promulgation of Occupational Health and Safety Standards

PROBLEM: Today, five years after enactment of the Occupational Safety and Health Act of 1970 (OSHAct), there are still annually 2-3 million injuries and over 100,000 deaths from occupational diseases and injuries--resulting in an annual societal cost of $20 billion from workmens' compensation payments, property damage losses, and third party product liability law suit damages. The OSHAct relies strongly on safety and health standards as a central focus for achieving the goal of a safe and healthful workplace. Although NIOSH in the Public Health Service, has recommended more than 50 occupational health standards (criteria documents), including several for occupational carcinogens, OSHA in the Department of Labor has promulgated only one health standard through the normal rulemaking process.

BACKGROUND: Under the OSHAct, NIOSH has the responsibility to develop recommendations for occupational health and safety standards. Since its passage, NIOSH's primary focus has been on occupational health through the development of criteria documents which thoroughly review and evaluate available scientific information and present a complete occupational health standard, including a permissible level of exposure, medical monitoring, training of employees, safe work practices and requirements for monitoring of workplace air. It is recognized that a major drawback in this effort has been information as to technical feasibility to meet a proposed standard. Consequently, NIOSH has initiated efforts to assess available information in this area.

In addition to this effort, NIOSH in cooperation with OSHA, initiated a Standards Completion Program in March 1974 to supplement some 400 occupational health standards which had been put into law soon after passage of the OSHAct and had been developed earlier by occupational health professional societies on a consensus basis. These standards consist only of an allowable workplace environmental limit of exposure and do not include information on monitoring, informing employees of the nature of the hazard, medical examinations and safe work procedures. NIOSH has completed its agreed upon share of the Standards Completion Program. However, OSHA has fallen behind in its role and has yet to promulgate any of these supplemental standards. Part of this delay is due to OSHA now unilaterally revising some of the initially agreed to concepts and procedures of the Standards Completion Program.

RECOMMENDED COURSE OF ACTION: OSHA should be directed and encouraged to move in a more expedious manner to promulgate standards. OSHA could employ innovative approaches, such as comprehensive standards for processes or industries and grouping a number of rulemaking efforts, e.g., a broad standard for carcinogens and one rulemaking effort for the Standards Completion Program. Also the process for determining economic feasibility

and inflationary impact should be reevaluated and streamlined with more emphasis placed on the economic benefits of preventing occupational illnessess and injuries. When this is done, NIOSH support can be integrated into a joint effort to achieve well defined goals. This course of action should also receive the support of both labor and management, who in the past have been faced with some uncertainty as to OSHA's regulation schedule and intentions.

ISSUE: Assuring coherence in formulating environmental health policy.

BACKGROUND: Recent environmental crises resulting from kepone and PCB contamination, and the continuing uncertainties about the efficacy of the catalytic converter highlight the fact that we do not yet have a coherent National environmental health strategy. Such a strategy should outline the necessary regulatory, research, and surveillance goals of the Nation in environmental health, and it should clearly define each Federal Agency's role in achieving those goals.

One major objective is to establish within DHEW a systematic process for policy formulation regarding the health aspects of the environment and for coordinating our involvement with other Federal Agencies, such as EPA and DOL, which have primary regulatory responsibilities in this area. This may require new organizational and decision mechanisms to assure scientific guidance to other Federal Agencies, and to offer leadership and technical assistance needed by State and local agencies to resolve environmental health problems.

As a first step toward this end, a subcommittee on environmental health of the PHS Policy Board has been formed. In addition, NIH, CDC, and FDA have been requested to complete by January 1977 an internal review of their environmental research, regulatory, and surveillance activities to facilitate a later reassessment of all PHS responsibilities in environmental health.

POSSIBLE ACTIONS/DECISIONS: The recent passage of the Toxic Substances Control Act reemphasizes the necessity for DHEW to develop a national environmental health strategy and the need to establish a more formal mechanism for fulfilling its responsibility in environmental health.

ISSUE: Improvements needed in efforts to help the mentally disabled return to and remain in communities? (deinstitutionalization)

BACKGROUND: As a result of its study on "deinstitutionalization" the GAO this past summer issued a draft of the report identified above. The draft report is currently being reviewed by the various agencies involved to develop comments to GAO on the document. At the completion of this process, GAO is expected to issue a final report (estimated to be finished early 1977).

The draft report identified that "many mentally disabled (i.e. both mentally retarded and mentally ill) persons have been released from institutions before sufficient community facilities and services were available and without adequate planning and follow-up. Many persons remain in, continue to enter, or reenter institutions unnecessarily. GAO indicated that many of the problems were due to "1) Federal programs which provide financial incentives that inhibit the appropriate placement of the mentally disabled and 2) the lack of leadership and action by many Federal agencies whose programs do, could, or should impact in community placement." In addition GAO identified as problems lack of coordination between Federal agencies, and within agencies and between the State and local governments and service systems (CMHCs and state institutions).

The draft report had recommendations to Congress; OMB; HEW (including PHS, Medicare, Medicaid, SSI, Vocational Rehabilitation); HUD and Labor.

ANTICIPATED ACTIONS: When the final report is issued each of the affected agencies can anticipate having to document what actions they are or have taken to address the GAO recommendations, or if no action is taken to justify such a move. In addition, because of the coordination problem identified the executive branch should anticipate having to deal with questions and concerns in this area.

11/18/76

ISSUE: PHS Uniform Charging Policy for Recipients of Services at Grant Supported Health Service Delivery Projects

BACKGROUND: The need for a definitive or uniform policy arose in FY 76 during a review of various program regulations and guidelines. It revealed widely divergent guidances to grantees on charging individuals for services. For three programs, Community Health Centers, Community Mental Health Centers and Migrant Health Centers, legislation passed in July of 1975 (P.L. 94-63) requires projects to:

-- establish fee schedules based upon the costs of operation;
-- establish discount schedules consistent with a patients' ability to pay; and,
-- secure payment from patient according to those schedules.

It seems desirable that in developing a policy to implement these provisions of P.L. 94-63, that we should not limit to these three programs the consideration of how one determines a person's ability to pay. We should develop a policy that will be equally applicable in all of our grant-supported health services delivery programs. Some of the programs considered for conclusion under this policy are:

-- Alcohol Treatment Projects
-- Community Health Centers
-- Community Mental Health Centers
-- Drug Abuse Projects
-- Family Planning Projects
-- Hemophilia Treatment Projects
-- Home Health Projects
-- Maternal and Child Health Projects
-- Migrant Health Projects
-- National Health Service Corp Sites

POTENTIAL DECISIONS/ACTIONS: PHS is in the process of formulating a basic policy. By December or early January we would expect to have before the Secretary a Regulations Development (RDP) which will detail our intended course of action in seeking public input on the proposed policy. It is anticipated that the proposed PHS charging policy will lead to similar policy considerations in other Departmental program supporting the delivery of services to individuals.

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ISSUE: What should be the Federal role in the medical malpractice insurance problem?

BACKGROUND: The subject area became a "crisis" in the Winter of 1974-75 when medical malpractice insurance became difficult to obtain in many areas. The availability problem has now largely abated, but the costs of malpractice insurance continue to rise at an average national rate of about 20% per year. Other factors, such as high legal costs, and low percentage of premium dollar reaching the injured persons, persist. The Department's policy has been that when government intervention is required, it should occur at the State level, since it is the States who traditionally have regulated the insurance industry and licensed hospitals and physicians. For its part, however, the Federal government has been instrumental in encouraging cooperation between the important groups--insurance commissioners, physicians, hospital administrators, law groups, and insurance representatives. In addition, the Federal government through HEW has been building a better base of information in which decisions by both the public and the private sectors can be based. This work has included acting as an information clearinghouse and conducting a number of research projects on priority question areas.

Although there remain numerous narrow questions on medical malpractice warranting research, the major questions identified initially have either been answered or are currently being addressed. However, as a result of this work, it has become apparent to a number of researchers in the area of malpractice that an initiative outside the tort liability system should be tried. Probably the easiest to try, and then only in a limited way, is the "designated compensable events compensation plan." With this plan, certain outcomes of medical care are determined to be usually avoidable, and when they occur, to be compensable without the necessity to show fault. This will eliminate the need to prove malpractice in some, but not all situations. The validity of the concept, and the cost, need to be studied, and if proven feasible, a pilot study should be initiated.

POSSIBLE ACTIONS/ISSUES: In order to further define the Federal role, HEW plans to sponsor the initial feasibility work on a pilot for a designated compensable event compensation plan. It is expected that the majority of funding, should the pilot be feasible, will come from sources outside the Federal Government.

It is expected that the costs of malpractice insurance will continue to rise, with some slowing as a result of changes in the tort system. In addition, periodically, small problem areas will arise. Thus, there will be pressure for Federal intervention.

ISSUE: BIO-RESEARCH MONITORING

Under the Federal Food, Drug, and Cosmetic Act, manufacturers carry the burden of demonstrating that their products meet the safety standards of the law. FDA does relatively little toxicology testing of its own and no clinical testing. Instead, we set requirements for teratogenic, carcinogenic, and mutogenic testing, and then review the data submitted by manufacturers to determine whether they meet these requirements. Animal studies of human drugs are of particular importance to determine whether new products can be safely tested in humans to assess their potential therapeutic effect. Because of the importance of animal toxicology data to decisions regarding the safety of drugs, food additives, chemical residues, and environmental contaminants, it is essential that these studies be conducted according to specifically sound protocols and with detailed attention to their quality control.

There have been several recent instances of improper withholding or submission of false animal data in support of new drug applications. Defects in the design, conduct, and reporting to FDA of animal toxicology studies by a major pharmaceutical manufacturer were uncovered. Serious flaws in research design and performance have also been discovered at independent laboratories. Inspections have indicated that in some cases significant animal toxicity data were not available to FDA for evaluation prior to approval of extensive testing in humans.

Because of the significance of the above findings, and because any program designed to address the total problem would be a new Agency-wide program, the FDA Policy Board established an Agency-wide steering committee, chaired by the Associate Commissioner for Compliance, to coordinate the implementation of the program. Five task forces were established: Toxicology Laboratory Task Group, Institutional Review Committee Task Group, Investigator/Sponsor Task Group, Food Additives Task Group, and Administrative Task Group. These task groups were set up to develop specific plans for the major part of the program, including inventories, formal agreements with other agencies, standards, enforcement strategies, etc.

In June FDA was allocated a budget supplement of 200 positions and $1.2 million for the transitional quarter to develop plans for a Bio-Research Monitoring Program. For full implementation, 606 positions were included in the fiscal year 1977 budget.

Proposed Good Laboratory Practices (GLP) regulations, published in the Federal Register on November 19, set standards for all aspects of animal and other laboratory studies, from facilities and equipment to personnel and record-keeping. Non-compliance with the regulations could result in rejection of data submitted to FDA in support of new drug or food additive application, withdrawal of approval of a marketed drug or food additive, or disqualification

of the laboratory in question. The proposed regulations would affect at least 550 U.S. laboratories as well as foreign laboratories conducting studies to be submitted to FDA.

During the next three months, FDA investigators will inspect approximately 40 laboratories to evaluate current practices in light of the proposed regulations as well as to get a broader view of the quality of current research.

POSSIBLE ACTION/DECISION

Early in 1977 FDA will hold a public hearing to promote an effective exchange of views concerning the scientific soundness and practicability of the proposed regulations. Final regulations will be issued after consideration of written comments and those received at the hearing.

ISSUE: Sterilization Services in HEW programs (Titles XIX and XX of the Social Security Act and various programs of the Public Health Service).

BACKGROUND: Surgical sterilization is considered a legitimate family planning method for those who have completed their families and for those for whom future childbearing carries a severe health risk. As with any other surgical procedure, age of legal consent for sterilization varies among states and jurisdictions of the U.S.

On June 14, 1973, two sisters, aged 12 and 14, were sterilized in a Montgomery, Alabama, family planning project supported by the Office of Economic Opportunity, with actual payment for the procedures made by Medicaid. The sterilizations occasioned a series of civil suits (Relf v. U.S.A., C.A. 74-244, a tort, claiming one million dollars in damages, National Welfare Rights Organization v. Weinberger (now Mathews) et al., C.A. 74-243 and Relf et al., v. Mathews et al., C.A. 1557-73).

Since July, 1973, the Department has issued a number of directives on its own and in response to Court Order. There are currently two such directives in effect: a moratorium (August 3, 1973) on federal financial assistance for sterilizations of persons under the age of 21 or legally incapable of giving consent; regulations (April 18, 1974) governing the consent procedures to be followed for sterilizations of persons 21 and older who are themselves legally able to give consent.

Between February, 1974, and October, 1975, in NWRO v. Mathews, the Department argued in Federal District Court, that it be permitted to set its own standards for family planning program services. The Department proposed that the age of consent be lowered to 18 for sterilization procedures (unless states imposed stricter age standards) and that sterilizations, with added safeguards, be permitted for certain persons legally incapable of giving consent, but capable of understanding the nature and consequences of surgical sterilizations. On October 22, 1975, the Court ruled against the Department on the matter of standards, but denied, without prejudice, plaintiff's motion that the Court intervene in enforcing the April 18, 1974, regulations.

POSSIBLE DECISIONS/ACTIONS: Both the Department and plaintiff (NWRO) appealed the October, 1975, decision of the U.S. District Court judge. Oral argument on the appeal is set for November 18, 1976.

Dates for further hearings in the tort (Relf v. U.S.A.) are not yet set.

The immediately available alternatives are:

1. The Department will continue its appeal of the October, 1975, U.S. District Court order, thereby arguing that it has a right to set administrative procedures for insuring the rights of persons who would be sterilized with federal funds.

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2. The Department will drop its appeal, thereby allowing the October, 1975 order to stand, and continuing in force the moratorium on federal financial participation of sterilizations of persons under age 21 or otherwise legally incapable of consenting, and the regulations of April 18, 1974.

ISSUE: The Need for Improved Mechanisms for Technology Transfer and Technology Assessment at the Health Research/Health Care Interface.

BACKGROUND: By long tradition within the research community, the main mode for dissemnination of research results is through publication in the open science literature, with some dependence also on conferences and workshops. This modus operandi adequately serves the needs of science. However, there has been increasing criticism in Congress and elsewhere that these research results are not getting into health care practice systematically or with even distribution, and that sometimes introduction is premature or unduly delayed. High points of effectiveness in this information interchange are (1) the teaching hospitals associated with main medical schools and (2) the major disease research centers, where there are also strong clinical care components. But the dominant picture is of wide variation in the availability of quality health care across the country.

It is quite clear that dissemination processes and mechanisms on both sides of the health research/health care interface are inadequate, and require improvement. It is also true that clear-cut mission and role assignments for these functions have not been made among the number of Federal agencies with health responsibilities.

With the above as perspective, the NIH has been exploring means to correct weaknesses on the research side of the interface. Specifically, the NIH has been trying to devise acceptable and effective mechanisms for further processing of research information within the research community, with this objective: to assure that clinically relevant information flowing from research is (1) identified promptly; (2) validated adequately for efficacy and safety; (3) assessed where appropriate for ethical or cost impact issues; and (4) recommended in easily accessed form for pick up by the health care system. (Where it is possible to achieve a reasonable consensus on optimal modes of diagnosis, treatment, or prevention, these will be a part of the transfer package.)

POSSIBLE ACTIONS/DECISIONS: Many controversial issues--including basic feasibilities--will have to be worked out within the research community. When these are settled, there will remain policy issues of added resource requirements, inter-digitation with processes on the health care side of the interface, and adjustments in agency missions and roles.

ISSUE

The pay and benefits for clinicians and researchers are substantially below that of comparable non-Federal positions and need to be raised so that top quality personnel can be recruited and retained.

BACKGROUND DISCUSSION

The Public Health Service (PHS) is an integral part of a large medical and research community which consists of hospitals, universities and medical schools, as well as private practitioners. Movement of staff between various institutions within this community is essential to the maintenance of creativity in each of its components.

In recent years the movement of experienced senior level staff between PHS and other medical and research institutions has increasingly become a one-way flow -- out of PHS. Now, when a key staff member accepts a better offer in a university or a hospital, it is always difficult and frequently impossible to attract outside candidates with comparable experience and stature. The major factor contributing to this trend is the difference between the salaries and benefits provided by non-Federal institutions and those available under the Civil Service system. Some median salary figures from the Association of American Medical Colleges Annual Salary Survey for Fiscal Year 1975-76 illustrate this point. During a period when the top salary for Civil Service employees was $37,800, half of the full-time professors of clinical sciences received at least $45,000 in salary and half of the full-time clinical science department chairmen received at least $57,000 in salary. Individuals who were in the top 20 percent of the range for clinical science faculty -- the group from which PHS is generally trying to recruit for research positions -- made at least $55,000 as full professors and $68,000 as department chairmen during this same 1975-76 period. Since benefits in academic institutions are generally superior to those in Civil Service, a total income comparison would show an even greater advantage for our competitiors.

Salary competition is not new to PHS but the problems we are facing as a result of it are much more critical than in the past. It is no longer just a question of individual, highly specialized positions that are difficult to fill. The cummulative effect of not providing adequate salaries over the last several years has dangerously eroded our capacity to retain staff who earlier committed themselves to a career with PHS and it has so significantly increased the economic sacrifice of those we try to attract that a substantial number are unwilling to even talk about the possibility of working for PHS.

ACTION RECOMMENDED

The Department should continue to urge the Commission on Executive Legislative and Judicial Salaries to substantially raise executive salaries and the ceiling on senior level Civil Service salaries.

ISSUE

Implementation of the Department's Three-Year Position Classification Review Program will require downgradings. Downgradings may have an adverse impact on program operations. This impact should be minimized.

BACKGROUND DISCUSSION

The Three-Year Review Program has as its objective, accurate classification of all Department positions. The Public Health Service (PHS) supports this objective and has developed a plan for implementing the findings of the review. We are now working on the three-year review. Already problems are appearing. The major problem has to do with the use of reduction-in-force (RIF) procedures. When a position is identified as inaccurately described and overgraded, RIF procedures are required to place the incumbent. Civil Service rules require that all positions involved in a RIF be accurately classified. Since our review is a three-year review, it will be three years before we can be sure that all positions that could be involved in a RIF are accurately classified. This leaves us with two alternatives. One, do the RIF and attempt to assure that all positions involved are accurately classified. Two, hold all RIF action until all reviews are completed. While we are following the first alternative, since we see no legal basis for delaying required action for three years, we expect appeals and court actions, some of which we may well lose. We also expect that considerable employee energy will go into resisting downgrading actions; energy that would otherwise go into programmatic activities. RIF's would also result in employees being placed in positions for which they are minimally qualified and delaying action for three years would not solve any problems. The threat of downgrading can only sap employee energy and encourage turnover. Turnover resulting from these circumstances usually means losing the better workers because they are the ones most attractive to other employers. The combined effects of employees resisting RIF action and increased turnover will diminish productivity.

ACTION RECOMMENDED

That the Department press vigorously for legislation that would guarantee grade and pay retention for employees found assigned to misclassified positions during the three-year review. Such retention would continue until the employee leaves the position voluntarily, in which case normal pay setting rules would be applied, or the position is abolished, in which case RIF procedures would be applied.

ISSUE: Reimbursement of Physician Extender Services

BACKGROUND: "Physician extender" (PE) is a term used to describe physician assistants and nurse practitioners who are trained to perform routine tasks that are normally performed only by physicians.

Under present Medicare law, PE services can be reimbursed only if the services are rendered under the direct (on the premises) supervision of a physician and if the service rendered is one normally delegated to auxiliary personnel. Inasmuch as PEs often practice in remote site locations without direct supervision and are trained to perform tasks usually performed by a physician, many of their services are not now reimbursed under Part B of Medicare.

This reimbursement policy is in contrast with Departmental support for PE training. Through FY 1976, DHEW allocated approximately $75 million for PE training programs. Some 8700 PEs have graduated from these programs, and a substantial number are still in training.

Recognizing the dichotomy in Departmental support for PE training but denial of reimbursement under Part B of Medicare, the Congress mandated a study of PE reimbursement under P.L. 93-603 enacted in 1972. This study is being conducted by SSA, but has encountered a number of organizational and administrative problems so that results of the study will not be available until 1978. Meanwhile, as number of PEs increases and concern about geographic maldistribution of health manpower continues, there is growing pressure on the Department to support a legislative proposal to reimburse for the full range of services under Part B of Medicare. (Medicaid regulations permit reimbursement for PE services that are rendered in accordance with State law.)

Several bills to permit PE reimbursement under Medicare were introduced during the last session of Congress, and new legislation will be introduced in 1977. Inasmuch as the Department will be asked to testify or comment on such legislation, there is a need to formulate a clear Department position on this issue.

POSSIBLE ACTIONS/DECISIONS: A number of major options are now under consideration in the Department.

1. Do not support proposals to expand Medicare coverage for PE services and try to expedite the SSA study.

2. Support reimbursement for PE services under Medicare on a limited scale--e.g., in PHS-supported projects or in practices located in underserved areas--until completion of the SSA study.

3. Support a legislative proposal that would extend Medicare coverage to include the full range of services rendered by physician extenders. (The employing physician or institution would bill for these services.)

4. Support a legislative proposal that would permit independent billing by PEs for selected services under Medicare and Medicaid.

5. Establish a new class of provider "clinics," which, among other things, would increase availability of support to PE.

   A major proposal is under development.

ISSUE: Redirection of mental health manpower clinical training programs.

BACKGROUND: From their inception in 1948, NIMH clinical manpower training programs have been developed and funded separately from other PHS health manpower training programs. Such support has substantially increased the nation's supply of psychiatrists, psychologists, social workers, and psychiatric nurses. Since 1972, however mental health manpower clinical training programs have been proposed for phase out by the Administration. Although the Congress has restored such program funds each year, it has been at progressively lower levels of funding.

During this same period, the Department formulated a general health manpower strategy which emphasizes the development of primary care practitioners as a means of solving shortage and maldistribution problems. In October of this year, the Congress also endorsed such a strategy for solving resource problems in passing P.L. 94-484, the new health manpower law which emphasizes primary care training. The development of the latter legislation, along with the Department's new manpower strategy brought about reconsideration by ADAMHA of the direction of its training programs. This reconsideration was given added incentive in this year's House Appropriations Committee hearings, when Members asked that ADAMHA keep the Congress informed of any efforts to redirect mental health manpower training funds.

ADAMHA PROPOSAL: Through a major redirection initiative, ADAMHA proposes a phase out of long term support for current psychiatric and other mental health manpower clinical training programs as existing commitments expire. In exchange, it provides for a phase in of a three-tiered program emphasizing primary care, research and development, and state manpower development.

1. Primary Care. Through time-limited grants, programs will be developed which integrate mental health education into the curricullum of primary care providers, including physicians, nurses, and physician assistants.

2. Research and Development. Through short term grants, mechanisms will be developed providing innovative approaches to mental health training as well as models which effectively and efficiently address mental health manpower maldistribution and other manpower problems.

3. State Manpower Development. This program would distribute funds to states for assistance and support to build capacity for mental health manpower planning, resource development, and utilization. States would be required to submit an annual plan and to work in cooperation with community mental health service providers and educational institutions.

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POSSIBLE DECISIONS/ACTIONS:

This proposal has been accepted in principle and will need to be incorporated into the upcoming session with the Secretary.

ISSUE: Revision of FDA Drug Legislation

BACKGROUND: FDA is developing specifications and justification for a comprehensive rewrite of drug laws to provide a manufacturer license, a product license, and a public standard (drug monograph) for the drug entity. It will cover all drugs -- prescription, over-the-counter, antibiotic, and insulin. The old drug/new drug considerations would be eliminated.

Drugs Under Investigation. Revised procedures are needed to enable FDA and its advisors to become involved early in drug development and review data in the early phases of drug investigation.

Plant Licenses (Manufacturers, Repackers, or Other Product Manipulators for Active or Inactive Ingredients). Under the proposed rewrite, each manufacturer would be issued a license for each facility on the basis of compliance with good manufacturing practices. Provisions would be included for amendment, revocation, suspension, and reinstatement of licenses.

Product Licenses. Each existing product would be granted a product license according to requirements set forth by FDA.

Miscellaneous Provisions.

1. Extend FDA authority to all drugs and drug handlers.

2. Authorize FDA to restrict distribution and dispensing of certain drugs.

3. Expand records and reports authority and provide subpoena authority.

4. Provide for drug embargo, civil fine, and expanded adminstrative authority.

5. Establish clear U.S. policy on drug exports.

POSSIBLE ACTIONS/DECISIONS: A consideration of this major legislative package will be required by mid-1977.

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ISSUE: Selection of a site for the main laboratory building of the National Institute for Occupational Safety and Health (NIOSH).

BACKGROUND: The NIOSH main laboratory operations involving research, technical assistance, and training have been located in several leased or Federally-owned structures in Cincinnati, Ohio, for a number of years. The structures are inadequate for research purposes and with substantial increases in personnel over the past several years, they are deficient in size.

About nine cities, aware of the facility need, wrote to the then-Secretary asking that their location be considered as the permanent site for NIOSH activities and offering to build and lease to the Government an appropriate structure. A site study team was formed to visit the locations, evaluate their potentials and provide the Secretary with a recommendation. The study was accomplished and, Houston, Texas and Cincinnati, Ohio, were recommended as the best of the nine sites. On April 26, 1973, the Secretary announced that Cincinnati had been selected.

The House Appropriations Subcommittee report of June 19, 1975, on the fiscal year 1976 budget was critical of the study and the selection of Cincinnati; it asked that a second study be initiated considering all potential sites rather than just those requesting consideration. The 1976 budget also contained about $1.1 million for the design of a Federally-constructed facility rather than a lease structure. Design work has been initiated and is about 30 percent complete. A second group was formed and evaluated all possible sites meeting program criteria previously established. No site visits were made because of time constraints imposed by Congress for reporting back to it. The group concluded that there were no compelling reasons to change the previous selection of Cincinnati and Secretary Mathews affirmed the earlier decision. Congressional criticism of site criteria, method of evaluation, and the speed with which the second report was concluded continued during hearings on the fiscal year 1977 budget.

The House-Senate conferees report of August 3, 1976, on the 1977 budget in referring to the NIOSH facility states, in part, ". . . the Conferees agree that the Secretary of HEW shall study site selection and report his results to the Congress prior to December 31, 1976." It has been decided to utilize an outside contractor to conduct the third study; the firm will be guided by a set of criteria incorporating program requirements and certain ancilliary needs that Congress believes appropriate to the evaluation. Contracting procedures will preclude meeting the December 31 date and the letter transmitting the draft criteria for the review of the Chairmen of the House and Senate Appropriations Subcommittees carries this notation.

It is not likely that the site survey report will be completed before March 1977. The report conclusions are not predictable; it could recommend Cincinnati or one of 20 to 25 other locations. It is also possible that several cities could be ranked as equally desirable.

ACTION REQUIRED: During March 1977, or shortly thereafter, a decision must be made on the permanent location of the main research facility for the National Institute for Occupational Safety and Health.

ISSUE: Transfer of St. Elizabeths Hospital to the District of Columbia and upgrading of the facility to meet JCAH standards.

BACKGROUND: The fiscal year 1977 budget proposed an appropriation authorization of $75 million for construction and/or renovation of mental health facilities at Saint Elizabeths Hospital taking into consideration the mental health facilities needs and resources of the District of Columbia. This authorization of $75 million (subsequent OMB concurrence of $100 million) was to be included in legislation, in the last Congressional session, supported by the D.C. and the Executive Branch to: 1) establish a future transfer date of the Hospital to administrative control of the District; 2) gradually reduce Federal support for operation of the Hospital after transfer; and 3) mutually arrive at critical decisions with respect to delineated responsibilities of the two governmental jurisdictions.

In September 1975, the Joint Commission on Accreditation of Hospitals conducted its most recent survey and, in November, notified the Hospital of the disaccreditation of its psychiatric facilities (the medical and surgical program received another one year accreditation). The major defects identified related to fire and safety items and staff shortages in specific program areas.

Both the 1974 and 1975 surveys identified needs in the area of internal management-- principally with respect to patients' records. The Hospital is addressing this problem, and will not require additional resources.

Several other actions are currently underway to correct the facility problems:

...In 1975, a total of $1,260,000 was reprogrammed from other facility projects, to initiate the early stages of work upon the recommendations set forth in the 1974 survey.

...In 1976, a total of $10,400,000 was appropriated for planning (conduct of a total engineering, architectural study of a physical plant, Report on the Master Plan, required by Congressional Appropriations Committees, to be submitted early January 1977), and move ahead with work necessary to comply with recommendations of the JCAH related to patient safety, patient privacy, improving facilities related to patient services, etc.

The supplemental appropriations request of $75,000,000 will permit proceeding with construction and renovation to relieve overcrowding of the Hospital and commence a phased plan of replacing obsolete buildings to comply with standards of JCAH, Life Safety Code, etc. This will further meet the commitment of President and Congress (funds are included in the concurrent resolution for FY 77) to regain accreditation and restore the Hospital to an accredited facility.

ACTION REQUIRED:

- On-going collaboration with D.C. with respect to planning for transfer to D.C.;

- Planning and preparation with D.C. for placement of some 1,300 patients in community settings to comply with Court Order in Dixon v. Weinberger;

- Activities related to improve operations and management;

- Further refinement of draft legislation for introduction at the earliest opportunity, in the next Congressional session, transferring the Hospital to the District, thereby establishing a single administrative authority for the District's Mental Health Delivery System.

ISSUE: The appropriate course of action to be taken with respect to the Public Health Service hospital system.

BACKGROUND: The Public Health Service hospital system was established in 1798 to provide medical care to merchant seamen. Over the years, other classifications of beneficiaries have been served by these facilities. At its peak, the system had hospitals located at all major ports on each coast, along the Gulf of Mexico, and on the major rivers of the inland waterways. Because of the decline in inland waterway traffic and certain coastal ports, utilization at certain hospitals declined to a point where their continued operation was no longer justified. After publication of the Hoover Commission Report in 1955 that recommended one Federal hospital system, repeated attempts have been made to close or transfer to community control all of the PHS hospitals. To date, all such attempts have failed because of strong congressional opposition although about a half dozen underutilized facilities have been closed one or two at a time. At present, there are eight General Medical and Surgical (GMS) hospitals in operation at Boston, Massachusetts; Staten Island, New York; Baltimore, Maryland; Norfolk, Virginia; New Orleans, Louisiana; Galveston, Texas; San Francisco, California; and Seattle, Washington. The National Leprosarium at Carville, Louisiana has not been included in hospital closure efforts and the need for care and research of Hansen's Disease which are unique to this facility has not been challenged.

In addition to providing care to American seamen, these hospitals also provide care to active duty personnel of the Coast Guard, National Oceanic and Atmospheric Administration, and the Public Health Service. Health care is provided on a reimbursable basis to other groups when permitted by physical and staff resources; included in these groups are beneficiaries of other Federal agencies, e.g., members of the Armed Forces and their dependents, foreign seamen and community residents. The hospitals also have major responsibilities in medical education and training, community health services, biomedical research, and responses to natural and man-made disasters.

Funding for needed maintenance and repairs during the past 21 years has been minimal and sporadic, most often occurring to meet exigent situations. Design funds authorized by the Congress in 1965 and 1966 for the modernization of the system were only partially expended; a significant portion was reprogrammed for other purposes and the remainder unobligated until 1974.

The failure to expend either all repair and improvement funds or modernization design money was due to the application of one of two rationales. The first of these concluded it was not justifiable to spend money on hospital facilities scheduled for closing or transfer from Federal ownership. The second rationale, applied in the 1960's, reasoned that with modernization planning under way, funds used for repairs and improvements in the interim would be lost when modernization work was initiated.

After a number of the previously mentioned efforts to discontinue operation of the PHS hospitals, Congress in 1973 enacted Section 818 of P.L. 93-155, which requires that the Secretary take such action as necessary to assure that services continue to be provided by the hospitals in like manner as such services were provided on January 1, 1973. Alternatively, the Secretary may propose legislation to the Congress to close hospitals provided the proposal is accompanied by the written approval of affected State and local health planning agencies. Within the last year, approvals of the planning agencies were solicited in anticipation of submitting legislation to close or transfer to community control the eight PHS hospitals. However, none of the requested approvals were received and the hospital system continues to operate at the January 1973 level.

The Federal Government can no longer risk the continued operation of these facilities in their current states of disrepair. Twenty-one years of neglect in maintaining the physical plants has led to their serious deterioration. Congress has recognized the situation and requested a Master Plan for modernization and renovation of the PHS hospital and clinic system by October 30, 1976.

ACTION REQUIRED: Because the condition of the PHS hospitals presents a potential threat to the safety and welfare of patients and staff, an early decision is required to either close these hospitals or designate them as research and demonstration centers in the delivery of health care services and embark on an immediate program to repair and improve them.

ISSUE: Financing of Home Health Services.

BACKGROUND: The Department is concerned about the high cost of medical care and the attendant problems in the health care delivery system. The role of home health care as a means of health care delivery that may have the potential for moderating costs is receiving considerable attention. There are numerous issues involved in delivering and financing home health services which are involved in this discussion including barriers to eligibility and range of services available for home health care as well as the perception that Federal regulations deter the rational development, expansion and coordination.

Partly in response to public reaction to 1975 proposed changes in the Title XIX program (Medicaid) regarding home health services, a series of public hearings were held between September 20 and October 1, 1976. A report, Home Health Care: Report On The Regional Public Hearings, on the proceedings was published October 29, 1976. This report highlights the major themes of those presenting testimony which are listed below:

1. Home health care is socially desirable and beneficial.

2. Coverage of services should be expanded both in scope and in range of individuals. That is more services such as homemaker, occupational therapy, transportation be added and that all age groups be included.

3. More information is needed on cost and methods of financing.

4. Administration of various programs must be better coordinated.

5. Mechanisms of planning, showing need for providers and assuring quality, need to be strengthened and enforced.

6. Fraud and abuse must be controlled and prevented.

7. Artificial barriers imposed by Federal requirements should be removed.

8. A more coherent Federal policy regarding home health care should be developed.

While the comments identified the problems as perceived by the witnesses at the hearings, there was little consensus on solutions. The effect of proposed changes on the Federal Funding programs; Titles XVIII (Medicare), XIX (Medicaid), and XX (Social Services) of the Social Security Act, as well as Titles III and VII of the Older Americans Act was not explored. It summarized the information presented at the hearings and can serve as a basic discussion document in efforts aimed at resolving the problems.

POSSIBLE DECISIONS/ACTIONS: A Department-wide Home Health Care Working Group was just designated to develop a paper which will set forth the options that the Department must address in achieving a policy position. Of particular concern will be possible expansion of benefits, optional financing mechanisms, the pros and cons of further demonstrations, need for quality assurance mechanisms and training, and cost of various options. The options paper will be ready in early 1977.

ISSUE: Invitation to Polish Minister of Health to Visit the United States

BACKGROUND: The Minister of Health and Social Welfare of the Polish People's Republic, Dr. Marian Sliwinski, is anticipating an invitation from the Department to visit the United States sometime early in 1977.

Since 1962, this Department has been involved actively in collaboration with health institutions in Poland which fall within the purview of the Ministry of Health and Social Welfare (MOH/SW). During this period, there have been several high level visits on both sides, most recently including a visit by Minister Sliwinski to the United States (March 1973); a reciprocal visit by Secretary Weinberger (August 1973); and a visit by Dr. Theodore Cooper to Poland (July 16-20, 1976). Even before Dr. Cooper's last visit, we were aware that Minister Sliwinski would have appreciated an invitation to visit the United States this fall. Due to numerous commitments surrounding the Bicentenial Celebration and the elections, the Poles were informally advised that an invitation could not be extended until after 1977. During Dr. Cooper's visit to Poland this summer, he reiterated our wish to have Minister Sliwinski visit the United States as soon as possible after the new administration was in place.

U.S.-Poland health activities are overseen by a binational "Joint Committee." The next sessions of this Joint Committee will take place in the United States in March 1977. During recent discussions with Polish authorities surrounding the agenda for this meeting, it was suggested by them that this would be an ideal time, from their perspective, for Minister Sliwinski's visit, although he himself would not take an active role in the meeting.

POSSIBLE ACTIONS/DECISIONS: We would advise the new Secretary of HEW to issue an invitation to Dr. Sliwinski to visit the United States in March 1977.

U.S.-Polish health cooperation has been among the most mutually advantageous bilateral relations in which this Department is engaged. Althouth they would suffer no irrepairable damage if an invitation could not be immediately forthcoming, we would agree with the Poles that this would be an excellent time to have him visit the United States.

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ISSUE: U.S.-Japan Health and Rehabilitation Agreement

BACKGROUND: U.S.-Japan Cooperation in the field of health began in 1965 as a consequence of discussions between then-President Lyndon B. Johnson and Prime Minister Sato. The two leaders agreed that it would be desirable to further scientific knowledge of Asiatic tropical diseases through collaborative research which would draw upon the technical expertise of both nations. The U.S.-Japan Cooperative Medical Science Program was established in October, 1965, to meet this need.

Over the next eight years, cooperation in many scientific and technical areas grew, and in 1973 the two nations agreed to review the extent of cooperation under the auspices of a Binational Review Panel on Science and Technology. Their final Report, published in November, 1974, recognized the strong existing cooperation in the health field under the U.S.-Japan Cooperative Medical Science Program and more recently established programs in Cancer Research, Vision Research, and Food and Drug Control. In its Recommendations, however, the Panel stated that strong interests existed on both sides to expand the basis of cooperation into additional areas and recommend that steps be taken to establish a mechanism for this purpose.

As a consequence of this Report and informal discussions between the U.S. and Japanese officials, the Department of Health, Education, and Welfare and the Department of State met in September, 1976, to discuss the future basis for health cooperation with Japan. At that meeting, it was agreed that a Government-to-Government level Agreement was indicated. It was also proposed by the Department of State that such an Agreement might be appropriately signed by the President or the Secretary of State in order to establish the cooperative program on a highly visible basis. (This trend toward having high level officials sign health agreements began with the signing of the U.S.-Egypt Health Agreement by Secretary Kissinger and Minister Fahmi in October, 1975, and reflects the growing use of bilateral health activities in achieving politically visible aims.)

POSSIBLE ACTIONS/DECISIONS: A U.S.-Japan Health and Rehabilitation Agreement has been developed in the field of health. We anticipate that the Agreement will be ready for signature in late Spring, 1977, and will be signed by either the President or the Secretary of State.

11/18/76

EDUCATION DIVISION

EDUCATION DIVISION ISSUES

A. General Federal Policy

1. There should be an analysis of when it is appropriate for the Federal government to deliver services directly, when Federal assistance should be administered and delivered through intermediaries (e.g., SEAs), and when income transfers might be employed.

2. In elementary and secondary education a decision needs to be made almost immediately on what the basic strategy of the new Administration will be -- categorial programs, general aid, consolidation (block grants), school finance equalization, or some combination. Under the Congressional Budget Act, an Administration bill covering most elementary and secondary education programs must be submitted to Congress by May 15, 1977. Programs affected include:

   A. Library Services and Construction Act currently on a one year extention, having expired in FY 1976.

   B. Handicapped discretionary programs

   C. P.L. 93-380 programs, including Title I (disadvantaged), Indian Education, SAFA, Bilingual, and the Title IV consolidated programs and others.

3. The Department has yet to receive a decision from OMB concerning its final FY 1978 recommendations for the education budget to be submitted by the President in January. Problem areas include:

   A. The overall level of Federal aid to education

   B. The need to reconsider the OE request sent in September in view of Education Amendments of 1976 passed in October. The new law extends financial aid eligibility to new groups of students, adds several new programs and contains a "trigger" mechanism which could force Congressional Appropriation Committees to provide additional funding for several authorized programs.

   C. Restrictions in Salary and Expense accounts, based on the assumption that no significant increase in programmatic or administrative responsibilities will be required of OE.

4. A coordinated policy to foster the linkage of educational and economic development in financially poor communities might be developed focusing primarily on inner city and isolated rural areas.

5. At present there are no unified Federal policies for dealing with early childhood, with the elderly, etc. Thinking has been more toward fragmented categories such as daycare, adolescent education or high school reform. The fragmentation and lack of coordination often leads to conflicting approaches and confusion in the field. Coordination between

educational, health, jobs and income maintenance strategies should be considered. Specifically regarding education, attention should be given to issues such as:

A. Assessment of hypotheses of "reverse causality" in social policy such as income maintenance leading to increased educational achievement and attainment.

B. The relationships between health, family planning, and parenting education in the schools, income maintenance strategies such as AFDC, and the cost and utility of Federal and state health insurance plans.

C. The relationshps between entry jobs, future educational opportunity, and long-term careers.

6. Creative consideration should be given to the respective roles that incentives, sanctions, and technical assistance should play in encouraging quality performance by grantees in education programs. Present sanctions are generally ineffective, incentive strategies are rarely used, and technical assistance could be greatly improved.

7. Serious consideration should be given to the many proposals for regulatory reform in Federal-State, Federal-local and Federal-University relationships. Yet care must be exercised to insure that actions taken to reduce paper requirements do not at the same time constrain the ability of the Federal government to provide funds for those intended -- e.g., the poor, the handicapped, etc.

B. Programmatic Issues

Title I

1. There is a difference of opinion at the Federal level on how much discretion LEAs should have in designing Title I programs. At present, they have wide discretion to implement academic or non-academic programs according to their own assessments of student needs. Some people favor Federal requirements to gear Title I programs more directly on the basic skills.

2. Should Title I continue to use a "double barreled" eligibility and targeting system (poverty criteria to the school level, then educational disadvantagement within the school to select individual children) or should the program be directed to low-achieving children regardless of income? The implied philosophical change is substantial. Allocations may also be drastically affected. (NIE is conducting a study of this issue mandated by Congress.)

3. Title I is currently serving less than one-half of the currently eligible population. The issue here is whether full or increased funding will be supported. Alternatively, could an incentive mechanism for State funding of similar programs be developed.

Indian Education

1. The funding of the various Indian education programs needs careful review to assure that funding levels are appropriate and predictable.

2. There needs to be a clarification between the Federal and State roles in Indian Education. What responsibilities does the Federal government have to Indians as Indians? What responsibilities do the States have to Indians as citizens?

3. The Federal government needs to assure that the Indian community has authority and responsibility over their educational system.

4. The organizational placement of Indian education programs within the Federal government should be carefully considered.

Student Assistance Strategy

1. Most of the current student assistance programs are distributed on the basis of economic disadvantagement. In recent months there has been much pressure from groups and Congressmen representing students from middle-income families to expand the eligibility for Federal student aid programs to those in this income category. Without large increases in the budgets of these programs, the impact of expanding eligibility would be to reduce the average award for very low-income students and theregy, possibly, reducing the effectiveness

of the student aid strategy in addressing the goals of equalizing access and opportunity. This general policy issue must be addressed in the near future.

Desegregation

1. What should the role of the Federal government be in desegregation?

2. A Federal policy on metropolitan desegregation might be considered. Working alliance with other governmental agencies particularly HUD, Justice, and the Civil Rights Commission, should be developed for this approach.

3. The provision of early support to desegregating communities with the goal of minimizing the conflict and trauma often associated with desegregation should be considered.

Adult Basic Education

1. About one out of every five adults in the United States do not have the ability to perform tasks which are daily requirements for most adults. The Adult Education Act, which addresses this national problem, is currently authorized at $210 million and funded at $71.5 million. The authorization expires at the end of FY 78. Both budget and legislative strategy decisions must be made in the next several months, eg., should a substantially larger appropriation be requested for FY 78 and should the general framework of the program be modified when developing replacement legislation?

Guaranteed Student Loan Program

1. The Guaranteed Student Loan program is a basic and very important component of the federal student assistance strategy (along with the Basic Grant, the College Work Study, and the State Student Incentive Grant Programs). For the overall strategy to be effective, a strong GSLP is imperative. In recent years, large number of lenders have stopped participating in the program for several reasons, among the most important being the low rate of return on investment relative to other alternatives. The problem of high default rates also is associated with the program. A Student Assistance Study Group is currently reviewing all OE student assistance programs and will present a report to the Secretary in six months. Following completion of this report, several Departmental decisions must be made regarding program structure, participation requirements, etc.

School Assistance in Federally-Affected Areas (SAFA)

1. The impact aid or SAFA program was designed to meet needs which may not be relevant in today's society. This program needs to be investigated with an eye toward reform which will distribute SAFA monies in a more equitable manner.

Handicapped Education

1. There are various issues concerning the definitions of handicapping conditions. The definitions will affect the questions of who should be served and what types of services they should receive.

2. Within the national goal of providing an appropriate free public education to every handicapped child, there is the budget or cost-sharing question of what proportions should be paid by the Federal government, State, and local levels of government.

Dissemination

1. While some efforts are now underway which make the results of research and development available to the education community, significant additional efforts need to be mounted to expand the use of properly validated and productive educational approaches.

C. Education Research and Analysis Issues

1. Analysis and coordination of Federal and other governments attempts to increase Basic Skills should be quickly accomplished. This should include thinking about such Federal programs as Title I, Handicapped, Bilingual, and Right to Read.

2. Too little consideration has been given to the issue of what children should be learning in schools beyond the basics. By 1990 it seems clear that issues of energy, the world wide population boom, and food will be dominant problems in the world and will influence the US directly. Moreover changing views of the family, demographic trends in the US including the declining or stabilizing birth rate, the position of women in the society, etc., will greatly influence the nature and structure of American society. Little has been done to consider long range implication of these areas as they impact on the schools.

3. Children and adults watch television somewhere near 3 hours a day on the average -- there is at present no serious attempt to understand the educational consequences of this.

4. Little is known about the overall impact of postsecondary student grant and student loan programs. Consideration

should be given to the possibility of a social experiment varying critical policy variables in the allocation of grants and loans. Special attention would be given to assessing impacts on equal opportunity and on private v. public institutions.

5. Informed Federal education policy requires the following knowledge about what is actually happening in the schools:

   a) Apparently between 1970 and 1973 there was a dramatic reshaping of the high schools toward far greater course offerings, flexibility in choice of offerings, etc. There may now be a move back toward structure. What is the nature and impact of these changes?

   b) We know that increased time in instruction leads to increased learning yet we do not know how much time our students spend in instruction during the school day. Some tentative evidence suggests that actual time in instruction is only on the order to 60% of the school day. What are the implications, if true?

   c) Data in some cities indicate that very large number of students on the rolls do not actually attend schools. Is this true? Why? Is there some way of redressing this?

d) We do not have good data on the "back to basics" movement: the use of different forms of curriculum, the use and influence of testing in these schools, the relationship between parents and the schools, etc. Descriptive data need to be developed.

6. As a result of recent legislation, a Federal policy must be developed around life-long learning. Is the emphasis over the next couple of years to be systematic planning and exploration of the nature and need for Federal intervention or a strategy for an uncoordinated and uninformed grants program?

7. How can the Federal government help reintroduce the issue of standards and quality into education? In the past there existed in peoples minds the identity of "high quality" schools such as Dunbar and New Trier. Do such schools presently exist? What is their location, characteristics, nature, etc? Has the present trend toward "minimal competency" requirements for graduation pulled the nation further away from any notion of "excellence?"

8. For the past ten years the Federal government has promoted the use of large scale evaluations for assessing the outcomes of educational programs. Yet too often these evaluations

have been of little use to the Congress, the executive branch, or the implementers of the programs. Serious thought must be given to the role, utility, and nature of evaluations utilized by the Federal government.

D. Management

1. During the past several years the Authorization Committees of Congress have increasingly directed different components of the Education Division to undertake specific categories in addition to normal program development, management evaluation activities. For example, the Assistant Secretary for Education, the Commissioner of Education and the Administrator of NCES have been directed to carry out specific studies and surveys in areas such as lifelong learning, compensatory education, and safe schools. The Appropriations Committees have tended to not provide the funds and/or positions required to carry out the mandated activities but have suggested the work be conducted within present resource allocations. This difference between the authorization and appropriations committees has resulted in severe management problems in the Education Division (especially OE and NCES) because people must be diverted from other important activities to comply with the specific Congressional mandates.

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF EDUCATION

TO : The Secretary
Through: OS/ES _____
ASE _____

DATE: NOV 19 1976

FROM : Commissioner of Education

SUBJECT: Major Issues

Per your request I am transmitting a list of the major issues, priorities and significant activities, affecting the Office of Education for consideration by the Transition Team. I have arranged these issues by Bureau/Office within the Office of Education. Issue papers expanding on each item identified are presently being refined in the Office of Education.

They include:

Office of Indian Education

- The position of Deputy Commissioner for Indian Education has been vacant since July, 1976.
- The Fiscal Year 1977 appropriation for Indian Education has been decreased from the Fiscal Year 1976 appropriation, adversely affecting the meeting of the critical needs of American Indians.
- There is a need to implement the Morton v. Mancari Supreme Court ruling of June 17, 1974, which calls for the implementation of the "Indian preference" laws by the Office of Education in filling all vacancies in the Office of Indian Education, including initial hirings, promotions, lateral transfers and reassignments.
- There is a severe and critical need for more professional educators, teachers and administrators among Indian and Alaskan natives and to initiate a massive effort in training and development of Indian professional educators.
- There is a need for a definition of special educational needs of Indian children.
- There is a need for coordinating all USOE programs providing educational support to Indians.
- There is a need to emphasize adult education for Indian people.
- There is a need to upgrade all local Indian communities to impact the education of their children.

- The current legislation for the Office of Indian Education is due to expire July 1978. There is a need to extend the Indian Education Act and to provide a set of recommended legislative changes for Congressional review.

- Due to the proposed legislation affecting the merger of the Bureau of Indian Affairs' Division of Education and the Office of Indian Education, it is recommended that a management analysis be initiated.

Office of Planning

- The overall level of funding for Fiscal Year 1978 has to be made.

- The decision needs to be made on amendments to the 1977 budget requests concerning implementation of the 1976 Education Amendments as they affect existing programs. The Amendments will add funding requirements for existing programs.

- Decisions are pending concerning funding for new programs authorized by the Education Amendments of 1976.

- Several major pieces of legislation expire in Fiscal Year 1976; decisions need to be made concerning legislative changes and reauthorizations.

- The form in which we present the legislation and budget proposals for Block Grants needs to be determined.

- In Fiscal Year 1976 the first Developing Institutions are scheduled for termination of Federal aid with the possible result of financial injury to their livelihood.

- Decisions concerning additional funding for these institutions under the AIDP Program need to be made.

Bureau of Postsecondary Education

- There is increasing pressure to expand Federal student assistance programs which have been targeted at the most needy to include students from middle income families.

- Proper procedures for recognizing and dealing with fraud and abuse in the student assistance programs need to be developed.

- The impact of inflation and the costs of implementing and administering Federally-mandated social programs will increase the pressure for institutional support.

- The interface between State and Federal programs needs to be examined so as to promote better coordination and more closely establish a true partnership relationship.

- Federal support of graduate education should be examined with a view toward increasing participation of minorities and assuring the quality of programs.

- Further progress in the area of civil rights and affirmative action may be achieved only by closely monitoring the problem of reverse discrimination and the enforcement of Title IX.

- Demographics indicate a change in the postsecondary population to smaller numbers of the traditional college-age segment and larger numbers in older-age groups. The needs of this new student population must be assessed and their requirements reflected through appropriate educational offerings.

Bureau of Elementary and Secondary Education

Dissemination of Promising Educational Practices

- Should the Federal Government more adequately support this Federal responsibility for education which during the past two years has made a substantial start and which when viewed as a vehicle for the transfer of productive educational programs as a rule that can be best performed by the Federal Government.

Educational Services to Indochinese Refugee Children

- The issue here is whether the Federal Government will continue support of Indochinese Refugee Children or will now turn the responsibility for their educational support over to the local school districts.

Parenting

- Should the Federal Government add increased support to systematically equipping both adults and adolescents to become better parents and to more directly augment education which takes place in the classrooms.

Continued Support for Strengthening State Departments of Education

- Shall the Federal Government continue support of State Departments of Education in an effort to further strengthen the State jurisdictions so that their active participation in the educational effort will continue to increase and improve.

School Assistance in Federally Affected Areas

- Shall the Administration continue to alleviate the stringent budget circumstances which describe the fiscal plight of local school districts through this legislative vehicle--what shall be the direction for reform and/or modification. Also, what steps shall be taken to reduce the present backlog of needed repair and remodeling of school facilities (present backlog--$434 million; projected backlog by 1978 about $700 million).

Reform of American High Schools

- What measures should be developed at the Federal level to respond to the trend among the States to require measured demonstration of competency in the basic skills and how can we turn active concern toward the problem of reciprocity among the States.

Categorical Grants vs. Consolidated Grants

- Should the Administration pursue the course for the consolidation of programs which presently operate under various legislative authorities and adequately enunciate educational needs as seen from the Federal prospective.

Bureau of Elementary and Secondary Education

School Finance

- What will be the Federal Government's direction to achieve an equitable distribution of educational resources so that no child is penalized for lack of resources; providing a relief on the property tax as a source of educational revenue and increasing to appropriate levels of the Federal share of the total cost of education.

Fundamental Goals in Education

- How will the Administration respond to the growing widespread opinion that increased emphasis should be laid upon the development of basic skills (this term is not yet completely defined).

School Desegregation

- Should the Administration assume a neutral posture or with its influence capitalize upon both past experience and systematic studies to reduce the trauma and conflict which frequently accompany desegregation school activities, also what is the Administration's posture on Metropolitan school desegregation.

Education for the Disadvantaged

- Shall the Federal Government increase its support of this effort so that a greater proportion of eligible children can be adequately served (slightly less than one-half of the eligible population).

Early Childhood Education

- Shall steps be taken to synchronize Early Childhood activities so that they become an integral part of the educational program and can more effectively act as positive change agents in public school curriculum, resulting ultimately in substantial increased programs for the education of children prior to the present entry age of six years.

Bureau of Occupational and Adult Education

- Federal Education and training efforts fragmented among many Federal Agencies.
- Sex Bias and Sex Role Stereotyping in Vocational Education and Employment.
- The low level of educational competency of 23.3 million adults.
- The expiration of the Adult Education Act and need for new comprehensive legislation for adults.
- The stance that should be taken by the Assistant Secretary for Education in the required January 1, 1978 report to Congress on Adult Education.
- The role of USOE in implementing the Vocational Education Amendments of 1976 concerning improved State planning, accountability, sex role stereotyping and evaluation.
- The level of Fiscal Year 1978 budget request for Vocational Education bilingual training.
- The high rate of youth unemployment and the related dirth of vocational education opportunities, especially in large urban centers.
- Introduction of efforts to convert to Metric System is construed as an effort which must start at ground zero.
- A significant number of people believe that Metric Conversion is the concern of technical and scientific persons only.
- It is difficult to impact the general, non-school, adult population. An alternative approach involves developing innovative strategies to motivate the adult learner to seek out instruction through continuing education courses, special programs, and specifically designed workshops at low cost to the Government.

Bureau of Education for the Handicapped

- What implications do the current diversity of State fiscal support systems for special education have for the Federal/State relationship in assuring the provision of a free appropriate public education to all handicapped children as mandated under P.L. 94-142?

- What are the needs for training of teachers and support personnel to implement P.L. 94-142? How will these needs be satisfied?

- What should be done to improve or extend vocational and other secondary education to the handicapped? What should be done to improve job opportunities for the handicapped?

- What are the ways to teach severely and profoundly handicapped individuals more effectively and by doing so to be more successful in maintaining these individuals in their natural environment?

- How can efforts providing programs for very early detection, infant intervention, and parent training, increase the benefits of education for the handicapped?

- Should educational services for preschool handicapped children (0-5 years) be expanded beyond current levels of services?

Bureau of Occupational and Adult Education

- Minimal allocation of program funds can be construed by a lack of commitment on the part of our government to a National Metric Conversion process. Until there is legislation mandating the use of the metric system, with adequate funds allocated to education in the use of the metric system, the general public will continue to believe that the govennment is not fully committed to metric conversion.

- Does the current and projected "general surplus" of educational personnel obviate the need for Federal support for special educational personnel development needs?

- Any serious effort to improve American education through supplemental Federal assistance must re-assess the relative potential of personnel development over the other types of inputs which the Federal Government currently funds.

- The delivery of vocational guidance and counseling services needs to be expanded so that a full range of services and information would be accessible to all individuals.

Education and Training Needs of the Displaced Homemaker

- The Vocational Education Amendments of 1976 include an emphasis on displaced homemakers and unskilled heads of households.

- As males and females increasingly combine the roles of homemaker and wage earner, the need exists for programs to prepare youths and adults for homemaking, parenting and as consumers.

- There is a national need for Consumers' Education.

- If the Consumer Education Program were divorced from the Special Projects where funds are limited to what is available under the "formula" arrangement, it could more adequately meet the mandates of the legislation in supporting continuations beyond one year, thus permitting more effective development, refinement, dissemination, evaluation and assessment.

- While there are many evidences of need for a National Consumers' Education Resource Center, or a system of regional center, it is imperative that already established efforts to establish such systems for dissemination and training be utilized fully.

- There is a need for coordination of Vocational Education and Comprehensive Employment and Training Act (CETA) Programs.

- The future relevance of the Community School movement to all Education Programs.