The original documents are located in Box 16, folder "Health (9)" of the James M. Cannon Files at the Gerald R. Ford Presidential Library.

THE WHITE HOUSE
WASHINGTON

DATE: 9/23

TO: Spence

FROM: ALLEN MOORE

SUBJECT:

ACTION:

FYI: Jive Seen

Share w/ Art as appropriate

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

SEP 22 1976

MEMORANDUM FOR THE HONORABLE JAMES CANNON

SUBJECT: Prospective Report

In accordance with your request, the following information is hereby submitted.

Potential Policy Matters

The Administrator of the Social and Rehabilitation Service will release a report on the review of the Cuban Refugee Program. The report will recommend that the Cuban Refugee Program be phased out within five years.

The Office for Civil Rights annual operating plan for Fiscal Year 1977 is scheduled to be published for public comment in the Federal Register. The plan sets forth the nature of civil rights investigative activity the Office will undertake in FY 77. Major emphasis is placed on investigating complaints and reducing the backlog of complaints of discrimination in the education area.

The National Institute of Environmental Health Sciences will hold a meeting September 23, in conjunction with the Environmental Protection Agency on the subject of Mothers' Milk. The meeting has been called because of the discovery of PCB's, a cancer-causing chemical, in mothers' milk.

Major Announcements

The Office of Education will announce the award of $2.1 million in grants and contracts for instruction projects within the United States for conversion to the metric measurement system.

Assistant Secretary Virginia Y. Trotter is attending a follow-up conference to the International Women's Year Conference held in Mexico City in 1975. The purpose of the meeting is to review the progress made toward achieving the goals of the World Plan of Action accepted in Mexico City.

The Office of Education will announce the award of $3.9 million to 42 Universities in 25 states to provide assistance to specialists in area studies and foreign languages.

Major Speeches

Numerous requests have been received from the TV networks for the appearance of Secretary Mathews or Dr. Theodore Cooper for October 1. The topic would be swine flu.

On September 22, Secretary Mathews will speak to the American Hospital Association at their meeting in Dallas, Texas.

Attached at Tab A are a listing of the Secretary's, Under Secretary's and a Departmental speaking schedule. The Under Secretary's speeches remain tentative due to her recent illness.

Major Testimonies

Commissioner of Social Security, James Cardwell, will testify before the House Ways and Means subcommittee on Legislative Oversight (Vanik) on September 23. The topic will be the committee's SSI Study Group Report.

On September 29, Dr. Arthur Flemming will testify before the Senate Special Committee on Aging (Church) concerning legal services for the elderly.

On September 30, Secretary Mathews will testify before the House Select Committee on Aging Subcommittee on Health and Long-term Care on regulatory reform.

See Tab B for additional items and future testimonies.

Critical State Issues

An update of critical state issues is included at Tab D.

Marjorie Lynch
Under Secretary

cc: James H. Cavanaugh
David Lissy

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

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/s/Marjorie Lynch

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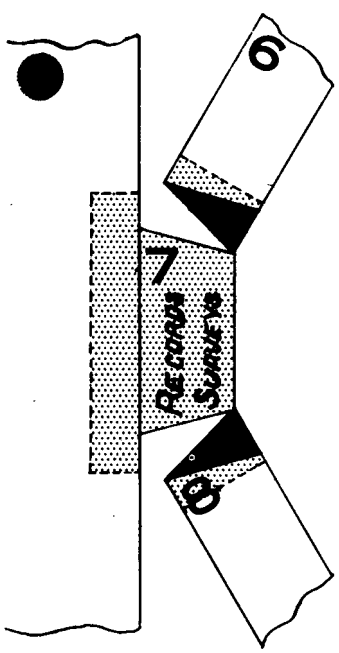

TABBED SEPARATOR SHEET
Form HEW-69D
(3-56)

September 17, 1976

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

94th Congress - 2nd Session

HEARINGS

COMMITTEE		DATE	WITNESS
Subcommittee on Oversight & Investigations (Moss) House Interstate & Foreign Commerce Committee	Cancer in Bell, W. Va. (Oversight)	9/20/76	Dr. Finklea Mr. Wagoner
Subcommittee on Health & Environment (Rogers) House Interstate & Foreign Commerce Committee	H.R. 15536, Medicaid Fraud	9/22/76	Mr. Morrill
Subcommittee on Health (Kennedy) Senate Labor & Public Welfare Committee	DNA Guidelines	9/22/76	Secretary Invited
" "	Management of Polio Vaccine	9/23/76	Dr. Dickson, Sencer & Schmidt
Subcommittee on Legislative Oversight (Vanik) House Ways & Means Committee	Committee's SSI Study Group Report	9/23/76	Mr. Cardwell
Subcommittee on Health & Environment (Rogers) House Interstate & Foreign Commerce Committee	H.R. 15543, S. 2515, Protection of Human Subjects	9/27 or 9/28/76	Not Yet Selected
Subcommittee on Alcoholism & Narcotics (Hathaway) Senate Labor & Public Welfare Committee	Women & Alcoholism	9/29/76	No Formal Request
Senate Special Committee on Aging (Church)	Legal Services for the Elderly	9/29/76	Dr. Flemming
Subcommittee on Health & Long-Term Care (Pepper) House Select Committee on Aging	Regulatory Reform	9/30/76	Secretary
House Select Committee on Narcotic Abuse & Control (Woolf)	HEW Drug Activities (Oversight)	9/30/76	Drs. Cooper & DuPont Mr. Haislip, Ms. Nowus
Senate Special Committee on Aging(Church)	Medicine & the Elderly	10/13/76	Dr. Butler

POSSIBLE HEARINGS

COMMITTEE	SUBJECT	DATE	WITNESS
Subcommittee on Oversight & Investigation (Moss) House Interstate & Foreign Commerce Committee	Utilization Review	Possible	No Formal Request
Subcommittee on Legislative Oversight (Vanik) House Ways & Means Committee	End Stage Renal Dialysis Regulations (Oversight)	Possible September	No Formal Request
Subcommittee on Health (Talmadge) Senate Finance Committee	EPSDT Program	Possible	No Formal Request
House Interstate & Foreign Commerce Committee (Staggers)	S. 2069, Consumer Redress (Senate Passed 8/4/76)	Possible	No Formal Request
Permanent Subcommittee on Investigations (Jackson) Senate Government Operations Committee	Medicaid Fraud	Possible	Secretary Requested
" "	Hearing Aids	Possible	No Formal Request
Subcommittee on Constitutional Rights (Tunney) Senate Judiciary Committee	Privacy of Drug Treatment	Possible	No Formal Request
" "	Rights of Prisoners	Possible	No Formal Request
Subcommittee on Alcoholism & Narcotics (Hathaway) Senate Labor & Public Welfare Committee	Domestic Council Report on Drug Abuse	Possible	No Formal Request

POSSIBLE HEARINGS (Continued)

COMMITTEE	SUBJECT	DATE	WITNESS
Subcommittee on Select Education (Brademas) House Education & Labor Committee	Rehabilitation Research	Possible	No Formal Request
Subcommittee on Health & Environment (Rogers) House Interstate & Foreign Commerce Committee	NIH (Oversight)	Possible	No Formal Request
Subcommittee on Administrative Practices & Procedures (Kennedy) Senate Judicial Committee	Freedom of Information: Agencies' Inability to Cover Costs for Pharmaceutical Requests	Possible	No Formal Request
Subcommittee on Public Assistance (Corman) House Ways & Means Committee	Welfare Reform	Possible	No Formal Request
House Agriculture Committee (Foley)	Labeling of Fats & Oils	Possible	No Formal Request
Subcommittee on Health (Kennedy) Senate Labor & Public Welfare Committee	S. 2696, S. 2697, FDA Reorganization	Possible	Drs. Cooper & Schmidt

EXECUTIVE SESSION

COMMITTEE	SUBJECT	DATE
Senate Finance Committee (Long)	H.R. 13272, AFDC-Reform (House Passed 5/19/76)	Week of 9/20/76
Subcommittee to Investigate Juvenile Delinquency (Bayh) Senate Judiciary Committee	S. 3411, Narcotic Sentencing & Seizure Act	Unknown
Senate Government Operations Committee (Ribicoff)	H.R. 14451, Federal Surplus Property (House Passed 8/24/76)	9/22/76
Subcommittee on Higher Education (O'Hara) House Education & Labor Committee	H.R. 14818, S. 972, Scholarships to Dependents of Public Safety Officers (Senate Passed 7/20/76)	Unknown
Subcommittee on Social Security (Burke) House Ways & Means Committee	H.R. 14429, SSA Totalization Agreements	Unknown
" "	Social Security Decoupling	Unknown
House Rules Committee (Madden)	H.R. 12048, Congressional Veto of Regulations (Judiciary Filed Report 4/8/76)	Unknown
Senate Labor & Public Welfare Committee (Williams)	S. 1325, Drug Compendium	Unknown
Subcommittee on Health & Environment (Rogers) House Interstate & Foreign Commerce Committee	H.R. 14289, FDA Amendments	Unknown
" "	H.R. 15346, Diabetes	Unknown

EXECUTIVE SESSIONS (Continued)

COMMITTEE	SUBJECT	DATE
Senate Labor & Public Welfare Committee (Williams)	S. 1282, National Center for Clinical Pharmacology	Unknown
	S. 2910, Diabetes	Unknown
Subcommittee on Health (Rostenkowski) House Ways & Means Committee	H.R. 12082, Medicare Catastrophic Health Insurance	Unknown
Subcommittee on Reports, Accounting & Management (Metcalf) Senate Government Operations Committee	S. 2947, Federal Advisory Committee Amendments (OMB Lead Agency)	Unknown
Subcommittee on Health (Kennedy) Senate Labor & Public Welfare Committee	S. 118, S. 215, S. 482, Medical Malpractice Insurance	Unknown
Subcommittee on Indian Affairs (Abourezk) Senate Interior & Insular Affairs Committee	S. 2801, Siletz Restoration (Interior Lead Agency)	Unknown

EXECUTIVE SESSIONS (Continued)

COMMITTEE	SUBJECT	DATE
House Interstate & Foreign Commerce Committee (Staggers)	H.R. 15187, PHS Personnel	Unknown
Subcommittee on Health (Kennedy) Senate Labor & Public Welfare Committee	S. 2902, National Health Research & Development (Cigarette Tax)	Unknown
Subcommittee on Health & Environment (Rogers) House Interstate & Foreign Commerce Committee	S. 963, Prohibition of DES	Unknown
" "	H.R. 12082, Medicare Catastrophic Health Insurance	Unknown
Subcommittee on Immigration & Naturalization (Eastland) Senate Judiciary Committee	S. 3074, Illegal Aliens (Justice Lead Agency)	Unknown
Subcommittee on Dairy & Poultry (Jones) House Agriculture Committee	H.R. 397, H.R. 1321, H.R. 1342, H.R. 2722, H.R. 4692, H.R. 10742, Inspection & Labeling of Imported Dairy Products	Unknown
Subcommittee on Public Assistance (Corman) House Ways & Means Committee	Title IV - D Child Support	Unknown
" "		
Subcommittee on Health (Talmadge) Senate Finance Committee	S. 3205, Medicare-Medicaid Reform	Unknown
Subcommittee on Consumer Protection & Finance (Murphy) House Interstate & Foreign Commerce Committee	H.R. 882, H.R. 884 Prescription Drug Labeling	Unknown
Senate Judiciary Committee (Eastland)	S. 1289, Open Communications Act (OMB Lead Agency)	Unknown

BILLS ORDERED REPORTED

COMMITTEE	SUBJECT	DATE
Senate Finance Committee (Long)	H.R. 12961, Consent to Suit Under Medicaid S.3801, Medicare-Medicaid Fraud	9/14/76
Senate Labor & Public Welfare Committee (Williams)	H.R. 10760, Black Lung	9/14/76
House Government Operations Committee (Brook)	H.R. 15390, Inspector General	9/14/76

FLOOR ACTION

HOUSE	DATE
H.R. 13502, Restricted Payments (AFDC)	Unknown
H.R. 5970, Emergency Health Insurance (S. 625)	Unknown
H.R. 8713, Illegal Aliens (Justice Lead Agency)	Unknown
S. 522, Indian Health (Senate Amended 9/9/76)	Unknown
H.R. 14319, Clinical Laboratories	Unknown
Conference Report on H.R.9019, HMO Amendments	

SENATE	
S. 422, Youth Camp Safety (House Passed H.R. 46, 4/17/75)	Unknown
S. 625, Health Insurance for Unemployed	Unknown
S. 2925, Zero Based Budget	Unknown
Conference Report on H.R. 12838, Arts & Humanities (Museums) (To be Filed)	Unknown
Conference Report on S. 3159, Toxic Substances	Unknown

BILLS IN CONFERENCE

SUBJECT	DATE
H.R. 5546, Health Manpower (Senate Acts First)	Unknown
H.R. 7575 (S. 200), Consumer Advocacy (Not Yet Requested) (OMB Lead Agency)	Possible September
S. 2657, Education Amendments (Senate Acts First)	Current
S. 2548, EMS & Burn Center (Not Yet Requested)	Unknown

ENROLLED BILLS

SUBJECT	LAST DAY FOR ACTION
H.R. 5465, Indian Health Employees	8/24/76
H.R. 10612, Tax Reform	Not Yet Received
H.R. 14232 Labor -HEW Appropriations	

NOMINATIONS

COMMITTEE	
Senate Labor & Public Welfare Committee (Williams)	Bertha Adkins, Mrs. John William Deverau, John Martin, Harry Holland, and Nat T. Winston, Jr. were nominated on 1/26/76 to be Members of the Federal Council on Aging.
Senate Finance Committee	Susan B. Gordon was nominated on 8/23/76 to be Assistant Secretary for Public Affairs.

B

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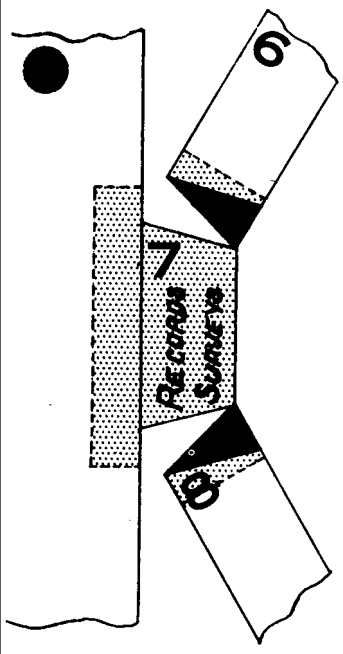


TABBED SEPARATOR SHEET
Form HEW-69D
(3-56)

September 15, 1976

SECRETARY MATHEWS' SPEECH ACCEPTANCES

DATE/TIME	EVENT	LOCATION
9/15	University of Texas, Conference on Social Policy	Austin, Texas
9/16	White House Conference on Handicapped, Industry Labor Council, first meeting	Washington, D. C. (South Portal)
9/16 Evening	NIH-Medical Society of D. C. Banquet	Washington, D.C.
9/21 Evening	National Conference on Education and Citizenship	Kansas City, Mo.
9/22	American Hospital Association	Dallas, Texas
9/23, 10:30 A.M.	106th Graduation Exercises of FBI National Academy	Quantico, Va.
9/25, Noon	College of Arts and Sciences, University of Alabama	University
9/26 2:00	Tuscaloosa Community Bicentennial Ceremony (Stillman College)	Tuscaloosa, Ala.
9/27	Lamar Society	Houston, Texas
9/29 10:30 A.M.	Distributive Education Clubs of America, Grand Opening National Center	Reston, Virginia
10/5 11:00-2:00	Laird Youth Leadership Foundation, University of Wisconsin	Stevens Point, Ws.
10/14 9:10 A.M.	National Conference - Hypertension in the Work Setting	Washington, D. C. (Washington Hilton
10/18	North Carolina State University, Inauguration of Dr. Joab Thomas	Raleigh, N. C.
10/26 2:30 P.M.	Texas Tech University-Inauguration of Cecil Mackey	Lubbock, Texas
10/27, A.M.	University of Southern California, Conference on Human Services	Los Angeles, Cal.

PREPARED BY SPEAKERS BUREAU 57548

AS OF August 30, 1976

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SPEECH SCHEDULE FOR UNDER SECRETARY MARJORIE LYNCH

Type Forum/Event	Issue/Subject	Time/Date Location	Size	Probable Media Covera
LONDON TRIP CANCELLED SPEECH IN DUBLIN - Dr. Richard L. Masland, Executive Director of the Commission for the Control of Epilepsy and It's Consequences will speak for Mrs. Lynch				
Washington State Day	Tentative - Due to ML Surgery	9/14/76 Wash., D.C.		
President's Executive Interchange Program	Individual vs. Government Responsibility for Social Progress	3:45p.m. 9/16/76 Wash., D.C.	William Morrill, P&E scheduled to speak for M.L.	
AMA Auxiliary State Legislative Chairman	How to be effective in the legislative & political field	6:00 p.m. 9/20/76 Wash., D.C.	60	~~local paper~~ cancelled
COSMOS - National Hispanic Symposium on Human Services	Bloc Grants	Noon - 9/23/76 Los Angeles, Calif.	500	~~Political~~ Bill Morri
California Asso. for Health Care Services at Home	Speech	9:30a.m. - 9/24/76 San Francisco, CA	175	Bob Fulton
Blue Shield	Speech	10/5/76 - Chicago	450	
American Academy of Pediatrics	Speech	9:00 a.m. - 10/19/76 Chicago, Illi	500	
Nat'l Asso. for Retarded Citizens	Keynote speaker	10/19/76 Indianapolis, Ind.	2000	cancelled
~~Wisconsin Psychiatric Asso.~~	Speech 10/22-23 Milwaukee, Wisc.		300	Bob Fulton
American Health Care Asso.		Noon - 10/28/76 Orlando, Florida	1000	cancelled
Ohio Uni., College of Osteopathic Medicine	Health	3:30p - 10/29/76 Athens, Ohio	300+	

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

SPEECH SCHEDULE FOR UNDER SECRETARY MARJORIE LYNCH

Type Forum/Event	Issue/Subject	Time/Date Location	Size	Probable Media C
American Public Welfare Regional Conference	Future Trends in Social Welfare	Noon - 11/10/76 Seattle, Wash.	600	
American Society of Allied Health Professions	Issues and Development in the Health Care field	11:00a - 11/18/76	500	
Public Relations Society of America (PRSA), San Francisco, Sacto and Peninsula Cahpters, and San Francisco Publicity Club		Noon - 11/18/76 San Francisco, CA.	80+	
County Supervisors Association		Noon - 11/19/76 San Diego, Calif.	1200	

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Speaking and Travel Engagements

September 1 - October 31, 1976

REGION I--BOSTON

SEPTEMBER

5	Cooper, T. OS	Boston	Speech--Opening session of First International Congress on Cell Biology.
15-17	Young, J. OS	Boston	Symposium on the Future of County Government--panel participant.
23	Fulton, R. SRS	Waltham, Mass.	Title XX Conference at Brandeis University.

OCTOBER

10	Pierce, W. OE	Cambridge, Mass.	Speech--International Management Training for Educational Change
11	Cooper, T. OS	Hartford, Conn.	Participate in panel on National Health Insurance at meeting of Association of Life Insurance Medical Directors of America.
21-22 (tentative)	Thomas, S. OS	Boston	National hearing on Recreation for the Handicapped.
28 (tentative)	Fulton, R. SRS	Hartford, Conn.	Speech--Horizons for Connecticut Older Americans.

REGION II--NEW YORK

SEPTEMBER

13	Cooper, T. OS	Cold Spring Harbor, N.Y.	Speech--Banquet sponsored by Cold Spring Harbor Laboratory and Harvard School of Public Hea

Prepared by
Office of Public Affairs 8-31-76

NEW YORK (Cont'd.)

OCTOBER

12	Trotter, V. OS	New York City	Remarks at SSA sponsored National Essay Contest for high school students.
14	Endicott, K. HRA	New York City	Address New York Academy of Medicine
27	Endicott, K. HRA	Cherry Hill, N.J.	American College of Osteopathic Internists--36th annual convention and scientific session
29	Endicott, K. HRA	New York City	Macy Foundation Residency Training meeting.

REGION III--PHILADELPHIA

SEPTEMBER

1	Hellman, L. HSA	Airlie, Va.	Speech--Interhemispheric Conferen on Adolescent Fertility.
8	Trotter, V. OE	Wash., D.C.	Series of meetings with representatives of the four major Art Education Associations.
13	Mathews, D. Secretary	Wash., D.C.	Conference for Journalists on the Aged in America--breakfast session.
13	Cardwell, J. SSA	Wash., D.C.	Speech--Conference for Journalist on the Aged in America
13	Morrill, W. OS	Wash., D.C.	Brookings Institution
14	Mathews, D. Secretary	Wash., D.C.	Speech--National Advisory Council on Minorities in Engineering.
14	Taft, W. OS	Gettysburg, Pa.	Speech--National Institute of Public Affairs
16	Mathews, D. Secretary	Wash., D.C.	White House Conference on Handicapped, Industry Labor Council--first meeting.

PHILADELPHIA (Cont'd.)

SEPTEMBER

16-18	Fulton, R. SRS	Belmont, Md.	Regional Commissioner's Retreat Executive Staff.
20	Knauer, V. OS	Wash., D.C.	Brand Names Foundation.
21	Hellman, L. HSA	Wash., D.C.	Speech--American College of Obstetrics and Gynecology
23	Mathews, D. Secretary	Quantico, Va.	106th Graduation Exercises of FBI National Academy.
23	Morrill, W. OS	Wash., D.C.	Brookings Institution Speech--National Health Insurance
24	Cooper, T. OS	Bethesda, Md.	Meeting on Hypertension sponsored by National Heart, Lung and Blood Institute.
27	Knauer, V. OS	Wash., D.C.	Speech--First annual American International Automotive Congress
27	Knauer, V. OS	Wash., D.C.	Speech--International Oil Industr

OCTOBER

5	Fulton, R. SRS	Harrisburg, Pa.	National Welfare Fraud Associatic annual conference.
6	Cardwell, J. SSA	Wash., D.C.	National Council of Social Security Management Association-speech.
13	Young, J. OS	Silver Spring, Md.	Speech--Association of Governmen Accountants.
13-14	Pierce, W. OE	Wilmington, Delaware	Participating in conference sponsored by 7001 Ltd.
16-17	Cooper, T. OS	Wash., D.C.	Meeting with Board of Governors, American Red Cross.

REGION IV--ATLANTA

SEPTEMBER

17	Thomas, S. OS	Miami Beach, Florida	Annual Conference--Florida Association for Retarded Citizens.
20	Morrill, W. OS	Biloxi, Miss.	Keynote speaker--62nd Annual Convention--International Assn. of Industrial Accident Boards and Commissions.
20	Thomas, S. OS	Hollywood, Fla.	Speech--National Conference of the National Rehabilitation Assn.
20	Hellman, L. HSA	Atlanta, Ga.	Association of State and Territorial Health Officers.
25	Mathews, D. Secretary	University, Alabama	Speech--College of Arts and Sciences, University of Alabama.
26	Mathews, D. Secretary	Tuscaloosa, Alabama	Tuscaloosa Community Bicentennial Ceremony (Stillman College)

OCTOBER

6	Knauer, V. OS	Columbia, S.C.	Speech before a Business-Consumer Relations Seminar (sponsored by Dept. of Commerce)
13	Knauer, V. OS	Atlanta, Ga.	Receiving Federal Person of the Year Award (National Association Mutual Insurance Agency).
18	Mathews, D. Secretary	Raleigh, N.C.	N.C. State University, Inauguration of Dr. Joab Thomas.

REGION V--CHICAGO

SEPTEMBER

8	Endicott, K. HRA	Chicago	Coordinating Council on Medical Education.
10	Mathews, D. Secretary	Columbus, Ohio	Ohio State University--Cornerston laying activities for new Medical Clinical Education Facility.

CHICAGO (Cont'd.)

SEPTEMBER

15	Fulton, R. SRS	St. Paul, Minnesota	Panelist--Central States Regional Meeting--American Public Welfare Association.
15	Fulton, R. SRS	St. Paul, Minnesota	Meeting with physicians at Hennepin County Department of Health and Social Services.
18	Cooper, T. OS	Chicago	Meeting with Board of Trustees--American College of Cardiology
28	Thomas, S. OS	Chicago	Regional Office Management Conference.
28	Knauer, V. OS	Chicago	Speech--W.E. Long Company, Independent Bakers Cooperative.
30	Fulton, R. SRS	Chicago	Meeting with State Welfare Administrators and Regional Offic Personnel

OCTOBER

1	Fulton, R. SRS	Chicago	CSA Conference at Conrad Hilton Hotel.
5	Mathews, D. Secretary	Stevens Point, Wisconsin	Laird Youth Leadership Foundation, Univ. of Wisconsin
8	Fulton, R. SRS	East Lansing, Michigan	Annual Convocation speaker for College of Osteopathic Medicine; receiving College's Patenge Award
9	Endicott, K. HRA	Detroit, Michigan	Speech--American Writers Assn.
12	Endicott, K. HRA	Chicago	1976 Clinical Congress of the American College of Surgeons.
15	Schmidt, A. FDA	Chicago	Speech--Chicago Gynecological Society.

REGION VI--DALLAS

SEPTEMBER

9	Mathews, D. Secretary	Oklahoma City, Oklahoma	President's Committee on Urban Development and Neighborhood Revitalization.
15	Mathews, D. Secretary	Austin, Texas	Meeting on Social Policy, University of Texas
15	Isbister, J. ADAMHA	New Orleans, La.	Speech--Alcohol and Drug Problems Association--Annual meeting.
27	Mathews, D. Secretary	Houston, Texas	Lamar Society.

OCTOBER

12	Cooper, T. OS	Houston, Texas	Speech and receiving the 1976 Achievement Award of the National Association for Hospital Development.

REGION VII--KANSAS CITY

SEPTEMBER

20	Trotter, V. OE	Kansas City, Mo.	Conference on Education and Citizenship.
20-23	Pierce, W. OE	Kansas City, Mo.	Conference on Education and Citizenship.
21	Mathews, D. Secretary	Kansas City, Mo.	Conference on Education and Citizenship
23-24	Young, J. OS	St. Louis, Mo.	Attending Intergovernmental Financial Management Conference.
30	Knauer, V. OS	Kansas City, Mo.	Missouri Optometric Association

OCTOBER

11	Trotter, V. OE	Kansas City, Mo.	Speech--American Home Economics Regional Association

REGION VIII--DENVER

SEPTEMBER

24	Fulton, R. SRS	Denver, Colorado	Regional Office visit.

OCTOBER -- none

REGION IX--SAN FRANCISCO

SEPTEMBER

22	Fulton, R. SRS	Los Angeles, Calif.	Hispanic Conference on Health and Human Services.
24	Pierce, W. OE	San Francisco, Calif.	Keynote speech--Convocation for Community College Centers' Faculty Members.
24	Isbister, J. ADAMHA	Los Angeles, Calif.	National Hispanic Symposium on Human Services.
27	Endicott, K. HRA	Los Angeles, Calif.	Speech--Conference on Statewide Coordination and Planning for Allied Health Manpower

OCTOBER

15	Knauer, V. OS	San Diego, Calif.	San Diego Community College and the San Diego Gas and Electric Co.
27	Fulton, R. SRS	Los Angeles, Calif.	Attending Social Policy Workshops--University of Southern California.

REGION X--SEATTLE

SEPTEMBER

1-2	Endicott, K. HRA	Fairbanks, Alaska	University of Alaska
7	Endicott, K. HRA	Pullman, Washington	Washington State University.

SEATTLE (Cont'd.)

SEPTEMBER

8	Endicott, K. HRA	Forest Grove, Oregon	Pacific University
8 (p.m.)	Endicott, K. HRA	Portland, Oregon	University of Oregon Health Science Center.
9	Endicott, K. HRA	Seattle, Washington	University of Washington.
12-15	Hellman, L. HSA	Alaska	Barrow Service Unit--participant.
27	Thomas, S. OS	Seattle	Regional Office Management Conference.

MISCELLANEOUS

SEPTEMBER

9-10	Fredrikson, D. NIH	Canada	Medical Research Council
14-22	Cooper, T. OS	Germany, Yugoslavia, and Poland	Meeting re. U.S.-German Agreement for Cooperation in Biomedical and Technical Research; protocol visit to Yugoslavia and Poland.
23	Fredrikson, D. NIH	Hamburg, Germany	Conferring with top German scientists regarding signing of U.S.-German health agreement.
26 - Oct. 1	Cooper, T. OS	Mexico City, Mexico	Directing Council--Pan American Health Organization. (PAHO).

OCTOBER

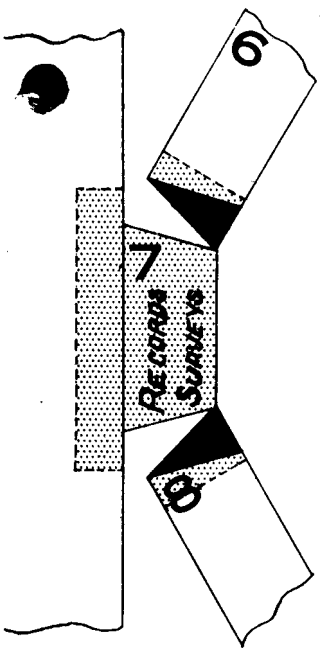
18	Cooper, T. OS	Paradise Island, Nassau	Speech--International Claim Association.
23-30	Cooper, T. OS	Windsor Ontario, Canada	Canadian-American Seminar.
24	Schmidt, A. FDA	Japan	Speech--Seminar on Safety of Food and Drugs.
25 - Nov. 3	Trotter, V. OS	Kenya	Attend as the U.S. Delegate to the UNESCO General Conference.

HOW TO USE
THESE SEPARATORS

Use one page for each separation.

Select appropriate tab, add further identification if desired, and cover it with scotch tape.

Cut off and discard all tabs except the one covered by tape.



TABBED SEPARATOR SHEET
Form HEW-69D
(3-56)

STATE: California DATE: September 16, 1976

ISSUE:

State Moves to Close San Francisco Nursing Home

BACKGROUND:

In May 1976, the Post Street Convalescent Hospital in San Francisco, the largest nursing facility in California, was officially notified by the State Health Department that prior operational deficiencies had been cleared up and that they were now in the top ten percent in terms of quality of services provided. In a sudden shift, the hospital was notified by the Health Department on September 13 that a demand for closure had been filed after a three week investigation allegedly uncovered two major and 80 less serious violations. About 350 of the 400 patients in the hospital are covered by Medi-Cal. As of this date, HEW has not been notified officially by the State of its intended action although the situation has received considerable press attention. The State, in fact, has refused to answer informal inquiries regarding the situation made by members of the Regional Office of Long Term Care. This is a particularly sensitive issue since the Long Term Care staff feels that the State's charges against the hospital may not have a basis in fact since it had concurred in the earlier finding of satisfactory performance.

ACTION TAKEN OR PENDING:

The Regional Office will continue to investigate the background surrounding this issue.

STATE: California DATE; September 16, 1976

ISSUE:

California Reaction to H.R. 8911

BACKGROUND:

California officials have expressed concern over H.R. 8911 (Supplemental Security Income Amendments of 1976), a bill which just passed the House of Representatives, because of its possible cost to the State. Section 10 requires States to pass along to SSI recipients all future cost-of-living increases and reportedly affords protection against increased costs only to "hold harmless" States. California has lost its "hold harmless" designation and officials are afraid the State's unprotected costs will rise. The bill still must pass the Senate, however, and its final version will likely be quite different.

ACTION TAKEN OR PENDING:

None.

STATE: Colorado DATE: September 13, 1976

ISSUE:

Reimbursement for In-patient Hospital Care -

BACKGROUND:

Colorado's approved Title XIX (Medicaid) State Plan provides for the establishment with each provider for in-patient services of a prospective reimbursement rate. Such a rate, according to the Plan, is negotiated with each provider on an annual basis.

It was learned that in December 1975, all Title XIX providers of in-patient services were informed that no further rate negotiations would take place, and that the rates would be "frozen" at the level that prevailed at that time.

After initial notification to the State by SRS in January 1976, that their December 1975 action raised questions as to compliance with Federal Title XIX requirements on reasonable cost reimbursement for in-patient care as well as with the provisions of their approved State Plan, protracted negotiations have been taking place with the State to resolve the compliance issue.

In the meantime, the Colorado Hospital Association, representing the Title XIX providers of in-patient services in Colorado, brought suit against the State in Federal court.

While some efforts have been undertaken by the State to resolve the compliance matter, such as securing a higher appropriation from the 1976 State Legislature and in requesting audited cost data from the hospitals, no new rates have yet been fully negotiated.

The SRS Regional Office has concluded at this time that the State has not acted in good faith and have not taken necessary steps to comply with Federal reasonable cost requirements and their own State Plan commitment. In addition, the Colorado Hospital Association vs State of Colorado suit is beginning hearings, and the court has raised question on whether or not DHEW should not be made a party to the suit because of its responsibility to enforce its program regulations.

ACTION TAKEN OR PENDING:

SRS Region VIII has submitted a recommendation to the Administrator that a compliance hearing be conducted on the matter. We are awaiting the decision on the recommendation. In the meantime, continued discussions are being held with the State with a view to having them come into compliance. If

necessary steps are fully taken by the State to comply with applicable Federal requirements, the recommendation will be withdrawn. It appears, however, that this will not happen immediately because of the hearings on the Colorado Hospital Association suit.

STATE: Guam DATE: September 16, 1976

ISSUE:

Medical Personnel Shortage

BACKGROUND:

Guam's approximate population of 100,000 has experienced for some time a shortage of medical personnel, especially nurses. This situation was created due to the low pay scale existing in Gaum. The Guam Department of Health employed and has positions for 35 nurses. Due to the low pay, all but 5 nurses have left for other positions, some now working for the Guam school system. This sudden critical shortage of nurses seriously jeopardizes programs such as Family Planning. Health services provided by these nurses to village health centers have come to a stand still as well. In addition, a critical shortage of physicians is also a possibility because of recent successful malpractice suits. Malpractice suits on Guam were rare previous to this time. The effect of such suits are that increasing number of physicains will also leave the island.

ACTION TAKEN OR PENDING:

The Regional Office's Public Health Service will be sending a staff member to Guam to consult with the Director of Health and Social Services in order to ameliorate the current situation as well as to develop long range solutions.

STATE: Illinois DATE: September 16, 1976

ISSUE:

Leonard Schaffer, the Director of the Illinois Bureau of the Budget, told regional Social and Rehabilitation Service (SRS) staff that he intends to contact Secretary Mathews, the Administrator of SRS, Robert Fulton, and if need be, members of his congressional delegation, over a dispute involving a deferral of $54 million to the State for purchase of mental health services.

BACKGROUND:

Last April, SRS deferred $54 million in claims by the Illinois Department of Public Aid (IDPA) for the purchase of mental health services from January 1, 1975 to September 30, 1975, because the money was spent on programs not covered in an agreement between IDPA and SRS for ineligible recipients.

ACTION TAKEN OR PENDING:

SRS staff has been negotiating with IDPA on this matter since last April, and has now given the State 15 days from September 9 to produce valid documentation that would substantiate the State's claim to the funds.

STATE: Illinois DATE: September 16, 1976

ISSUE:

(Update. See July 29 Report for full background)

The U.S. Department of Housing and Urban Development (HUD) has asked the Law Judge in the HEW-Chicago School Board Title VI case to cut off $6 million in federal funds to the Board because of the alleged Civil Rights violations.

BACKGROUND:

At the hearing on September 8, HUD made the request of Law Judge, Everett Hammarstrom. The $6 million, which is given through the Model Cities program, and which HUD administers, is used for services to six inner-city schools and various special reading and early childhood education programs. The Office for Civil Rights (OCR) has rejected a School Board plan limiting the number of teachers of any race to 70 percent in each school. The District has suggested a 70-30 ratio. OCR has said it would accept a plan where no more than 60 percent of a school's faculty would be of any one race.

ACTION TAKEN OR PENDING:

Judge Hammarstrom set a new trial date of October 13 because of HUD's entry into the case.

STATE: Ohio DATE: September 16, 1976

ISSUE:

(Update. See August 12, 1976 report for complete background.)

The Ohio Welfare Department recently notified Aid to Dependent Children recipients that their assistance checks would be cut by 12 percent beginning October 1. The step was taken, according to the Director of the Welfare Department, Kwegyir Aggrey, because the legislature failed to find extra funds needed to meet an anticipated Medicaid shortage.

BACKGROUND:

Aggrey has also stated that the move was made in order to keep from closing down the Medicaid program entirely. The Medicaid deficit has been estimated to be $120 million in fiscal 1976 and another $80 million in fiscal 1977. Medicaid recipients will also be asked to pay for a portion of their services as another method to cut the deficit.

ACTION TAKEN OR PENDING:

The Democratic members of the State legislature are said to have a plan, which they feel, will meet the Medicaid problem and help increase efficiency within the Department. That plan was to be acted on sometime this month.

STATE: New York DATE: September 16, 1976

ISSUE:

Medicaid Program

BACKGROUND:

The credibility of the Medicaid program in New York State is suffering greatly because of the lack of effective action against abusers as well as the less than effective administration of the program by State and local Departments of Social Services and Health. Clearly, a strong corrective action plan must be formulated and implemented.

Both administrative and fraud and abuse problems in the New York State Medicaid program are long-standing. SRS, Regional Audit Agency, Regional Task Force findings, Special State Prosecutors, U.S. Attorney prosecutions and the recent Moss Subcommittee hearings have highlighted the failures and faults of the system.

ACTION TAKEN OR PENDING:

A minimum of two kinds of action are now required. One deals with fraud and abuse which the state is now developing (and implementing); the other, with the need for effectuating administrative systems and mechanisms to prevent and minimize the possibility of fraud and abuse from occurring. This latter issue is being addressed by the Regional Director, the SRS Administrator, and the SRS Acting Commissioner at a meeting on September 16 in Washington.

STATE: Pennsylvania DATE: September 16, 1976

ISSUE:

Cancer Drug Laetrile and the Pennsylvania Legislature

BACKGROUND:

On Tuesday, September 14, the Health and Welfare Committee of the Pennsylvania House of Representatives held a legislative discussion on the controversial cancer drug, Laetrile. The Department was represented by the Office of the Regional Director and a spokesman from FDA, Rockville. We were also able to provide a spokesman from the National Cancer Institute. The discussion was taped for education T.V. and covered by a local commercial T.V. station.

A national lobby has established itself to promote "freedom of choice" in the use of cancer drugs. The Legislative Committee was presented with a sophisticated film advocating Laetrile as a miracle treatment. The FDA representative was well able to counter the advocate arguments with the following basic points:

. Laetrile has been well tested and has demonstrated no positive effects in the treatment of cancer; and

. Laetrile proponents, by advocating against accepted medical and surgical procedures, actually endanger the life of cancer patients. Follow up meetings between the Committee Leadership and FDA representatives will be held in FDA national offices.

The problem for the Legislature is the effectiveness of the emotional arguments presented by Laetrile advocates, the persuasiveness of the "right to choose" position, and the political pressure that can be easily developed.

ACTION TAKEN OR PENDING:

The Regional Director projects that the effectiveness of the FDA's presentation and subsequent follow up will result in a Committee decision against the bill in Pennsylvania and recommends that the Department be alert to early efforts by Laetrile advocates in other Legislatures if we are to prevent a "snow balling" pressure to legalize this "drug".

STATE: Washington DATE: September 16, 1976

ISSUE:

Seattle School District Noncompliance with Emergency School Aid Act

BACKGROUND:

Please note the previous discussions of this issue in the Weekly Reports dated May 19 and 28 and June 4,10, and 17.

Two issues remain unresolved in the Seattle School District's application for Emergency School Aid Act (ESAA) funding: (1) Maintenance of effort and (2) implementation of the desegregation plan. Resolution of these issues is critical since the end of the fiscal year is approaching within two weeks.

It should be noted that Secretary Mathews signed waivers this week on the two issues that earlier had garnered widespread and intense community and Congressional interest: (1) reassignment of certificated staff to assure desegregation and (2) the provision of educational services to limited-English-speaking students.

ACTION TAKEN OR PENDING:

In a letter to the Regional Director dated September 15, 1976, the Superintendent of Seattle Schools stated that the District (1) is working vigorously to provide the necessary data on the maintenance of effort issue and (2) has committed full staff resources to work with Regional HEW officials to resolve the areas of disagreement in the desegregation implementation plan. He made the commitments despite the need to divert staff resources to end the school teachers' strike which has delayed the opening of Seattle's schools.

Meetings are under way between the District and HEW--both the Office of Education and the Office of Civil Rights--to resolve both issues.

STATE: Wisconsin DATE: September 16, 1976

ISSUE:

State management of the $410 million Medical Assistance (Medicaid) program in Wisconsin is seriously inadequate, and administrative negligence has increased State costs by millions of dollars, according to a report by the Wisconsin Legislative Audit Bureau.

BACKGROUND:

The Bureau undertook a survey of Medicaid administration eight months ago at the request of Lt. Governor Martin Schreiber. The report states that the State Department of Health and Social Services, which administers the Medicaid program, lacks sufficient control over such basic elements as the formula for nursing home reimbursement and fee schedules for certain health services. Because of errors, the Health and Social Services Agency has not collected more than $600,000 in federal funds for the administration of the program since it began in 1966, the report said.

ACTION TAKEN OR PENDING:

The Wisconsin Secretary of Health and Social Services has said that his department agrees with most of the findings and has already initiated policy changes to correct or improve management of the program.

H&W

THE WHITE HOUSE

WASHINGTON

DECISION
Last Day: September 29, 1976

September 28, 1976

MEMORANDUM FOR THE PRESIDENT

FROM: JIM CANNON

SUBJECT: Enrolled Bill H.R. 14232 - Departments of Labor and Health, Education and Welfare and Related Agencies Appropriation Act, 1977

Attached for your decision is H.R. 14232 which appropriates for the Departments of Labor and Health, Education and Welfare, the Community Services Administration, the Corporation for Public Broadcasting, and ACTION, $56,381,379,575 for fiscal year 1977 and advance funding of $116,628,000 for fiscal year 1978 and $120,200,000 for fiscal year 1979.

Background

Approved by a vote of 279-100 in the House and a voice vote in the Senate, the enrolled bill provides a total net increase of $3.988 billion above your budget request, including:

-- $3.921 billion in FY 1977
-- $37 million in FY 1978
-- $30 million in FY 1979

These changes increase spending by:

-- $1.684 billion in FY 1977
-- $1.780 billion in FY 1978

(The detailed budgetary programmatic impact is analyzed in Jim Lynn's Enrolled Bill Memorandum in Tab A.)

Also, Section 209 of the Enrolled Bill limits the financing of abortion under the Medicaid program to instances "where the life of the mother would be endangered if the fetus were carried to term."

Staff and Agency Recommendations

DOL	Approval
Hartmann	Approval. "This was carefully designed to force a Presidential veto of every holy 'compassion' program, and then override it. Hold your nose and sign it."
HEW	Disapproval
OMB	Disapproval
Buchen (Kilberg)	Disapproval. "Veto statement should not mention Hyde Amendment."
Seidman	Disapproval
Friedersdorf	Disapproval. "Veto likely cannot be sustained, however, because of extreme budget impact, I recommend veto."
Jeanne Holm	Disapproval. "I concur with the recommendation of OMB and with the proposed statement for the President. I note that in the latter, there is no mention of the limitations that this bill would impose on the use of HEW funds for abortion. I fully agree with this."

Recommendation

I concur with the recommendation of HEW, OMB, and the White House Staff that you veto H.R. 14232 because of the substantial adverse impact of nearly $4 billion in appropriations above your budget request.

Decision

1. _____ Sign H.R. 14232. (Tab B)

2. _____ Veto H.R. 14232. (Veto statement at Tab C; approved by Doug Smith.)

file

THE WHITE HOUSE

WASHINGTON

September 29, 1976

MEMORANDUM FOR: BRENT SCOWCROFT

FROM: JIM CANNON

SUBJECT: Congressional Inquiries Concerning CIA Involvement in Genetics Research

This memorandum is to bring to your attention inquiries from the Senate Health Subcommittee concerning CIA involvement in genetics research.

BACKGROUND

On June 23 the National Institutes of Health (NIH) released guidelines for the conduct of research involving the creation of new forms of life used in studying genetics (recombinant deoxyribonucleic acid (DNA) experiments). The guidelines establish carefully controlled conditions for experiments in which foreign genes are inserted into microorganisms, such as bacteria. The objective of the guidelines is the containment of these possibly dangerous organisms while permitting research of great potential benefit to mankind.

To assure coordination and compliance of federal agencies with the guidelines, the Secretary of HEW has formed an interagency committee. A memorandum was sent on September 22 from the President to all heads of departments and agencies requesting their cooperation with this committee (attached at Tab A).

On September 22 the Senate Health Subcommittee under the direction of its Chairman, Senator Edward M. Kennedy, conducted oversight hearings on Federal actions in this research area. The focus of the Senate hearings was on (1) the extension of the NIH guidelines to all Government agencies conducting or supporting such research and (2) the adoption of these guidelines by private industry so engaged. Dr. Donald S. Fredrickson, Director of the NIH, who appeared on behalf of the Administration, was questioned closely about the extent of this research conducted or supported by other relevant Federal agencies and about agency compliance with the guidelines. Senator Richard S. Schweiker asked to what extent the Central Intelligence Agency (CIA) is involved in the research and

what indication, if any, it has given toward compliance with the guidelines.

In response to Senator Schweiker's question, Dr. Fredrickson testified that he personally is unaware of any CIA involvement in this research, but that he has not consulted the CIA on this matter. He also told Senator Schweiker that his concerns about potential CIA involvement would be conveyed to the appropriate Administration officials.

COMMENTS

I would like to ask you to designate a member of your staff to discuss with Sarah Massengale, of the Domestic Council staff, an appropriate Administration response to the questions raised by Senator Schweiker. It is important to note that DOD considers the Biological Weapons Convention as prohibiting its involvement in this research area at the present time. Apparently, DOD is awaiting further guidance from a subcommittee of the National Security Council that is currently engaged in developing appropriate legislation with other department and agency representatives for implementation of the convention. The Office of General Counsel of the United States Arms Control and Disarmament Agency, in response to inquiries from interested scientists, has advised that the Biological Weapons Convention does prohibit production of recombinant DNA molecules for purposes of constructing biological weapons.

I am attaching copies of letters the NIH has received relevant to this matter from DOD (Tab B) and from Professor David Baltimore of the Massachusetts Institute of Technology, a Nobel laureate involved in this research area, who wrote to the Arms Control and Disarmament Agency on the matter (Tab C). I am also attaching a copy of Dr. Fredrickson's testimony at the September 22 hearings of the Subcommittee on Health (Tab D).

I look forward to discussing this with you at your earliest convenience.

THE WHITE HOUSE

WASHINGTON

September 22, 1976

MEMORANDUM FOR THE HEADS OF DEPARTMENTS AND AGENCIES

On June 23 the National Institutes of Health released guidelines for the conduct of research involving the creation of new forms of life used in studying genetics (recombinant DNA experiments). These guidelines establish carefully controlled conditions for experiments in which foreign genes are inserted into microorganisms, such as bacteria. The objective of the guidelines is the containment of these possibly dangerous organisms while permitting research of great potential benefit to mankind.

The guidelines extend a moratorium that the scientists themselves imposed on certain experiments involving recombinant DNA. I am advised by the Secretary of Health, Education, and Welfare that recombinant DNA research has great potential in medicine as well as in science and technology generally. There are risks, however. The NIH guidelines prohibit certain types of experiments and require special safety conditions for other experiments. The provisions are designed to afford protection with a wide margin of safety to workers and the environment.

The Department of Health, Education, and Welfare expects these guidelines to be supported by the largest part of the scientific community and will use them to govern research at laboratories of the National Institutes of Health and at those of its grantees and contractors.

Secretary Mathews will be convening an interagency committee to review Federal policies on the conduct of research involving recombinant DNA.

I expect the full cooperation of each department and agency conducting or supporting recombinant DNA experiments with Secretary Mathews, who will take the lead in this.

Gerald R. Ford

DIRECTOR OF DEFENSE RESEARCH AND ENGINEERING
WASHINGTON, D. C. 20301

21 SEP 1976

Dr. Donald S. Fredrickson, M.D.
Director
Public Health Service
National Institutes of Health
Department of Health, Education,
and Welfare
Bethesda, Maryland 20014

Dear Dr. Fredrickson:

As requested, the Department of Defense (DoD) has reviewed the guidelines for conducting recombinant DNA research. In our opinion, the guidelines, as published, represent an acceptable set of rules that will permit the safe resumption of this research. Any future DoD research requiring recombinant DNA research will be accomplished within the guidelines. Further, we support your position, as stated in the draft Environmental Impact Statement, Guidelines for Research Involving Recombinant DNA Molecules, that future revision of the rules should be based upon experience rather than a continuing paper analysis of the issues surrounding this sensitive research area.

The DoD is not conducting research that falls within the scope of recombinant DNA research at this time. Presently we have no plans to initiate such work. However, the DoD remains vitally interested that research and technology development in this area be continued by the civil sector to assure its availability to DoD for use in meeting any military surprise which might arise from a nation or group. This technology will serve as the data base for DoD research programs to develop therapeutic measures and defensive equipment to counter such a threat. Any further delay in the resumption of this research to permit further refinement of the guidelines is judged counterproductive in meeting our defensive role.

Sincerely,

Malcolm R. Currie

JUL 9 1975

UNITED STATES ARMS CONTROL AND DISARMAMENT AGENCY

WASHINGTON, D.C. 20451

July 3, 1975

Professor David Baltimore
Massachusetts Institute of Technology
Center for Cancer Research
77 Massachusetts Avenue
Cambridge, Massachusetts 02139

Dear Professor Baltimore:

Dr. Ikle has requested that I respond to your letter of May 22, 1975, in which you raise the question as to whether the Biological Weapons Convention prohibits production of recombinant DNA molecules for purposes of constructing biological weapons. In our opinion the answer is in the affirmative. The use of recombinant DNA molecules for such purposes clearly falls within the scope of the Convention's provisions.

I am enclosing, for your information, a copy of the transcript of the hearing before the Senate Foreign Relations Committee. You will note that the Committee shared your concern about the scope of the Convention, as evidenced by the following question, appearing on p. 29:

"Question 15. Would the Biological Convention prohibit future types of biological warfare which might employ techniques beyond the current "state of the art", for example, some means of altering the structure of genes so as to modify behavior?"

ACDA responded that: "The Biological Weapons Convention would prohibit any future type of warfare which employed biological agents or toxins, regardless of whenthe agent or toxin was first developed or discovered. This also applied to weapons, equipment and means of delivery. In other words, the Convention prohibits not only existing means of biological and toxin warfare but also any that might come into existence in the future."

This interpretation is based upon the negotiating history as well as the explicit language of the Convention, and, we believe that it is shared by the other signatories.

Sincerely,

James L. Malone

James L. Malone
General Counsel

Enclosure:
As stated.

PROHIBITION OF CHEMICAL AND BIOLOGICAL WEAPONS

HEARING

BEFORE THE

COMMITTEE ON FOREIGN RELATIONS
UNITED STATES SENATE

NINETY-THIRD CONGRESS

SECOND SESSION

ON

Ex. J, 91–2

PROTOCOL FOR THE PROHIBITION OF THE USE IN WAR OF ASPHYXIATING, POISONOUS, OR OTHER GASES, AND OF BACTERIOLOGICAL METHODS OF WARFARE

Ex. Q, 92–2

CONVENTION ON THE PROHIBITION OF THE DEVELOPMENT, PRODUCTION, AND STOCKPILING OF BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS, AND ON THEIR DESTRUCTION

AND

S. Res. 48

RELATING TO A COMPREHENSIVE INTERPRETATION OF THE GENEVA PROTOCOL

DECEMBER 10, 1974

Printed for the use of the Committee on Foreign Relations

U.S. GOVERNMENT PRINTING OFFICE

45-156 WASHINGTON : 1974

Given the need to act quickly if a situation requiring the use of RCAs arises, would not necessarily be practical to obtain Presidential authorization on a case-by-case basis. On the other hand, a blanket prior authorization would not be issued.

We expect that authorization would be limited only to those specific geographic areas and types of situations in which the need to use RCAs had already been clearly demonstrated.

Question 13. Assuming the Senate were to give its advice and consent to ratification on the grounds proposed by the Administration, what legal impediment would there be to subsequent Presidential decisions broadening the permissible uses of riot control agents?

Answer. There would be no formal legal impediment to such a decision. However, the policy which was presented to the Committee will be inextricably linked with the history of Senate consent to ratification of the Protocol with its consent dependent upon its observance. If a future administration should change this policy without Senate consent whether in practice or by a formal policy change, it would be inconsistent with the history of the ratification, and could have extremely grave political repercussions and as a result is extremely unlikely to happen.

Question 14. With regard to the first of the excepted uses of riot control agents, what type of "riot control circumstances" other than prisoner of war riots might be contemplated in which riot control agents might be used?

Answer. This exception would permit use of RCAs only in riot situations in areas under direct and distinct U.S. military control, for example, in occupied areas which are under martial law.

Question 15. Would the Biological Convention prohibit future types of biological warfare which might employ techniques beyond the current "state of the art", for example, some means of altering the structure of genes so as to modify behavior?

Answer. The Biological Weapons Convention would prohibit any future type of warfare which employed living agents or toxins, regardless of when the agent or toxin was first developed or discovered. This also applies to weapons, equipment and means of delivery. In other words, the Convention prohibits not only existing means of biological and toxin warfare but also any that might come into existence in the future.

not as important as "development" prohibition in Convention

Question 16. Was the use of civilians to "mask or screen" attacks commonplace in Vietnam?

Answer. Documented situations of this type in Vietnam are rare.

Question 17. Which of the Middle Eastern nations are parties to the Geneva Protocol and the Biological Convention? Would you provide a current list of the parties and signatories?

Answer. The following Middle Eastern countries are Parties to the Geneva Protocol: Cyprus, Egypt, Iran, Iraq, Israel, Kuwait, Lebanon, Pakistan, Saudi Arabia, Syrian Arab Republic, Turkey, and the Yemen Arab Republic.

The following Middle Eastern countries have signed the Biological Weapons Convention: Afghanistan, Cyprus, Egypt, Iran, Iraq, Jordan, Kuwait, Lebanon, Pakistan, Saudi Arabia, Syrian Arab Republic, Turkey, United Arab Emirates, Yemen Arab Republic (San'a), and People's Democratic Republic of Yemen (Aden). Of these, Cyprus, Iran, Kuwait, Pakistan, and Turkey have already ratified.

Current lists of parties and signatories are provided.

Question 18. In your answer to the Chairman's questions, in the course of your statement you referred to a Presidential Directive relating to RCA's used for law enforcement purposes. Would you provide the Committee with a copy of the Presidential Directive in question?

Answer. A copy has been provided.

[The information referred to is classified and in the Committee files.]

Question 19. Would you describe the NSC studies which have been undertaken since the Committee's last hearings on the Protocol and would you provide copies of them for the Committee files and summarize their individual conclusions for the purposes of this record.

What conclusions did they reach with regard to the military utility of herbicides and RCA's?

FOR RELEASE UPON DELIVERY

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

STATEMENT BY

DR. DONALD S. FREDRICKSON, DIRECTOR

NATIONAL INSTITUTES OF HEALTH

ON RECOMBINANT DNA RESEARCH

BEFORE THE

SUBCOMMITTEE ON HEALTH

SENATE COMMITTEE ON LABOR AND PUBLIC WELFARE

SEPTEMBER 22, 1976

Mr. Chairman and Members of the Subcommittee:

It is a pleasure to appear before you today to discuss the NIH guidelines on recombinant DNA research.

In June, the National Institutes of Health, with the approval of the Secretary of HEW and the Assistant Secretary for Health, issued guidelines to govern NIH-supported research on recombinant DNA molecules. Accompanying the guidelines was a document describing in detail the issues which the Director of NIH considered in reaching the decision to release the guidelines. These guidelines, governing research conducted at the laboratories of NIH as well as projects supported by grants and contracts, delineate stringent safeguards for the conduct of experiments involving the production of recombinant DNA molecules and their insertion into organisms such as bacteria. The object of the guidelines is to minimize the risks associated with recombinant DNA research--primarily through a series of procedures aimed at physical and biological containment of possibly dangerous organisms--while permitting research of great potential benefit to mankind. The NIH guidelines replaced the recommendations from the 1975 Asilomar Conference on Recombinant DNA Molecules, which permitted research under less strict conditions.

Recombinant DNA molecules are formed in the laboratory from recombination of segments of deoxyribonucleic acid, the material that determines the hereditary characteristics of all living cells. These techniques, permitting genetic information from quite different organisms to be combined, have a remarkable potential for furthering the understanding of fundamental biochemical processes of both lower and higher organisms.

Recombinant DNA research has strong potential in medicine as well as in science and technology generally. In medicine it is capable of providing hitherto unobtainable knowledge of the organization and expression of genes in health and disease. It possibly may also permit economical production of important medicinals. Potential benefits in agriculture and industry include more abundant crops and synthesis of industrially important biochemical agents such as enzymes.

There are risks, however, as well as potential benefits in the new research. For example, bacteria with transplanted genes may prove hazardous to man or other forms of life. Like many of the potential benefits, these risks remain speculative, for there is still scanty evidence that genes from one form of life can be expressed in any other form. We must assume, however, that they may be. Thus our present state of knowledge dictates strict controls on this form of experimentation.

The NIH guidelines prohibit certain types of experiments--those, for instance, that might produce disease germs with increased resistance to antibiotics. Other experiments will go forward under special safety conditions. The guidelines have a definitive administrative framework for assuring that safety is an essential and integrated component of research involving recombinant DNA molecules. The section dealing with roles and responsibilities sets forth a developed review structure involving the principal investigator, local biohazards committees, and the NIH Advisory Committee, as well as peer review committees. The guidelines now provide extensive opportunity for advice, from the local to the national level. Several levels of review and scrutiny are

provided, ensuring the highest standards for scientific merit and conditions for safety. TWe believe these provisions will afford protection, and with a wide margin of safety, to workers and the environment while permitting this type of research to proceed. And the NIH is sponsoring additional experimental work to determine possible hazards and new safety practices and procedures.

Development of the Guidelines

Recombinant DNA research brings to the fore certain problems in assessing the potential impact of basic science on society as a whole, including the manner of providing public participation in those assessments. The field of research involved is at the leading edge of biological science. New information is accruing rapidly and requires continuing evaluation and re-synthesis. The experiments involved are extremely technical and complex. Molecular biologists active in this research require diligence to keep abreast of the newest developments. It is not surprising that scientists in other fields and the general public have difficulty in understanding advances in recombinant DNA research. Yet public awareness and understanding of this line of investigation is vital.

It was the scientists engaged in recombinant DNA research who called for a moratorium on certain kinds of experiments in order to assess the risks and devise appropriate guidelines. At their behest, the National Academy of Sciences created a committee that organized an international conference at Asilomar Conference Center in California, held February 1975. The committee also called on the NIH to establish

an advisory committee to draft guidelines for the conduct of this research. At Asilomar, temporary guidelines were issued pending issuance of NIH guidelines.

In response, the NIH Recombinant Advisory Committee (formally "NIH Recombinant DNA Molecule Program Advisory Committee") was established in October 1974 to advise the Secretary of HEW, the Assistant Secretary for Health, and the Director of NIH to accomplish these tasks. The several meetings at which the Recombinant Advisory Committee developed its proposed guidelines in 1975 were announced in the Federal Register and were open to the public. The committee, after working several draft versions, reached agreement on a recommended revised version of proposed guidelines that were referred to the NIH Director for review in January 1976.

A special meeting of the Advisory Committee to the Director, NIH, was convened in February of this year to review these proposed guidelines. In addition to current members of the committee, a number of former committee members as well as other scientific and public representatives were invited to participate in the special February session. There was ample opportunity for comment and an airing of the issues, not only by the committee members but by public witnesses as well. All major points of view were broadly represented.

The proposed guidelines were reviewed in the light of the comments and suggestions made by the participants at the public hearing as well as extensive written correspondence received after the meeting. The NIH has published a volume containing the transcript of the public hearing of the Director's Advisory Committee, all correspondence directed

to the NIH on this matter, and summaries of meetings with representatives from Government, Departments, and Agencies, Congressional staff, and industry. The Decision of the Director, NIH, that accompanied the release of the guidelines in June is based on that record.

Steps are underway for further opportunity for debate, scrutiny, and subsequent decisions relevant to the guidelines. The guidelines were published in the Federal Register on July 7, and a 120 days' period was allowed for comment. Further, in response to the recommendations of public commentators, the NIH undertook an environmental impact assessment in accordance with the National Environmental Policy Act of 1969. A draft environmental impact statement was published in the Federal Register on Thursday, September 9, 1976, for public comment. The statement was given widespread distribution to interested environmental Federal, State, and local groups for comment. In this way, yet another review will be provided from the perspective of the environmental impact of this research.

Application to Public and Private Sector

The Department and NIH have given high priority to the implementation of the NIH guidelines and their application beyond the NIH. A meeting was held with representatives of relevant HEW agencies and other departments of the Federal Government on April 8. The purpose was to exchange information on recombinant DNA research and to discuss the applicability of NIH guidelines to research or regulatory activities of other departments and agencies.

A meeting was also held on June 2 with representatives of private industry to provide them with full information about the guidelines and to help determine the present and future interest of industrial laboratories in this type of research. The meeting afforded one of the first opportunities for industry representatives to convene for discussion of this research.

The expressed concern for the extension of these guidelines to other Federal agencies and the private sector is shared by the NIH and the Department of Health, Education, and Welfare. The letter from you, Mr. Chairman, and Senator Javits to the President expressed well these timely concerns. Following the NIH initiatives, the Department has been reviewing an appropriate mechanism to allow for a policy review of Government activities in this research area, including relevant activities in the private sector. The Department has proposed to the President that an interagency committee be created to review the activities of all Government agencies conducting or supporting recombinant DNA research or having regulatory authority relevant to this scientific field. This committee could also coordinate activities with the private sector. The President has written to relevant Department Secretaries and Agency Heads urging their cooperation and participation in naming representatives to serve on this committee.

The interagency committee will assist in facilitating compliance with a uniform set of guidelines for the public and private sectors and provide coordination among the several Government agencies that support or conduct this research. It is mandated to suggest appropriate administrative or legislative proposals deemed appropriate for national

implementation. For this purpose a review of authorities--the Public Health Service Act, the Occupational Safety and Health Act, the National Environmental Policy Act, and other relevant statutes--will be carried out.

It should be noted that the National Science Board has adopted by resolution the NIH guidelines for all such research supported by the National Science Foundation. We anticipate similar letters of endorsement from all of the Federal agencies that are now conducting or supporting such research, or consider that they may do so in the near future.

Since the NIH meeting with private industry in June and following publication of the NIH guidelines in the Federal Register, the Pharmaceutical Manufacturers Association has been reviewing the applicability of the guidelines to industry research activities. The PMA has expressed general support for the guidelines with relatively minor revisions considered necessary to meet the needs of industry.

In order to ensure that implementation of the guidelines within the NIH be achieved without delay, an NIH Office of Recombinant DNA Activities was created in June to administer and coordinate activities. This office will serve as liaison to the institutional biohazard committees for administration of the guidelines. There will be special emphasis on activities pertaining to the operation and implementation of containment and safety practices and procedures. The NIH office will also closely monitor reports and information concerning accidents, containment, and safety research innovation.

To ensure that those who conduct recombinant DNA research will have notice and adhere to the guidelines, the NIH distributed the guidelines to approximately 25,000 grantees and contractors. The investigators and institutions supported by the NIH have a special responsibility for maintaining the safety practices outlined in the guidelines, and the NIH will work closely with them to fulfill that objective.

In response to public concern that broad support for the guidelines be solicited, the NIH undertook to distribute them through a number of channels. Letters were sent to professional organizations soliciting support for the guidelines among their member scientists and to editors of journals requesting editorial endorsement. The guidelines were also sent to all science attaches of foreign embassies located in Washington and to U.S. science attaches in our embassies in foreign countries. Various international health and scientific organizations have also been briefed on the guidelines.

The NIH recognizes its responsibility to continuing discussions on the international level to ensure that there be as uniform a standard of guidelines as possible to govern the conduct of this research in all nations. As an example of international cooperation, the European Molecular Biology Organization recently announced plans for a voluntary registry of recombinant DNA research in Europe. Following this EMBO initiative, NIH shall similarly maintain a voluntary registry of investigators and institutions engaged in such research in the United States. Plans for establishing this registry are under way, and the new interagency committee will be asked to address the scope of the registry as one of its earliest tasks. Great Britain has endorsed continuation of

recombinant DNA research, and a Government report has just been issued containing guidelines that technically are similar to the NIH guidelines.

Patent Policy Review

Currently there is also a review underway of the Department patent policies as they relate to discoveries in recombinant DNA research. A number of universities where such research is being conducted are reviewing possible patent applications for these discoveries. Stanford University and the University of California have filed patent claims in this research area and have solicited the views of the Department and the NIH. These patent activities, the certitude that other important inventions in this field are forthcoming, and the public's apprehension over control of recombinant DNA research compel inquiry into whether the Department's policies for allocating invention rights are consonant with the concerns about this research.

Invention rights are normally allocated in either of two ways under current Department patent regulations:

The Department has institutional patent agreements with 65 universities having identified technology transfer capabilities. Such an agreement provides the institution the first option to ownership in all inventions made in performance of Department research, subject to a number of conditions deemed necessary to protect the public interest. Stanford and the University of California are among the institutions that hold such agreements with the Department.

Second, for those institutions who do not have an institutional patent agreement, the Department defers determination of ownership until an invention has been made. Under the deferred determination policy, an innovating institution may petition the Department for ownership of an invention after it is identified. In the past, approximately 90 percent of all such petitions have been granted.

The Department's policy of allocating invention rights is designed to facilitate the transfer of technology from the bench to the marketplace by inducing industrial investment and continued development of inventions generated with Department support. The incentives provided by Department patent policy have encouraged the development of new technology in general and afforded patent protection for some inventions to the economic benefit of the United States. The control of DNA research envisioned by the guidelines, however, requires a delicate balance between need for rapid exchange of information and a potential means for achieving greater uniformity in safety practices by setting conditions for safety in licenses under patent agreements.

Stanford and the University of California have indicated a willingness to consider modification of their patent agreement with the Department as it relates to such research. A number of possible policies, short of the present allocation of rights under the agreement, are currently being considered by the NIH as possible alternatives to the present allocation of rights made under all such agreements. As part of that review, the NIH has solicited the views not only of members of the NIH

community but of the public as well, including all those who participated in the public hearing on the guidelines.

The prudence and caution inherent in the guidelines must also be reflected in patent policies underlying administration of recombinant DNA research inventions.

Conclusion

In summary, the potential benefits and risks of recombinant DNA research have posed a singular challenge. The prospects of harnessing these techniques to the benefit of man are indeed great. From what we know today, we must assume that if these promises are to be realized, our efforts must be marked by extraordinary diligence to avoid harm. This combination of benefits and risks provides not only opportunity but obligation for the scientific community and the public to proceed together in assessment of risks and benefits and to agree upon procedures that will allow the continuation of these investigations under conditions of minimal risk.

Our immediate task is threefold: First, to maintain a satisfactory process for updating and revising the guidelines in the light of both public scrutiny and new research developments. Secondly, to pursue steps to ensure that all sectors of the scientific enterprise in this country concur and adopt these or comparable guidelines, and to use all influence available to us to encourage a consistent policy throughout the world. Thirdly, we must now, in concert with all interested parties, consider whether additional measures to assure a common approach to problems here are advisable. Let me assure the Committee that the

Department will make every effort to accomplish these tasks.

Thank you for the opportunity to discuss these issues before the Committee. My colleagues and I would be happy to try to answer questions you or other members may have.

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THE WHITE HOUSE INFORMATION

WASHINGTON

September 30, 1976

MEMORANDUM FOR THE PRESIDENT

FROM: JIM CANNON

SUBJECT: Required Increase in Deductible for Medicare Hospital Care

This memorandum from Secretary Mathews informs you that he is announcing an increase in the deductible amount for Medicare inpatient hospital care.

This means that after October 1, 1976, patients must pay the first $124 of inpatient care (up from $104) before Medicare benefits are granted.

For anyone on Medicare, this is a 19% increase in the initial payment above what he or she is paying now for each hospital stay.

These increases are required under a formula established by law. It is unfortunate that we did not learn of this sooner.

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

SEP 29 1976

MEMORANDUM FOR THE PRESIDENT

This is to inform you that by October 1, I must announce an increase from $104 to $124 in the inpatient hospital deductible paid by beneficiaries under Medicare.

Under Medicare, a beneficiary who receives inpatient hospital services is responsible for the payment of an inpatient deductible upon admission to a hospital. Originally, this amount was $40; but for spells of illness beginning in 1969 and succeeding years the deductible is promulgated by the Secretary of Health, Education, and Welfare according to a formula stated in the law. A rate of $104 was promulgated for 1976. Between July 1 and October 1 of 1976, I am required by law to determine and announce the amount of the deductible to be applicable for spells of illness beginning during calendar year 1977.

I have no real discretion in this matter, since the formula mathematically produces an automatic result based upon reported statistics. For inpatient services in 1977 the formula requires that the deductible be $40 times the ratio of the average per diem hospital cost under the program for insured persons for 1975 to the corresponding average for 1966 rounded to the nearest multiple of $4. Based on final analysis of the latest tabulation of hospital bills for 1975, the prescribed computation produces an amount of $124.12 which must be rounded to $124.

As you know, the deductible is designed to play a role in controlling Medicare costs. It reduces the amount that would be paid out of the Hospital Insurance Trust Fund and is intended to discourage unnecessary utilization of services. Nevertheless, continued increases in hospital costs per patient day will lead to an increase of about $2 billion in Medicare expenditures during calendar 1977.

The beneficiary is also responsible, after certain lengths of stay in a hospital or skilled nursing facility, for other cost-sharing amounts under the hospital insurance program which are proportionate to the hospital deductible. These amounts, therefore, will also be increased for 1977.

Secretary