The original documents are located in Box 16, folder "Health (6)" of the James M. Cannon Files at the Gerald R. Ford Presidential Library.

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July 14, 1976

Dear Tom:

Many thanks for your letter of July 7 restating your telegram to the President on S. 3184. It's great to hear from you, and I'll make sure your views on S. 3184 are carefully considered.

With deep appreciation to you for writing directly to me, and warm regard,

Sincerely,

Nelson A. Roskefeller

Mr. Thomas P. Pike
Chairman
National Council on
Alcoholism
707 Wilshire Boulevard
Suite 3157
Los Angeles, California 90017



MAR/GRA/dlb bcc: Jim Cannon with copy of incoming

976 JUL 19 PM 6 17

THOMAS P. PIKE

707 WILSHIRE BOULEVARD
SUITE 3157
LOS ANGELES, CALIFORNIA 90017

July 7, 1976

The Honorable Nelson A. Rockefeller Vice President of the United States Washington, D.C. 20540

Dear Nelson:

Following is the telegram I have just sent to the President on S. 3184: "Strongly urge you sign into law S. 3184 passed unanimously by the Senate and with only three dissenting votes in the House. Having worked on this vital comprehensive alcoholism legislation since 1969, I was instrumental in prevailing on former President Nixon to sign it as P. L. 91-616 on December 31, 1970, over the veto recommendation of OMB and HEW. Although HEW's NIAAA has made tremendous progress in combatting alcoholism since then, several more years of Federal funding and leadership are desperately needed to consolidate gains and complete the foundations. Katherine and I know this first hand through our continuous involvement as members of HEW's National Advisory Council on Alcoholism since 1970. Mr. President, Katherine and I earnestly bespeak your signature on S. 3184 on behalf of ten million American alcoholics and the forty million members of their families. Warm personal regards."

I'm deeply convinced the country desperately needs a continuance of this alcoholism legislation and a veto seems certain to be overridden by Congress.

I hope that you will make the President aware of my views before he makes his decision and that you will urge him to sign S. 3184.

Since rely.

Chomas P. Pike

Chairman

National Council on Alcoholism

TPP:md



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

JUL 16 1976

Acalth

MEMORANDUM FOR THE HONORABLE JAMES M. CANNON

I am writing in response to your memorandum of June 24 in which you request further information concerning my memorandum of June 18 to the President. As you know, the National Institutes of Health (NIH) released guidelines on June 23 for recombinant deoxyribonucleic acid (DNA) research supported or conducted by NIH. The purpose of the committee I proposed to the President in my memorandum would be to review and coordinate Federal agency policies and actions in this research area in light of the NIH guidelines.

In response to your questions concerning the proposed committee, it is my intent that this committee shall be composed solely of Federal officers and employees representing all departments and agencies which conduct, support, or have possible regulatory authority over the conduct of recombinant DNA research. Such a committee is specifically excluded from the provisions of the Federal Advisory Committee Act. The relevant section of that Act is as follows:

- Sec. 3. For the purpose of this Act-
- (2) The term "advisory committee" means any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof (hereafter in this paragraph referred to as "committee"), which is--
 - (A) established by statute or reorganization plan, or
 - (B) established or utilized by the President, or
 - (C) established or utilized by one or more agencies,

in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal Government, except that such term excludes (i) the Advisory Commission on Intergovernmental Relations, (ii) the Commission on Government Procurement, and (iii) any committee which is composed wholly of full-time officers or employees of the Federal Government. (Emphasis added.)

Thus, the proposed committee, inasmuch as it would be composed solely of Federal officers and employees, would not need to be chartered under this Act.

You also ask how this proposed committee relates to S. 2515, which would modify the present National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In the bill, which recently passed the Senate, there is a provision concerning recombinant DNA research. The Commission is authorized to conduct a study of the ethical, social, legal, and safety implications of recombinant DNA research and devise guidelines, if appropriate. I am enclosing a copy of a letter that I am planning to send to Congressman Harley O. Staggers, Chairman of the Committee on Interstate and Foreign Commerce of the House of Representatives, commenting on the bill. In the letter is outlined the Department's stated opposition to S. 2515, including comments that the study of recombinant DNA research proposed for the Commission would duplicate the efforts of NIH.

In my view, it is most important that we be able to proceed as expeditiously as possible to organize an intergovernmental committee to review the experience of NIH and, where appropriate, make recommendations for the other Federal departments and agencies and possibly for the private sector. Legislative prospects for S. 2515 are uncertain at best. Further, even if the Congress were to pass legislation to create such a Presidential Commission, over the Administration's objections, and it were to become law, there would be certain administrative delays in reorganizing and reconstituting such an entity. And even if the Commission were to undertake such a study, it would still not meet the stated needs of the committee that I am proposing. The committee would have a far broader mandate and a broader representation of interested parties.

I have received a considerable amount of correspondence on this research activity in the past several months. In these letters there has been special emphasis by public commentators on the need for uniformity in the conduct of recombinant DNA research. The committee I propose would be most responsive to this public concern. I strongly urge you to recommend to the President that I be allowed to proceed in this matter without undue delay.

/s/Marjorie Lynch

Auting Secretary .

Enclosure

DRAFT



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

The Honorable Harley O. Staggers Chairman, Committee on Interstate and Foreign Commerce House of Representatives Washington, D.C. 20515

Dear Mr. Chairman:

This is in response to your request for a report on S. 2515, a bill "To amend the Public Health Service Act to establish the President's Commission for the protection of human subjects involved in biomedical and behavioral research, and for other purposes."

In summary, we oppose S. 2515 as passed by the Senate because the existing statutorily established National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research has yet to complete its recommendations. These are to include the development of an effective Federal administrative mechanism for applying its ethical guidelines to research programs conducted or supported by Government departments or agencies, including its definition of the function and authority of the proposed National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research.

We feel that the recommendations of the present National Commission will make an invaluable contribution toward the development of a consistent Government-wide plan for the protection of human subjects of biomedical and behavioral research. Assuming that such an administrative framework will be based on the guidelines currently being recommended to the Department of Health, Education, and Welfare, we favor an Executive Order to extend Departmental regulations on the protection of human subjects uniformly to all other Federal agencies and departments rather than legislative creation of a new Presidential Commission.

S. 2515, as amended, would in effect replace the Commission created in Title II of the National Research Act. The new President's Commission would be permanent and would contain eleven members plus ex officio advisors from the Department of Health, Education, and Welfare, the Department of Defense, the Central Intelligence Agency, the Science Advisor to the President, and the Veterans Administration. The President's Commission would assume the functions, powers, and duties of the current National Commission and expand its jurisdiction to encompass all Federal departments and agencies conducting research involving human subjects.

In addition to the duties prescribed for the National Commission, the President's Commission would be responsible for continually reviewing and analyzing the ethical, social, and legal implications of all research on human subjects supported by the Federal Government, and for making appropriate recommendations concerning the protection of human subjects to the supporting agency. These recommendations would be published in the Federal Register and, if the responsible agency chooses not to follow them, the negative determination and the reasons for it would be published in the Federal Register.

The President's Commission would also be required to study the ethical, social, legal, and safety implications of recombinant DNA research on research personnel, human subjects of the research, and the public at large.

We strongly endorse efforts to protect human subjects of biomedical and behavioral research. However, in addition to establishing a mechanism which we do not believe is necessary, the structure of the proposed commission contains some administrative shortcomings.

First, the President's Commission would be independently advisory to the several Federal agencies and departments, rather than to the Government as a whole. Thus, there would be an opportunity not only for uncoordinated advice but for disparate, inconsistent, and possibly conflicting responses on the part of agencies conducting similar research. Second, the proposed ex officio membership would not represent the extent of biomedical research carried out by other Federal agencies, such as the Energy Research and Development Administration, National Aeronautics and Space Administration, Department of Transportation, or Department of Agriculture. Third, there are no positions or funds authorized to support the activities of the proposed Commission.

One of the recommendations already made by the National Commission for the Protection of Human Subjects is that there be established a national review body to consider ethical problems raised by research proposals whenever the application of recommended standards proves difficult. The Department of Health, Education, and Welfare is establishing an Ethical Advisory Board to provide advice to the Public Health Service and other components of the Department on ethical issues and on classes of applications or proposals which (1) must be submitted to the Board or (2) need not be submitted to the Board (45 CFR 46.204). Creation of the Ethical Advisory Board will create a more flexible instrument for dealing with ethical dilemmas concerning human research subjects than the proposed Presidential Commission.

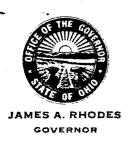
Finally, we are very aware of the controversy over recombinant DNA research and have recently released guidelines according to which support may be given for research conducted by grantees, contractors, and intramural scientists. The National Institutes of Health, Public Health Service, has gone to great lengths to involve the Congress, the public, and the press in the decisionmaking process which has addressed the social, legal, ethical, and safety implications of such research. It has sought and received advice from many sectors—scientists, ethicists, lawyers, and consumer representatives—and has taken all comments into account in preparing the guidelines for this activity. While we do not oppose having the guidelines reviewed by another advisory body, we feel this is already being done under present authority.

We therefore recommend that S. 2515 not be favorably considered at this time, and that any legislative initiatives concerning Federal regulation of research involving human subjects be delayed until the existing National Commission for the Protection of Human Subjects has made its final report and recommendations to the President and the Congress as required by the National Research Act.

We are advised by the Office of Management and Budget that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

Secretary



STATE OF OHIO OFFICE OF THE GOVERNOR COLUMBUS 43215

July 20, 1976

The Honorable David F. Mathews Secretary of Health, Education, and Welfare Washington, D. C. 20201

Dear Secretary Mathews:

Ohio faces a severe financial crisis in its Medicaid program. The severity of this crisis is apparent when you compare the appropriation of \$471 million (state funds plus projected federal earnings) which is available for fiscal year 1977 with the projected expenditures of \$597 million required to support the FY 77 Medicaid program in its present form.

This situation is further compounded by the fact that Ohio is under court order not to reduce the scope of the current program until pre-reduction hearings are provided to eligible recipients.

The projected deficit of \$126 million in the Medicaid program has been the subject of much publicity, legislative committees have examined the program and many medical provider associations have provided suggestions and recommendations. Since the projected deficit includes both state funds and federal earnings, Ohio needs your recommendations as to how this situation might best be resolved. I understand that the federal funds required to support the program are indeed available to Ohio but only if the state certifies that it can provide the necessary state matching funds. Your verification of this requirement would be most helpful,

Without an increase in state matching funds, Ohio cannot continue the existing Medicaid program. The problem becomes critical on November 15, 1976, when the federal estimates for the January-March 1977 quarter are due. Without an increase in state funds prior to this date, Ohio will not be able to certify the availability of sufficient state funds to maintain the Medicaid program for FY 77. It is anticipated that the current appropriation will be exhausted in February 1977 and Ohio will be forced to discontinue the Medicaid program for lack of funds.

I plan to propose a reallocation of state funds that will insure the continuation of Ohio's Medicaid program through fiscal year 1977. Immediate action is necessary if Ohio is to avoid a repeat of the FY 76 crisis when Medicaid funds were exhausted on May 11, 1976. I need your support to reinforce the necessity for a speedy but effective solution to the Medicaid crisis. Attached is a suggested letter for your signature which would accomplish that purpose.



Dack

Secretary David F. Mathews July 20, 1976 Page 2

Also attached is a letter from Clyde V. Downing of the Chicago Regional Office showing that this estimate of the total funds to continue Ohio's Medicaid program for FY 77 is \$540 million. To this estimate must be added the backlog of unpaid FY 76 bills amounting to over \$68 million. This letter will provide assurance that the fund requirements for Ohio's Medicaid program have not been overstated and that additional funds are truly required if the Medicaid program is to continue.

There is also attached a copy of a memo from my Office of Budget and Management attesting to the appropriation of both state funds and federal earnings that is currently available to support Ohio's

FY 77 Medicaid program.

Sincerely

AMES A. RHODES

Governor

JAR:em

Attachments



Draft of a letter from Secretary Mathews to Governor Rhodes:

Dear Governor Rhodes:

Responding to your recent inquiry concerning the requirement for state matching funds in the Medicaid program, I must advise you that the availability of federal funds is dependent upon the assurance from the state that state matching funds are available to support the total program expenditures. Without such assurance there is no legal basis for the provision of federal funds.

I should also point out that Ohio's state plan for the Medicaid program has been accepted and approved as a plan for a continuing program that would operate only for a limited time during a fiscal period dependent upon the availability of funds. The state-federal partnership in the funding of the Medicaid program is based upon the premise that each of the partners will commit the necessary resources to insure continuing operation of the program. Failure of either party to provide such assurance can only serve to negate the concept upon which the federal-state partnership is based.

I would encourage you to do everything within your power to insure that Ohio provides the necessary state matching funds to support the continuation of Ohio's Medicaid program which is so vital to health care needs of Ohio's citizens.

Sincerely,

DAVID F. MATHEWS Secretary





State of Ohio • Office of Budget and Management 30 East Broad Street • Columbus, Ohio 43215

(614) 466-3085

July 20, 1976

MEMORANDUM TO:

FROM:

William W. Wilkins, Director Office of Budget and Management William W. FY 77 Medicaid Am

SUBJECT:

This will certify the amounts appropriated to support Ohio's Medicaid These appropriations include projected Federal matching funds.

From Amended Substitute HB 155 -

\$ 410,631,513

From Amended Substitute HB 1508-

60,000,000 *

Total Appropriation

\$ 470,631,513

* Subject to release by the State Controlling Board

WWW:cb



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

REGION V

CHICAGO, ILLINOIS 60606

SOCIAL & REHABILITATION

June 30, 1976

76 JUL -2 Plaz (

Mr. Kwegyir Aggrey, Director Ohio Department of Public Welfare State Office Tower, 32nd Floor 30 E. Broad Street Columbus, Ohio 43215

Dear Mr. Aggrey:

The Regional Office estimate of total expenditures for the Medicaid Program in Ohio, as requested in your letter of June 17, is \$539,872,000 for the period July 1, 1976 through June 30, 1977, compared to your May 3 estimate of \$536,662,000 for the same period.

This estimate was derived for Federal Budget purposes from historic medical expenditure trends as provided by the State, through its normal statistical and monetary reporting system. It is based on the program continuing in its present form and providing the identical service classifications.

Sincerely,

Clyde V. Downing

Regional Commissioner, SRS

Region V



THE UNDER SECRETARY OF HEALTH, EDUCATION, AND WELFARE WASHINGTON, D.C. 20201

July 21, 1976

MEMORANDUM TO THE HONORABLE JAMES CANNON

Enclosed are the Department's Reports on Major Initiatives which you requested.

Under Secretary

Enclosures

cc: Mr. David Lissy Dr. James Cavanaugh Miss Sarah Massengale

OVERVIEW OF TITLE XX

Title XX of the Social Security Act was a farreaching reform of public social services. The title provided for goal oriented services, allowed the States to determine which services they would provide, and required that States develop an open planning process with citizen participation. The clear intent of the law was to allow States greater flexibility in the planning and delivery of social services.

After the first year of Title XX operation, HEW in connection with States, counties, State legislatures and cities undertook a comprehensive review of Title XX regulations. The purpose of this review was to remove those aspects of the regulations which reduced State flexibility or caused serious administrative problems. These regulations are being revised to the extent possible within the statute to remove these barriers. The President introduced the Community Services Block Grant which would further remove the statutory barriers to State flexibility for public social service programs. A more detailed description of Title XX is attached.

EMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE OFFICE OF THE SECRETARY

: Michael Licata TO

DATE: July 20, 1976

FROM : Glenn Kamber

ORR

SUBJECT: Major Initiatives Report for the Domestic Council

The Secretary has made regulatory reform one of his highest priorities in the Department. In order to coordinate the efforts of the Department in regulatory reform, the Secretary established the Office of Regulatory Review on February 3, The Secretary announced a two-fold objective for regulatory reform in the Department:

- Improve the process by which new regulations, either proposed or final, are developed, cleared and reviewed; and,
- Review existing regulations to recommend which ones can and should be modified, simplified, or eliminated.

To accomplish these two major objectives and to incorporate the Secretary's initiative to open the processes of HEW to more public involvement the following six major activities have been initiated:

- Meetings about the regulations development process to solicit ideas for changes needed in that process have been held with over 150 HEW-related interest groups as well as with all key Department personnel.
- A high-level Departmental Task Force composed of representatives from each agency within the Department was formed to review the regulations development process and presented recommendations for change to the Secretary on April 8, 1976. Included in these recommendations are methods to open the system to more meaningful public involvement, to provide for earlier decision-making by the Secretary and Under Secretary, to assure more timely development of regulations and to formalize the "periodic review" of regulations to evaluate their impact and effectiveness.

- . A Task Force composed of personnel from the <u>Federal</u> <u>Register</u>, SRS, SSA and H, was established in June to recodify the Medicaid regulations (which will include a review of all regulations, guidelines, memoranda and policy letters).
- . A Task Force composed of personnel from the Office of Education will be formed in August to develop regulations for the Higher Education and Vocational Education Acts. The two-fold objective of this OE Task Force is to provide a model for implementing regulations as mandated by the new legislation and to recodify the existing pertinent regulations to produce a unified, consistent and clearly written set of final regulations.
- Training sessions in the regulations process and clear writing of regulations are being conducted within each agency. The goal of these pilot training sessions is to develop a training program which can be applied throughout the Department so that regulations will be written in clear, simple and easily understood manner. Current regulations are often written in legal and program jargon which often cannot be understood by the ordinary citizen. These courses are being developed with the cooperation of Federal Register personnel.
- . A study is underway to investigate how computer technology can be applied to the regulations development process. Included in the study will be the possible uses of computer systems for internal monitoring for the entire development process and for cataloging existing regulations.

Excluding the Food and Drug regulations, HEW regulations currently cover 3,167 pages of the <u>Code</u> of <u>Federal Regulations</u>. Approximately 500 items that must be signed by the Secretary will be sent to the Federal Register this year.

We believe that these activities to reform the regulation process and review existing regulations are positive and constructive responses by the Department to the public as it is affected in the vital areas of service delivery in the numerous areas that are touched upon by policies and programs emanating from the Department of Health, Education and Welfare.

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE SOCIAL AND REHABILITATION SERVICE

Office of the Administrator

TO

Michael J. Licata Executive Secretary to the Department DATE:

July 21, 1976

FROM:

Administrator

Social & Rehabilitation Service

SUBJECT:

Major Initiatives Report

Attached is material pertinent to the Title XX proposals to be used as part of a summary of major initiatives undertaken or completed during the last two years.

Robert Fulton

Attachment

1. Then and now facts

The title XX social services program is the result of a collaborative effort on the part of the Congress, the Department, the State administrators, the National Governors Conference, and numerous organizations concerned with services for children, the aged, the handicapped and other groups. By creating title XX (Public Law 93-647) this coalition resolved an impasse of some 20 months when no one could agree on new regulations for titles IV-A and VI and what direction public social services should take.

Effective October 1, 1975 in the 50 States and the District of Columbia, the title XX program began, providing services for needy families and children (formerly served under title IV-A of the Social Security Act), needy aged, blind and handicapped (previously served under title VI of the Act), and, at State option, intact families, childless couples, and single (not old, not handicapped) persons with incomes not exceeding 115% of the State or national median income as adjusted for family size. Under title IV-A, fees could be charged for child care. Under title XX, fees were mandatory for persons with a gross monthly family income above 80% of the median income and up to 115% of it. But while the universe of population under title XX seemed broader than for the predecessor titles, the focus was still on the poor as shown by the legislation which required that an amount equal to 50% of the Federal contribution be used for service expenditures for recipients of AFDC (title IV-A), SSI (the Supplemental Security Income program under title XVI), and Medicaid.

Gone were the "former" and "potential" recipients of title IV-A and VI and the determination of eligibility on a group basis.

Title XX introduced a new concept of "universal" services - that is two services which a State might provide to anyone without regard to their incomes: information and referral services and services to prevent or remedy abuse, neglect or explaination of children or adults.

The requirement for providing services on a Statewide basis remained; but under title XX, a State could divide itself into geographic areas (encompassing the whole State) and vary services by geographic areas according to the needs of the eligibile persons there and availability of resources.

The same ceiling remained on social services, \$2.5 billion, and the allocation formula was still on the basis of population. However, if States did not certify complete usage of their allocations under title XX, \$15 million of the remainder could be allocated to Puerto Rico and \$500,000 each to the Virgin Islands and Guam for services under title I, IV-A, X, XIV or XVI (AABD). There was no change in the Federal match: 75% for services and administration; 90% for family planning services. States could still receive donations from public or private agencies under the same circumstances to use as the State match, and services could be provided by title XX staff, by referral, or by purchase. As under the previous titles, States with title XX programs may be found out of compliance and be subject to withholding of Federal funds. However, under title XX the

HEW Secretary has the option of withholding 3% of funds otherwise payable to the State for each requirement out of compliance, as well as withholding all funds.

State

The same/organizational unit which operated title IV-A had to operate the program under title IV-B (child welfare services). Likewise, the tifle XX State agency must operate the IV-B program (except in Illinois where there is a separate child welfare services unit).

There were numerous mandatory services under the "old" titles. This concept is vestigial under title XX; three SSI services in each geographic area, family planning services for all AFDC recipients who request them, and at least one service in each geographic area to carry out each of title XX's national gogls. These goals are; self-support, self-sufficiency; services to prevent or remedy abuse, neglect or exploitation of children or adults; reuniting families; deinstitutionalization when appropriate; institutionalization or services within some institutions when necessary. Title XX is completely goal-oriented both in assessing the needs of an applicant and reporting on services given.

Title XX departs radically from the two former programs in that it decentralizes planning out of Washington and places it in the States where the leadership and people are closer together and can presumably better articulate needs and allocate resources. The vehicle for this thrust is the open planning process conducted on a yearly basis. The statute spells out how the State must develop, publish and make generally available a proposed services plan 90 days before the program year begins. Minimally, the State must publish a display advertisement in newspapers covering each geographic area detailed in the plan and provide copies of the plan or a summary of it. A comment period of 45 days follows publication of the ad. States also use public hearings, radio and TV to solicit public input. What the public is commenting on is the contents of the plan: who is eligible for what services in what geographic area; criteria for eligibility; description of each service offered; fee schedule if any; the Federal allotment and how much the State will spend of it, the State contribution (also local and donated); the needs assessment; how evaluation and reporting will be conducted; projected estimates of numbers of persons to be served with what services where; how it will coordinate with other human services programs; how the title XX agency is organized. (Priorntothhe start of the program, SRS issued a Citizens Handbook to explain the program to the public. Many thousands were put into circulation.) When the 45 days are up and comments are analyzed, a final services plan is published (minimally in a display ad in the same newspapers as before) explaining the differences, if any, between the proposed and final plans.

final

There is a procedure for amending the/services plan which is like that for a proposed services plan but has a 30-day comment period.

This kind of open planning permits great flexibility, affords an opportunity for initiative at the grassroots, and is expected to result in programs more nearly meeting the needs of the State's residents.

The title XX agency must also prepare a second plan covering administrative aspects of the program - such as fair hearings, use of Merit System for agency personnel, safeguarding information, standards, etc. This plan must be submitted for approval to SRS. The services plans are reviewed by SRS to see that they montain all the items required by the legislation and regulation, but SRS does not have approval authority.

The Federal role under title XX is to provide technical assistance, monitor and evaluate the program and report to Congresson it.

2. Highlights and key numbers

- Almost \$3 billion was expended for title XX in FY 1976, of which \$2.2 billion, or 75%, was the Federal share.
- Expenditures increased 40% from \$1.6 billion in FY 1974.to \$2.2 billion in FY 1976. Expenditures are projected at \$2.35 billion in FY 1977.
- In FY 1974, expenditures represented 63% of the States' entitlements, increasing to 88% in FY 1976, and estimated at 94% in FY 1977.
- In FY 1974 only 7 States used their full entitlements compared to 21 in FY 1976 and estimated at 34 States in FY 1977.
- Child day care, the largest single service provided accounted for \$546 million, or 25% of the Federal expenditures in FY 1976.
- Expenditures for training and retraining of persons engaged in the delivery of title XX services increased from \$43 million in FY 1974 to \$54 million in FY 1976.

3. Concerns or problems encountered in the title XX program in the last two years (major areas):

a. Making the transition from the two preceding services programs

Setting up and implementing a new planning process on a yearly cycle, educating the public to the new concept and developing methods to obtain public input into the planning;

Converting contracts under the "old" titles to conform to the requirements for purchase of services under title XX;

Setting up information systems for reporting title XX services and expenditures.

b. Determining eligibility

Methods of performing initial determination of eligibility and redetermination, including time periods and availability of FFP; pressure for determining eligibility on a group basis (as had been possible under titles IV-A and VI), especially for senior citizens (legislation constantly being introduced); pressure for considering as one-person families various groups such as youth for certain services (family planning, drug abuse), handicapped youth and adults living with family members; children in foster care. The regulations were amended three times to deal with matters of eligibility.

c. Child Care

Although the Federal Interagency Day Care RequirementsI(FIDCR) had been required under title IV-A, the title XX legislation specified their use and the regulations made it a matter of FFP if States did not adhere to these requirements and additional ones on staffing for children under six years of age in day care outside their homes, required by the regulations. Some States could not meet these standards and legislation was always being introduced to afford some relief to the States. One suspension of the new staffing standards was in effect to the end of January 1976 and another bill has passed the House to continue this suspension and otherwise assist the States in child care matters.

d. Confidentiality

With heavy emphasis on confidentiality of records throughout the nation and a growing fear of the citizenry of centralized government "data banks," much concern has been expressed by services consumers about providing information necessary for acountability of expenditures and demographic knowledge about the program. Service providers are also reluctant to supply such information about the title XX eligibiles they serve with title XX funding. Several suits were brought against the Department and others threatened.

e. Rigidity of the statute

The statute is very specific about details of planning and preparing

and publicizing the proposed and final services plans and specifying time frames in which certain tasks must be accomplished. This lack of flexibility often has jeopardized FFP to the States when a specific procedure or required content of the plan has been inadvertently overlooked. Since the regulations must implement the law, they are often criticized for being "too tight."

In an effort to accommoda te to the realities s of operation of the program, the Department has amended the regulations four times already and is now embarked on a fifth, major, comprehensive amending — all within the first year of the program. The purpose is to simplify the administrative requirements as much as possible and remove to the greatest extent the potential for having to penalize the States financially.

4. Key quotes

a. Senator Walter F. Mondale (D., Minn.) who introduced the "Social Services Amendments of 1974 on behalf of himself and Senators Javitz, Packwood and Bentzen, in the Senate, September 20, 1974:

"This program...provides special help for the elderly and disabled, alcoholism and drug rehabilitation, and a host of other services directed toward preventing welfare dependency, avoiding unnecessary institutionalization, and strengthening family life."

b. Former Secretary of HEW, Caspar W. Weinberger, announcing his support for the bill, October 3, 1974:

"The proposed amendments make the State social services program answerable primarily to the State's citizens, within broad Federal guidelines. I am convinced that this new approach can free us all to concentrate on getting services to people."

c. President Ford on signing the bill, January 4, 1975:

"The provisions concerning the Federal-State partnership program for social services successfully concludes many long months of negotiations among the Congress; the Department of Health, Education, and Welfare; governors; State administrators; and spokesmen for producers and consumers. Ending a long impasse, the efforts of all exemplify my call for communication, cooperation, conciliation and compromise when I assumed the office of President..."

"I am particularly pleased that this legislation follows a desireable trend in Federal-State relations. It will improve the results of programs previously hampered by unrealistic assumptions of Federal review and control. These decisions related to local conditions and needs will be made at the State level, while Federal responsibilities are clearly delineated. Indeed, the interests of not only the Federal and State governments, but also producers and consumers are recognized and protected. I also believe that this new legislation significantly improves program accountability and

focuses on those most in need of services.

"In summary, I regard the social services provisions as a major piece of domestic legislation and a significant step forward in Federal-State relations."

5. Reference to or contact with outside groups

The collaborative effort which resulted in development and enactment of the Social Services Amendments of 1974 (Title XX) has continued. There is constant consultation between the Department (principally through the Social and Rehabilitation Service and its Public Services Administration) on policy development with State administrators, relevant members of Congress, national voluntary advocacy groups, the National Governors Council, NERO, NACO, other parts of HEW and other Federal agencies. The Department meets with these groups, communicates by telephone and mail and solicits input into regulations in the developmental stage and when regulations are issued in proposed form. One of the major coalitions which serves in an advisory capacity is the Human Resources Forum.

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE SOCIAL SECURITY ADMINISTRATION

то

: Executive Secretary to the Department

DATE:

July 20, 1976

REFER TO: IPE-4

FROM : Harris Factor, Director

Executive Secretariat, SSA

SUBJECT: Major Initiatives in Medicare Legislation (Your memorandum of 7/20) -- ACTION

Attached for your use in responding to the request from the Domestic Council for a summary of major initiatives in Medicare legislation is a brief discussion paper on the Administration's proposed Medicare Improvements of 1976.

Harris Factor

Attachment

Report from the Commissioner of Social Security Concerning Major Initiatives in Medicare Legislation

Over the course of the last 2 years the Social Security Administration's major legislative initiatives concerning the Medicare program have been proposals which would: provide protection against catastrophic illness; restructure beneficiary cost sharing; and introduce other features into the Medicare program to help reduce the rate of inflation in medical care costs generally and the corresponding growth in Medicare program expenditures.

The Administration's most recent legislative proposal was submitted to the Congress on February 11, 1976, as the "Medicare Improvements of 1976." The proposal would modify Medicare's cost-sharing structure to provide: (1) unlimited days of covered hospital (except psychiatric hospital) and skilled nursing facility care; (2) a coinsurance equal to 10 percent of all charges above the inpatient hospital deductible amount (currently \$104) for all services covered under Medicare's hospital insurance (part A) program; (3) an increase in the annual deductible amount under Medicare's supplementary medical insurance (part B) program from \$60 to \$77 in 1977; (4) a coinsurance equal to 10 percent of charges above the deductible amount for all hospital-based physicians and part B home health services; and (5) under part A, a maximum cost-sharing liability limit of \$500 per year in 1976 and 1977, and under part B, a maximum cost-sharing liability limit of \$250 in 1977. The part B deductible amount and the cost-sharing liability limits under part A and part B would be increased after 1977 in proportion to increases in social security cash benefits.

The Medicare Improvements of 1976 also contains cost-control provisions under which Medicare would not recognize for reimbursement purposes increases in hospital, skilled nursing facility, or other provider costs of more than 7 percent, or increases in charges for physician's and other part B covered services of more than 4 percent.

In his message transmitting to the Congress several Administration proposals for improvements in programs serving the elderly, the President outlined the purposes of the Medicare proposal as follows:

"There are weaknesses in the Medicare program which must be corrected. Three particular aspects of the current program concern me: 1) its failure to provide our elderly with protection against catastrophic illness costs, 2) the serious effects that health care cost inflation is having on the Medicare program, and 3) lack of incentives to encourage efficient and



economical use of hospital and medical services. My proposal addresses each of these problems.

"In my State of the Union Message I proposed protection against catastrophic health expenditures for Medicare beneficiaries. This will be accomplished in two ways. First, I propose extending Medicare benefits by providing coverage for unlimited days of hospital and skilled nursing facility care for beneficiaries. Second, I propose to limit the out-of-pocket expenses of beneficiaries, for covered services, to \$500 per year for hospital and skilled nursing services and \$250 per year for physician and other non-institutional medical services.

"This will mean that each year over a billion dollars of benefit payments will be targeted for handling the financial burden of prolonged illness. Millions of older persons live in fear of being stricken by an illness that will call for expensive hospital and medical care over a long period of time. Most often they do not have the resources to pay the bills. The members of their families share their fears because they also do not have the resources to pay such large bills. We have been talking about this problem for many years. We have it within our power to act now so that today's older persons will not be forced to live under this kind of a shadow. I urge the Congress to act promptly.

"Added steps are needed to slow down the inflation of health costs and to help in the financing of this catastrophic protection. Therefore, I am recommending that the Congress limit increases in medicare payment rates in 1977 and 1978 to 7% a day for hospitals and 4% for physician services.

"Additional cost-sharing provisions are also needed to encourage economical use of the hospital and medical services included under Medicare. Therefore, I am recommending that patients pay 10% of hospital and nursing home charges after the first day and that the existing deductible for medical services be increased from \$60 to \$77 annually.

"The savings from placing a limit on increases in medicare payment rates and some of the revenue from increased cost sharing will be used to finance the catastrophic illness program.

"I feel that, on balance, these proposals will provide our elder citizens with protection against catastrophic illness costs, promote efficient utilization of services, and moderate the increase in health care costs."

It is estimated that the cost-sharing modifications in the Medicare program would reduce the costs of the program by \$327 million in fiscal year 1977. The cost-control provisions are estimated to reduce Medicare outlays by an additional \$1.2 billion. Together, these provisions would reduce by one-third the projected 23-percent increase in Medicare program outlays in fiscal year 1977 under the provisions of present law.

A number of congressional committees have held hearings on the proposed Medicare Improvements of 1976. However, no committee has acted on this legislation or reported it for consideration by the Senate or the House of Representatives. The Administration is currently reconsidering this legislation with a view toward submitting its recommendations to the 95th Congress.



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE WASHINGTON, D.C. 20201

OFFICE OF THE SECRETARY

July 20, 1976

NOTE TO MICHAEL LICATA

Subject: Major Initiatives Report

In response to your memorandum, attached is the major iniative report on the Health Block Grants.

Ira Goldstein

Attachments

MAJOR INITIATIVES REPORT: HEALTH BLOCK GRANT

1. Then and Now Facts

On February 25, 1976, the President proposed to improve the efficiency and equity of health services to the poor by consolidating sixteen federal health programs, including Medicaid, into one \$10 billion block grant to the States. Every State would receive more in fiscal years 1977, 1978 and 1979 than was received in fiscal year 1976. No State would ever receive less than it did in fiscal year 1976.

2. Highlights and Key Numbers

The President submitted to Congress the Financial Assistance for Health Care Act. Its objectives are to:

- o improve access to quality health care at reasonable costs;
- o achieve, over time, a more equitable distribution of federal health dollars among States in relationship to those persons most in need;
- o increase State and local control over health spending to:
 - a. allow each State to set its own priorities for health programs based on the particular needs of its low-income population and its resources;
 - b. allow each State to integrate its programs into a cohesive total; and
 - increase the States' motivation to control rising health care costs;
- o restrain the growth of federal spending and the federal bureaucracy and reduce red tape.

The proposal includes a requirement for a State-developed "State Health Care Plan." Public participation in the development of the plan is required to ensure that increased State responsibility is coupled with expanded public involvement in the formation of State health policies.

3. Problems Encountered in the Last Two Years

No congressional committee hearings have been held, or likely are to be held, on the bill.

HEW and OMB staff have consulted extensively with representatives of State and local governments. Major issues raised are:

- o Funding levels under the block grant are insufficient.

 Both initial grants and subsequent inflation increments
 are not adequate to maintain existing program levels or
 keep pace with escalating health costs.
- o The allocation formula results in too drastic a redistribution of federal dollars.
- o Will the Federal Government or Congress overlay elaborate regulatory requirements on States in the future? States are concerned that subsequent regulations and standards implementing the consolidation would be exceedingly costly and require large increases in State health expenditures.
- The required State Health Care Plan and the planning process should be the responsibility of State government. Under P.L. 93-641, the National Health Planning Act, States were given regulatory responsibility, but no control over planning for the allocation of State, local and private health resources. The law gave planning to private, non-profit agencies that reported to the Secretary of HEW.
- o Compliance, audit and enforcement procedures should be the responsibility of each State.

4. Key Quotes

From the President's message to Congress, February 25, 1976:

"In the past 10 year period (1965-1975) Federal spending for health has increased from \$5 billion to \$37 billion. With greater Federal funding has come a multitude of Federal programs, regulations and restrictions — all motivated by the best of intentions but each adding to the confusion and overlap and inequity that now characterizes our efforts at the national level.

"The Financial Assistance for Health Care proposal is being submitted after extensive consultation with organizations representing the publicly elected officials who will be responsible for administering the program. I believe this proposal represents a major step toward overcoming some of the most serious defects in our present system of Federal financing of health care.

"My proposal is designed to achieve a more equitable distribution of Federal health dollars among States and to increase State control over health spending. My proposal also recognizes the appropriate Federal role in providing financial assistance to State and local governments to improve the quality and distribution of health services.

"The enactment of this legislation will achieve a more equitable distribution of Federal health dollars by providing funds according to a formula giving primary weight to a State's low-income population. The formula also takes into account the relative tax effort made by a State and the per capita income of that State."

5. Contact with Outside Groups

National Governors' Conference

National Association of County Officials

National Conference of Mayors

National League of Cities

National Conference of State Legislatures



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

OFFICE OF THE SECRETARY WASHINGTON, D.C. 20201

July 20, 1976

To:

Michael Licata

Executive Secretary

From:

Director

Office for Civil Rights

Subject: Major Initiatives Report for Domestic Council on

Section 504 of the Rehabilitation Act of 1973

I. Background and Status

On September 26, 1973, the Rehabilitation Act of 1973 became law. Section 504 of the Act broke new legislative ground in that it was the first major civil rights enactment to protect the rights of the twenty-five million handicapped persons in the United States. This section provides that no qualified handicapped person shall be denied the benefits of or be discriminated against in any federally assisted program or activity. (See Tab A.) In 1974, the definition of handicapped person in the Act was amended so that the protections of section 504 apply to any person who has a physical or mental impairment which substantially limits one or more of that person's major life activities, any person who has a record of such an impairment, and any person who is regarded as having such an impair-Section 504, however, applies only to qualified handicapped persons. Thus, the Act would allow an employer to refuse to hire a blind bus driver but would not allow the automatic disqualification of a blind teaching applicant because of blindness.

On April 28, 1976, President Ford issued Executive Order 11914, which provides for a governmentwide enforcement scheme under which the Secretary of Health, Education, and Welfare is assigned responsibility to coordinate the federal government's implementation of section 504. (See Tab B.) The Secretary is to develop standards for determining who are handicapped persons and guidelines for determining what are discriminatory practices. The executive order also delineates specific enforcement procedures and sanctions for noncompliance, including termination of federal financial assistance.

Responsibility for development and implementation of a section 504 compliance program for HEW was delegated to the Office for Civil Rights. On May 17, 1976, the Department published in the Federal Register a Notice of Intent to Issue Proposed Rules under section 504. (See Tab C.) This notice raised a number of fundamental issues concerning section 504 and sought public comment on these issues before the Department published a notice of proposed rulemaking. The Department received over 400 comments as a result of this notice and, after analyzing them, published in the Federal Register on July 16, 1976, a Notice of Proposed Rulemaking allowing at least 60 days for public comment. (See Tab D.)

II. Highlights and Problems

While section 504 raises a myriad of issues, several are so basic and critical that they should be highlighted: the definition of handicapped person, the elimination of architectural barriers and the provision of services to beneficiaries of federal programs. The phrase "regarded as having such an impairment" in the statutory definition is open-ended and presents a problem of interpretation. This part of the definition recognizes that a person who is not otherwise significantly handicapped may be disdriminated against on the basis of being perceived as handicapped. In this category are included persons who are grossly disfigured, dwarfs and persons who limp.

Architectural barriers exclude handicapped persons from programs and employment opportunities by preventing access to and use of the facilities where such programs are offered. While the intent of section 504 is to prohibit the existence of such barriers, the statute does not address this issue separately and the expense involved in eliminating architectural barriers in existing facilities is consider-The Department's approach to this situation requires that recipients of federal funds devise and implement a plan which will, within three years, ensure that its federally assisted program, when viewed in its entirety, be accessible. This provision would not require that every building or part of every building be made free of architectural obstacles but encourages flexibility and creativity in making sure that no beneficiary is denied access to federal programs because of handicap.

The thrust of section 504 in the provision of education, health and social services is to ensure that handicapped persons receive an equal opportunity to participate in federally assisted services. Thus, providers of services must ensure that notice and information is given to

their beneficiaries in such a manner that it can be understood by handicapped persons with impaired sensory or speaking skills. In the area of elementary and secondary education, the proposed regulation is consistent with numerous recent court decisions and Public Law 94-142, the Education for All Handicapped Children Act of 1975. It requires that a recipient provide as suitable, adequate and free an education to each handicapped person of school age, regardless of the nature or severity of the person's handicap, as it provides to nonhandicapped persons; that the education be provided in the most normal setting feasible; that, before placement of a student in a specialized instruction setting, the student be properly evaluated and given certain due process rights; that no handicapped child be excluded from the educational process on the basis of handicap; and that nonacademic and extra-curricular services and activities be provided in a nondiscriminatory manner.

Several factors contributed to the Department's delay in promulgating proposed rules for section 504. The lack of Congressional guidance on the enactment of the statute has been a persistent problem in formulating proposed rules. Similarly, the amendments to the definition of handicapped person contributed to the difficulty of drafting a regulation for section 504 and added to the delay. Finally, the need to develop an inflationary impact statement, which estimated the regulator's economic costs and benefits, added substantially to the amount of time which it took the Department to prepare proposed rules.

III. Contact with Outside Groups

The Department has involved non-HEW people in a meaningful manner at all stages of development of the proposed rules. Before the publication of the May 17 Notice of Intent, the Office for Civil Rights met with over sixty national organizations, constituent groups and agencies of federal and state governments. The Office has conducted seminars with recipients of federal funds, service organizations and consumer groups and has participated in a number of national conferences. In addition to receiving the comments from the May 17 notice, the Office for Civil Rights held ten seminars across the country to solicit public comment on the issues raised in the May 17 notice. OCR is presently planning to hold town meetings in twenty-two cities across the United States in August and September to generate public interest in and knowledge of section 504 and the Department's responsibility in enforcing section 504.

Martin H. Gerry

Page 4 Mr. Licata

Section 504, Rehabilitation Act of 1973 Tab A:

Tab B:

Executive Order 11914
May 17, 1976 Notice of Intent to Publish Proposed Rules
July 16, 1976, Notice of Proposed Rulemaking Tab C:

Tab D:



Public Law 93-112 93rd Congress, H. R. 8070 September 26, 1973

REHABILITATION ACT OF 1973

NONDISCRIMINATION UNDER FEDERAL GRANTS

Sec. 504. No otherwise qualified handicapped individual in the United States, as defined in section 7(6), shall, solely by reason of his handicap, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.

Sec. 7. For the purposes of this Act:

(6) The term "handicapped individual" means any individual who (A) has a physical or mental disability which for such individual constitutes or results in a substantial handicap to employment and (B) can reasonably be expected to benefit in terms of employability from vocational rehabilitation services provided pursuant to titles I and III of this Act.



Public Law 93-516 93rd Congress, H. R. 17503 December 7, 1974

REHABILITATION ACT AMENDMENTS OF 1974

Sec. 111. (a) Section 7(6) of such Act is amended by adding at the end thereof the following new sentence: "For the purposes of titles IV and V of this Act, such term means any person who (A) has a physical or mental impairment which substantially limits one or more of such person's major life activities, (B) has a record of such an impairment, or (C) is regarded as having such an impairment."

Nondiscrimination With Respect to the Handicapped in Federally Assisted Programs

Executive Order 11914. April 28, 1976

By virtue of the authority vested in me by the Constitution and statutes of the United States of America, including section 301 of title 3 of the United States Code, and as President of the United States, and in order to provide for consistent implementation within the Federal Government of section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), it is hereby ordered as follows:

Section 1. The Secretary of Health, Education, and Welfare shall coordinate the implementation of section 504 of the Rehabilitation Act of 1973, as amended, hereinafter referred to as section 504, by all Federal departments and agencies empowered to extend Federal financial assistance to any program or activity. The Secretary shall establish standards for determining who are handicapped individuals and guidelines for determining what are discriminatory practices, within the meaning of section 504. The Secretary shall assist Federal departments and agencies to coordinate their programs and activities and shall consult with such departments and agencies, as necessary, so that consistent policies, practices, and procedures are adopted with respect to the enforcement of section 504.

SEC. 2. In order to implement the provisions of section 504, each Federal department and agency empowered to provide Federal financial assistance shall issue rules, regulations, and directives, consistent with the standards and procedures established by the Secretary of Health, Education, and Welfare.

SEC. 3. (a) Whenever the appropriate department or agency determines, upon all the information available to it, that any recipient of, or applicant for, Federal financial assistance is in noncompliance with the requirements adopted pursuant to this order, steps to secure voluntary compliance shall be carried out in accordance with standards and procedures established pursuant to this order.

(b) If voluntary compliance cannot be secured by informal means, compliance with section 504 may be effected by the suspension or termination of, or refusal to award or continue, Federal financial assistance or by other appropriate means authorized by law, in accordance with standards and procedures established pursuant to this order.

(c) No such suspension or termination of, or refusal to award or continue, Federal financial assistance shall become effective unless there has been an express finding, after opportunity for a hearing, of a failure by the recipient of, or applicant for, Federal financial assistance to comply with the requirements adopted pursuant to this order; however, such suspension or termination of, or refusal to award or continue, Federal financial assistance shall be limited in its effect to the particular program or activity or part thereof with respect to which there has been such a finding of noncompliance.

SEC. 4. Each Federal department and agency shall furnish the Secretary of Health, Education, and Welfare such reports and information as the Secretary requests and shall cooperate with the Secretary in the implementation of section 504.

SEC. 5. The Secretary of Health, Education, and Welfare may adopt rules and regulations and issue orders which he deems are necessary to carry out his responsibilities under this order. The Secretary shall ensure that such rules, regulations, and orders are not inconsistent with, or duplicative of, other Federal Government policies relating to the handicapped, including those policies adopted in accordance with sections 501, 502, and 503 of the Rehabilitation Act of 1973, as amended, or the Architectural Barriers Act of 1968 (42 U.S.C. 4151 et seq.).

GERALD R. FORD

The White House, April 28, 1976.

[Filed with the Office of the Federal Register, 11:07 a.m., April 28, 1976]

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE OFFICE OF THE SECRETARY

ro : Mr. Michael J. Licata

Executive Secretary to the Department

DATE: July 20, 1976

THROUGH: The Under Secretary

FROM : Director, Office of Investigations

SUBJECT: Major Initiatives Report Re Your Memo of July 20

- 1. Secretary Mathews announced the formation of an independent Office of Investigations reporting directly to the Under Secretary effective November 30, 1975. This unit was to investigate all allegations of criminal fraud and related matters. The new office has no responsibility for physical security, personnel security clearances, or for personnel investigations except as they related to fraud or conflict of interest. On December 28, 1975, the Investigations Branch of the Office of Administrative Appraisal and Planning, Social Security Administration, was transferred to the Office of Investigations.
- 2. Congressional approval to increase the staff of the new Office of Investigations to 74 was obtained. A career appointment of an experienced, professional investigator to the position of Director, Office of Investigations was made April 19, 1976.

In a series of announcements, the Secretary and Under Secretary affirmed their complete support and backing for this office and their intention to see that it was operated in an independent, professional, and non-partison manner. The new Director was directed to open and close investigations on his own authority and to present cases directly to the Department of Justice for prosecution.

Since April 1976, efforts have been under way to select experienced and competent personnel to fill the authorized complement. Personnel are now on board in all ten of the HEW Regional Offices. Twenty-five professional investigators are in the field and at headquarters. Offers are pending to three more investigators and selections are now being processed to fill vacant slots. Cases are being investigated, presented to the Justice Department, and prosecutions are going forward.

Mr. Michael J. Licata -- page 2

Other moves were made to emphasize the Department's interest in the elimination of fraud and abuse. A close rapport was established between the HEW Audit Agency and the Office of Investigations and steps were taken to increase the independence of the Audit Agency. A special Fraud and Abuse Unit for Medicaid was established within the Social and Rehabilitation Service to seek out program areas where potential fraud and program abuse might exist. Teams from this unit have initiated pilot projects in Massachusetts and Ohio to formulate and improve techniques to detect potential fraud and abuse.

John J. Walsh

THE WHITE HOUSE

WASHINGTON

July 27, 1976

MEMORANDUM FOR THE HONORABLE DAVID MATHEWS

SECRETARY OF HEALTH, EDUCATION AND WELFARE

FROM:

JIM CANNO

At the Midwestern Governors Conference yesterday, Governor Rhodes spoke to me about these two matters.

Would you ask someone on your staff to arrange to have an appropriate response sent directly to Governor Rhodes?

Thank you.



THE OHIO STATE UNIVERSITY

July 19, 1976

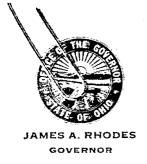
The Honorable James A. Rhodes Governor, State of Ohio Columbus. Ohio 43215

Dear Governor Rhodes:

This is in response to your request for information relating to significant Federal—State actions pending regarding The Ohio State University Comprehensive Cancer Center.

- 1. A Construction Grant for \$3,000,000 in Federal funds to construct a \$4,000,000 Cancer Research Center is being resubmitted to the National Cancer Institute on 1 October 1976. \$1,000,000 of State matching funds are included in the University's 1977-83 Capital Plan submitted to the Board of Regents on July 6, 1976. This reapplication has been discussed with Drs. Rauscher and Fox of the National Cancer Institute.
- 2. On June 28, 1976 The Ohio State University submitted to the National Cancer Institute a Grant Application for \$1,806,138 for the three year April 1, 1977 to March 31, 1980 time period to fund a <u>Developmental Cancer Control Program</u>, for the Ohio Valley Region. (See Attachment 1). This application is under consideration by the National Cancer Institute.
- 3. On January 28, 1975 The Ohio State University submitted to the National Cancer Institute a Grant Application for \$1,055,369 to fund a three year (September 1, 1975 to August 31, 1978) grant entitled "Carcinogenic Mechanisms: In Vitro Studies" (See Attachment 2). This grant application was recommended for approval by the National Cancer Institute staff in the reduced amount of \$596,169 (See Attachment 3). This grant is still pending and funding is dependent upon the availability of funds and project priority.

Your support and interest in the OSU Medical Center, our Comprehensive Cancer Center and the enhancement of our ability to provide better medical



STATE OF OHIO OFFICE OF THE GOVERNOR COLUMBUS 43215

July 20, 1976

The Honorable David F. Mathews Secretary of Health, Education, and Welfare Washington, D. C. 20201



Dear Secretary Mathews:

Ohio faces a severe financial crisis in its Medicaid program. The severity of this crisis is apparent when you compare the appropriation of \$471 million (state funds plus projected federal earnings) which is available for fiscal year 1977 with the projected expenditures of \$597 million required to support the FY 77 Medicaid program in its present form.

This situation is further compounded by the fact that Ohio is under court order not to reduce the scope of the current program until pre-reduction hearings are provided to eligible recipients.

The projected deficit of \$126 million in the Medicaid program has been the subject of much publicity, legislative committees have examined the program and many medical provider associations have provided suggestions and recommendations. Since the projected deficit includes both state funds and federal earnings, Ohio needs your recommendations as to how this situation might best be resolved. I understand that the federal funds required to support the program are indeed available to Ohio but only if the state certifies that it can provide the necessary state matching funds. Your verification of this requirement would be most helpful.

Without an increase in state matching funds, Ohio cannot continue the existing Medicaid program. The problem becomes critical on November 15, 1976, when the federal estimates for the January-March 1977 quarter are due. Without an increase in state funds prior to this date, Ohio will not be able to certify the availability of sufficient state funds to maintain the Medicaid program for FY 77. It is anticipated that the current appropriation will be exhausted in February 1977 and Ohio will be forced to discontinue the Medicaid program for lack of funds.

I plan to propose a reallocation of state funds that will insure the continuation of Ohio's Medicaid program through fiscal year 1977. Immediate action is necessary if Ohio is to avoid a repeat of the FY 76 crisis when Medicaid funds were exhausted on May 11, 1976. I need your support to reinforce the necessity for a speedy but effective solution to the Medicaid crisis. Attached is a suggested letter for your signature which would accomplish that purpose.

Health

THE WHITE HOUSE WASHINGTON

7/27/76

TO: SPENCE JOHNSON

FROM: JIM CANNON

What is the status on this?





Sta Lus

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

OFFICE OF THE SECRETARY

WASHINGTON, D.C. 20201 JUL 16 1976

MEMORANDUM FOR THE HONORABLE JAMES M. CANNON

I am writing in response to your memorandum of June 24 in which you request further information concerning my memorandum of June 18 to the President. As you know, the National Institutes of Health (NIH) released guidelines on June 23 for recombinant deoxyribonucleic acid (DNA) research supported or conducted by NIH. The purpose of the committee I proposed to the President in my memorandum would be to review and coordinate Federal agency policies and actions in this research area in light of the NIH guidelines.

In response to your questions concerning the proposed committee, it is my intent that this committee shall be composed solely of Federal officers and employees representing all departments and agencies which conduct, support, or have possible regulatory authority over the conduct of recombinant DNA research. Such a committee is specifically excluded from the provisions of the Federal Advisory Committee Act. The relevant section of that Act is as follows:

- Sec. 3. For the purpose of this Act-
- (2) The term "advisory committee" means any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof (hereafter in this paragraph referred to as "committee"), which is--
 - (A) established by statute or reorganization
 - (B) established or utilized by the President,
 - (C) established or utilized by one or more agencies,

in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal Government, except that such term excludes (i) the Advisory Commission on Intergovernmental Relations, (ii) the Commission on Government Procurement, and (iii) any committee which is composed wholly of full-time officers or employees of the Federal Government. (Emphasis added.)

Thus, the proposed committee, inasmuch as it would be composed solely of Federal officers and employees, would not need to be chartered under this Act.

You also ask how this proposed committee relates to S. 2515, which would modify the present National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In the bill, which recently passed the Senate, there is a provision concerning recombinant DNA research. The Commission is authorized to conduct a study of the ethical, social, legal, and safety implications of recombinant DNA research and devise guidelines, if appropriate. I am enclosing a copy of a letter that I am planning to send to Congressman Harley O. Staggers, Chairman of the Committee on Interstate and Foreign Commerce of the House of Representatives, commenting on the bill. In the letter is outlined the Department's stated opposition to S. 2515, including comments that the study of recombinant DNA research proposed for the Commission would duplicate the efforts of NIH.

In my view, it is most important that we be able to proceed as expeditiously as possible to organize an intergovernmental committee to review the experience of NIH and, where appropriate, make recommendations for the other Federal departments and agencies and possibly for the private sector. Legislative prospects for S. 2515 are uncertain at best. Further, even if the Congress were to pass legislation to create such a Presidential Commission, over the Administration's objections, and it were to become law, there would be certain administrative delays in reorganizing and reconstituting such an entity. And even if the Commission were to undertake such a study, it would still not meet the stated needs of the committee that I am proposing. The committee would have a far broader mandate and a broader representation of interested parties.

I have received a considerable amount of correspondence on this research activity in the past several months. In these letters there has been special emphasis by public commentators on the need for uniformity in the conduct of recombinant DNA research. The committee I propose would be most responsive to this public concern. I strongly urge you to recommend to the President that I be allowed to proceed in this matter without undue delay.

Marine Lynch

Enclosure

DEPARTMENT OF HEALTH, EDUCATION. AND WELFARE



DRAFT

The Honorable Harley O. Staggers Chairman, Committee on Interstate and Foreign Commerce House of Representatives Washington, D.C. 20515



Dear Mr. Chairman:

This is in response to your request for a report on S. 2515, a bill "To amend the Public Health Service Act to establish the President's Commission for the protection of human subjects involved in biomedical and behavioral research, and for other purposes."

In summary, we oppose S. 2515 as passed by the Senate because the existing statutorily established National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research has yet to complete its recommendations. These are to include the development of an effective Federal administrative mechanism for applying its ethical guidelines to research programs conducted or supported by Government departments or agencies, including its definition of the function and authority of the proposed National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research.

We feel that the recommendations of the present National Commission will make an invaluable contribution toward the development of a consistent Government-wide plan for the protection of human subjects of biomedical and behavioral research. Assuming that such an administrative framework will be based on the guidelines currently being recommended to the Department of Health, Education, and Welfare, we favor an Executive Order to extend Departmental regulations on the protection of human subjects uniformly to all other Federal agencies and departments rather than legislative creation of a new Presidential Commission.

S. 2515, as amended, would in effect replace the Commission created in Title II of the National Research Act. The new President's Commission would be permanent and would contain eleven members plus ex officio advisors from the Department of Health, Education, and Welfare, the Department of Defense, the Central Intelligence Agency, the Science Advisor to the President, and the Veterans Administration. The President's Commission would assume the functions, powers, and duties of the current National Commission and expand its jurisdiction to encompass all Federal departments and agencies conducting research involving human subjects.

In addition to the duties prescribed for the National Commission, the President's Commission would be responsible for continually reviewing and analyzing the ethical, social, and legal implications of all research on human subjects supported by the Federal Government, and for making appropriate recommendations concerning the protection of human subjects to the supporting agency. These recommendations would be published in the Federal Register and, if the responsible agency chooses not to follow them, the negative determination and the reasons for it would be published in the Federal Register.

The President's Commission would also be required to study the ethical, social, legal, and safety implications of recombinant DNA research on research personnel, human subjects of the research, and the public at large.

We strongly endorse efforts to protect human subjects of biomedical and behavioral research. However, in addition to establishing a mechanism which we do not believe is necessary, the structure of the proposed commission contains some administrative shortcomings.

First, the President's Commission would be independently advisory to the several Federal agencies and departments, rather than to the Government as a whole. Thus, there would be an opportunity not only for uncoordinated advice but for disparate, inconsistent, and possibly conflicting responses on the part of agencies conducting similar research. Second, the proposed ex officio membership would not represent the extent of biomedical research carried out by other Federal agencies, such as the Energy Research and Development Administration, National Aeronautics and Space Administration, Department of Transportation, or Department of Agriculture. Third, there are no positions or funds authorized to support the activities of the proposed Commission.

One of the recommendations already made by the National Commission for the Protection of Human Subjects is that there be established a national review body to consider ethical problems raised by research proposals whenever the application of recommended standards proves difficult. The Department of Health, Education, and Welfare is establishing an Ethical Advisory Board to provide advice to the Public Health Service and other components of the Department on ethical issues and on classes of applications or proposals which (1) must be submitted to the Board or (2) need not be submitted to the Board (45 CFR 46.204). Creation of the Ethical Advisory Board will create a more flexible instrument for dealing with ethical dilemmas concerning human research subjects than the proposed Presidential Commission.

Finally, we are very aware of the controversy over recombinant DNA research and have recently released guidelines according to which support may be given for research conducted by grantees, contractors, and intramural scientists. The National Institutes of Health, Public Health Service, has gone to great lengths to involve the Congress, the public, and the press in the decisionmaking process which has addressed the social, legal, ethical, and safety implications of such research. It has sought and received advice from many sectors—scientists, ethicists, lawyers, and consumer representatives—and has taken all comments into account in preparing the guidelines for this activity. While we do not oppose having the guidelines reviewed by another advisory body, we feel this is already being done under present authority.

We therefore recommend that S. 2515 not be favorably considered at this time, and that any legislative initiatives concerning Federal regulation of research involving human subjects be delayed until the existing National Commission for the Protection of Human Subjects has made its final report and recommendations to the President and the Congress as required by the National Research Act.

We are advised by the Office of Management and Budget that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

Secretary

IV/12/16/5743) PANAS

THE WHITE HOUSE

WASHINGTON

July 30, 1976

MEMORANDUM FOR:

JIM CANNON

FROM:

SPENCE JOHNSON

SUBJECT:

Invitation to the President to address American Hospital Association convention

to be held September 20 - 23.

This would be an excellent opportunity for the President to make a major health policy statement in the Fall. This will be the largest health conference with nationwide representation between Labor Day and the election. I would strongly recommend that if the President is going to make a major health address, this forum be used.

THE WHITE HOUSE WASHINGTON

Kald Andrewson C.

RECEIVED P. 7 21976 DENTRAL FILE

THE WHITE HOUSE

WASHINGTON

July 22, 1976

MEMORANDUM FOR:

JIM CANNON

FROM:

WILLIAM NICHOLSON W W N

SUBJECT:

Invitation to the President to address American Hospital Association convention to be held September 20-23 in Dallas

I would appreciate your comments and recommendation on the attached invitation to the President.

Thank you.

COMMENTS:

IN/1976/5743 | Dallas

July 22, 1976

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FROM:

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SUBJECT:

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I would appreciate your comments and recommendation on the attached invitation to the President.

Thank you.

COMMENTS:



RECEIVED

JUL 2 3 1976

CENTRAL FILES

July 19, 1976

Dear Mr. McMahon:

On behalf of the President, I wish to acknowledge and to thank you for the letter you addressed to him on June 30 in which you invited him to appear before the American Hospital Association convention in Dallas on Monday September 20 or on Thursday, September 23.

We are carrying this invitation forward for consideration as the President's calendar for this time frame is under advisement and we will be back in touch with you as soon as it is possible to give you a more definite answer.

In the meantime, please be assured of the President's appreciation for your thoughtfulness and his warm, good wishes.

Sincerely,

William W. Nicholson Director Scheduling Office

Mr. J. Alexander McMahon President * American Hospital Association 840 North Lake Shore Drive Chicago, Illinois 60611

cc/w incmg to M. Widner for Sept. 20 xxxxx follow_up cc: two opies to nancy Gemmell

JUL 2 0 1976
CENTRAL FLES



American Hospital Association

J. ALEXANDER McMAHON
President

June 30, 1976

My dear Mr. President

A recent Gallup Poll indicated that the American public considers the issue of health care one of the highest priorities that the federal government can address. Therefore, it is appropriate and it is with pleasure that the \$40 billion hospital industry offers you a forum before our Association convention in Dallas, September 20-23, 1976.

The American Hospital Association represents most of the nation's 7,000 hospitals who are providing inpatient and outpatient care for approximately 150 million people this year.

Other U.S. Presidents, including your predecessor, have used this industry's rostrum to discuss health and related issues. More than 14,000 delegates, who represent three million hospital employees, are expected at Dallas for this annual conference which will be heavily covered by the national media, as well as the health care press. These delegates, and the hospital industry, would be most anxious to hear how you perceive the issue of health care in the next four years.

We would be pleased to have you speak either to our plenary session on Monday, September 20, or the plenary session on Thursday, September 23. These sessions will be of equal length, and we are also offering Mr. Carter the same opportunity to speak at one of these sessions.

So that the necessary arrangements can be made, may I hear from you as soon as possible.

Sincerely yours

J. Alexander McMahon

cc: Mrs. Mary Louise Smith Chairman National Republican Party

President Gerald R. Ford The White House Washington, DC 20500 THE WHITE HOUSE

July 30, 1976

MEMORANDUM FOR:

JIM CANNON

FROM:

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SUBJECT:

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Thank you.

COMMENTS:

RANGUERAN DE BARAN

cc: Art Quern

Staffed out by comp.

THE WHITE HOUSE

WASHINGTON

August 5, 1976

H. E. J.)

ADMINISTRATIVELY CONFIDENTIAL



ME MORANDUM FOR:

JIM CANNON

FROM:

JIM CONNORS JEE.

The attached articles were returned in the President's outbox with the following notation:

"Good P.R."

Please follow-up with appropriate action.

cc: Dick Cheney

The Atlanta Lournal Covers Dixie Like the Dew

Since 1883

James M. Cox, Chairman 1939-1957-James M. Cox Jr., Chairman 1957-1974

Jack Tarver, Publisher

Jack Spalding, Editor

14-A ****

JULY 26, 1976

Worth Trying

THE INDIANAPOLIS STAR

Where the Spirit of the Lord is, there is Liberty
II Corinthians 3:17

EUGENE C. PULLIAM—1889-1975

Publisher 1944-1975

EUGENE S. PULLIAM, Publisher

"Let the people know the facts and the country will be saved."—Abraham Lincoln

Asking The People

THE DALLAS TIMES HERALD EDITORIALS

Regulations reform

2-C*** Tuesday, July 27, 1976.

Page A4—Austin, Texas Tuesday, July 27, 1976

Jim Fain, Publisher; Ray Mariotti, Editor; Bill Meroney,

Jim Fain, Publisher; Ray Mariotti, Editor; Bill Meroney, General Manager; Bob Easter, Circulation Director; Tim Brown, Systems Director; Everett Bushell, Advertising Director; George W. Spaulding, Classified Manager.

Public agency



"Oklahoma's Greatest Newspaper" EUGENE LORTON 1869-1949

Poge 8-A

Monday, July 26, 1976

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WALTER BISCUP, Editor of Editorial Page
ALEX ADWAN, Associate Editor

SID STEEN, Executive Editor PHIL DESSAUER, Associate Editor TRAVIS WALSH, Managing Editor

BIBLE THOUGHT

Always and for everything giving thanks.—Eph. 5:20.

Welfare Goes Public

THE DAILY OKLAHOMAN

E. K. GAYLORD (1873-1974)

Published Every Morning by The Oklahoma Publishing Co., 500 N. Broadway Post Office Box 25125. Oklahoma City 73125 Telephone (405) 232-3311

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10

Wednesday, July 28, 1976



. S. Fowler 45-7263

The Tuscaloosa News **EDITORIALS** and COMMENTS

News Staff Writer This page contains opinions and comments. Editorials in the lefthand column express The News' viewpoints. Other items which appear are expressions of those whose name appears and may, or may not,

Stevenson

reflect The News' opinions. Comments on subjects of general public interest from readers are accepted All letters must be signed, home address given, and conform to published standards limiting length to 300 Monday, July 26, 1976 3

words, be in good taste and reason. THE EDITORS.

It appears the U.S. Department of Health, Education and Welfare has ended up with egg on its bureaucratic face once too often and HEW Secretary

The state of the s

San Francisco Chronicle

Founded 1865 by Charles and M. H. de Young George T. Cameron, Publisher 1925-55

> Charles de Young Thieriot Editor and Publisher

Gordon Pates Managing Editor Richard Thieriot Associate Editor

Templeton Peck Editorial Page Editor

Editorials

Public Input
To HEW Rules

22-A MORNING ADVOCATE, Baton Rouge, La., Wed., July 28, 1976

Editorial

Taking Bureaucracy Out of the Vacuum Herbert S. Fowler, 245-7263

The Tuscaloosa News-

EDITORIALS and **COMMENTS**

This page contains opinions and comments. Editorials in the lefthand column express The News' viewpoints. Other items which appear are expressions of those whose name appears and may, or may not, reflect The News' opinions. Comments on subjects of general public interest from readers are accepted. All letters must be signed, home address given, and conform to published standards limiting length to 300 words, be in good laste and reason. THE EDITORS. 1111 v 25 1076

HEW Secretary Mathews is to be commended for his revamp efforts

EDITORIALS

HEW Reform of Regulations Is Good News for the Public

The Miami Merald

ALVAH H. CHAPMAN, Jr., President DON-SHOEMAKER, Editor . BEVERLY R. CARTER, Gen. Mgr. JOHN S. KNIGHT, Editor Emeritus CEORGE BEEBE, Associate Publisher

JOHN D. PENNEKAMP, Associate Editor

LARRY JINKS, Executive Editor RON MARTIN, Monaging Editor Sunday, July 25,

3-E

Daily Record Morristown, N.J. July 27, 1976

Our Opinion

HEW Reforms

Do you believe in the HEW? That is do you

A Good Idea

Airlymond Times-Dispatch

LEARD, Executive Editor ALF Goodproontz, Managing Edibb ALAN S. DONNAHOR, President and Associate Publisher DAVED TENNANT BRYAN, Chairman and Publisher EDWARD GRIMSLEY, Editor of the Editorial Page MOHN E

Monday, July 28, 1976

Wash. Post July 27, 1976, EDIT. HEW and Rulemania

The Washington Star

JOE L. ALLERITTON, Publisher

JAMES G. BELLOWS LEditor

SIDNEY EPSTEIN, Managing Editor

EDWIN M. YODER JR., Associate Editor

FRIDAY, JULY 23, 1976

HEW: Regulating the regulators

A'le HEW

THE WHITE HOUSE

WASHINGTON

August 12, 1976

MEMORANDUM FOR:

SECRETARY DAVID MATHEWS

FROM:

JIM CANNON

I am writing in response to your memoranda of July 16 and June 18 in which you propose to create an interagency committee to review and coordinate Federal agency policies and actions in DNA research supported or conducted by NIH in light of the recent NIH guidelines.

Since you would have the authority to establish the committee without the President's approval, according to the General Counsel of HEW, we have no objection and feel the decision is best made by you.

If you decide to create such a committee and feel that a letter from the President to the heads of departments and agencies urging their cooperation would be useful, please send me a draft letter.



Office of the White House Press Secretary

THE WHITE HOUSE

STATEMENT BY THE PRESIDENT

I have been following with great concern the investigations into the cause of the tragic outbreak of illness in Pennsylvania this past week. All Americans join me, I am sure, in their sympathy for the families of the more than 20 people who have died and their hope for the speedy recovery of those people currently under treatment.

I am greatly relieved that these tragic deaths were not the result of swine flu. But let us remember one thing: they could have been. The threat of swine flu outbreak this year is still very genuine. Data from the scientific community still clearly supports the need for a full-scale inoculation program. Clinical tests conducted to date clearly demonstrate that the vaccine is both safe and effective. There is no excuse to let the legislative program that I proposed seven weeks ago — a program that could safeguard the lives of many, many Americans — be delayed any longer.

Health, Education, and Welfare Secretary Mathews and the leaders of Congress reported to me on Wednesday that after long hours of hearings, discussions, and negotiations, Congress finally would act yesterday to pass legislation to provide swine flu vaccine to all the American people. Needless to say, I was keenly disappointed to learn last evening that the news from the doctors in Pennsylvania has led to another slowdown in the Congress.

I am frankly dumbfounded that Congress, which took the time and effort to enact ill-advised legislation to exempt its own Members from State income taxes, has failed to act to protect 215 million Americans from the threat of swine flu. Drug manufacturers have produced over 100 million doses of swine flu vaccine in bulk form, but the vaccine has not been prepared in suitable dosage form, pending action by the Congress.

Because of these legislative delays, we are, at this moment, at least six weeks away from beginning an effective inoculation program. Had Congress acted promotly after I submitted my proposal, we would have been in a position to dispatch shipments of vaccine today.

As President, I cannot accept any further dilly-dallying by the Congress on this legislation that could be vital to the health and safety of our people.

I call on the Congress to act quickly -- before its next recess -- so that the health of the American people will be fully protected.

#



THE WHITE HOUSE WASHINGTON

August 27, 1976

MEMORANDUM FOR:

DICK CHENEY

THRU:

JACK MARSH

FROM:

MAX FRIEDERSDORF ##. /2.

Press inquiries have been received from Nick Thimmesch and John Lofton regarding the administration's position on the amendment to the Labor/HEW appropriations bill banning the use of federal funds for abortions.

As you know, the Hyde amendment passed the House and is in disagreement with the Senate version.

The inquiries from Lofton to me came in the form of a letter which I have merely acknowledge.

Thimmesch's questions came after I retured his fifth phone call this afternoon with the concurrence of Jack Marsh who anticipated what the question might be.

Thimmesch said that Carter has taken a position in support of the Hyde amendment which, of course, if inconsistent with other Carter statements and the Democratic platform.

At the time of the floor consideration of the Hyde amendment Hyde requested our position and I ran the amendment through the system here at the White House but we never took a formal position.

I recommend this issue be analyzed by Jim Cavanaugh and Mike Duval because I am sure we can anticipate further press inquiries because of the strong focus on the Congressional legislation.

Ron Nessen cc: Jim Cavanaugh Mike Duval Jim Cannon



Rile

THE WHITE HOUSE Who Comest, 2 Asus now? Donester Couval? or others?