The original documents are located in Box 16, folder "Health (8)" of the James M. Cannon Files at the Gerald R. Ford Presidential Library.

Carter to Confront Ford on Medicaid

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Calling the problem "a national disgrace," Carter told a senior citizens rally in Phoenix: "The Republican administration has not provided tough, competent management to make our scarce health dollars go to help patients or to prevent disease."

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No.

This is a ~~young & Johnson~~ B programs,
mentioned by one of
put through by

The system that created medical fraud
Brought through, problem, in
NY. City, was managed by
one of your advisers.

Jules Sugarman -

THE WHITE HOUSE
WASHINGTON

9/15/76

TO: SPENCER JOHNSON

FROM: JIM CANNON

1. What is date of report?

2. What are the "59 things"?

Many thanks.

Carter to Confront Ford on Medicaid

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THE WHITE HOUSE
WASHINGTON

Date 9/15

To: Allen Moore

From: Spencer C. Johnson

X FYI

____For Appropriate Action

Comments:

Johnson handled by phone. V.P. candidate Dole appeared.

THE WHITE HOUSE
WASHINGTON

Date 9/14

To: Art / Allen

From: Spencer C. Johnson

____FYI

____For Appropriate Action

Comments:

Sarah and I have received exactly the same letter. Also we recommended that a member of the First Family go. (Memo attached) If a member of the First Family goes then none of us need go. If not, then Sarah or I can go, Connan need not unless he has a special interest.

Spence

National Multiple Sclerosis Society
National Capital Chapter
1200 15th Street, N.W.
Suite 400
Washington, D. C. 20005
Tel. (202) 296-5363

file

September 10, 1976

Mr. James M. Cannon
Director, Domestic Council
West Wing, 2nd flr.
The White House
Washington, D.C. 20500

Dear Mr. Cannon::

The National Multiple Sclerosis Society on the occasion of its 30th Anniversary, will be holding its National Chapter Conference in Washington, D.C. from September 16-19, 1976, at the Statler Hilton Hotel.

We expect about 400 delegates from all over the country to attend and would feel honored if you could find some time in your busy schedule to drop by to make a brief statement.

The delegates at this Conference represent the 800,000 MS volunteers across the country who are looking to the Administration for leadership in the areas of disease control and health care. Your presence at this National Anniversary gathering will further exemplify that the Federal Government is truly concerned with the health of all Americans.

We look forward to hearing from you.

Sincerely,

Nicholas M. Klaich
Executive Director

RSVP:

296-5363

National Multiple Sclerosis Society
National Capital Chapter
1200 15th Street, N.W.
Suite 400
Washington, D. C. 20005
Tel. (202) 296-5363

September 10, 1976

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Rm. 235, Old Executive Office Bldg.
Domestic Council
The White House
Washington, D.C. 20500

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We look forward to hearing from you.

Sincerely,

Nicholas M. Klaich
Executive Director

RSVP:

296-5363

CLEARANCE SHEET

DATE: 9/9/76

JMC ACTION
Required by: Immediate

STAFF RESPONSIBILITY Johnson

SUBJECT: Invitation to President address National Multiple Sclerosis Society

RECEIVED FROM: Nicholson DATE RECEIVED: 9/8

STAFF COMMENTS:

An appearance before this organization would be very appropriate for a member of the First Family.

Steve Johnson

QUERN/MOORE RECOMMENDATION:

✓ APPROVE

_____ REVIEW & COMMENT

_____ DISCUSS

CANNON ACTION: DATE: 9/10

Material Has Been:

_____ Signed and forwarded

_____ Changed and signed

_____ Returned per conversation

✓ Noted Shared w/ RR

JIM CANNON

Comment:

THE WHITE HOUSE

WASHINGTON

September 8, 1976

HIGH PRIORITY

MEMORANDUM FOR: JAMES CANNON

FROM: WILLIAM NICHOLSON

SUBJECT: Invitation to the President to address National Multiple Sclerosis Society annual meeting in Washington September 16-19

I would appreciate your comments and recommendation on the attached invitation. Would an appearance before this organization be appropriate for a member of the First Family?

Thank you.

COMMENTS:

yes. Absolutely.

cc: Susan Porter-fyi

File

Health

THE WHITE HOUSE

WASHINGTON

September 16, 1976

Dear David:

Governor Rhodes of Ohio is asking for help on his Medicaid program. Specifically, he wants to borrow Richard Donovan.

Is this possible?

Many thanks.

Sincerely,

James M. Cannon
Assistant to the President
for Domestic Affairs

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

cc:Quern fyi

STATE OF OHIO
OFFICE OF THE GOVERNOR
COLUMBUS 43215

JAMES A. RHODES
GOVERNOR

September 8, 1976

Under Secretary Marjorie W. Lynch
U. S. Department of Health, Education
and Welfare
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Under Secretary Lynch:

Ohio, like many states, has encountered difficulty in controlling the rapid increases in utilization and costs of its Medicaid program. Governor Rhodes has taken a personal interest in finding the answers to the problems that accompany our Medicaid program.

Mr. Richard E. Donovan is an HEW auditor assigned to the Ohio Department of Public Welfare. Governor Rhodes has requested Mr. Donovan to take a leave of absence, or some similar arrangement, from Federal employment, to work full-time with the Ohio Department of Public Welfare in helping solve some of its financial management problems. The Governor is impressed with Mr. Donovan's work and believes that he could play a vital role in assisting the department if he were assigned to it on a full-time basis.

Mr. Donovan has reviewed several possibilities, and I would request of you at this time that he be promoted to the grade of GS-14, step 10; that following his promotion, he be placed on a detached special assignment to the Department of Public Welfare, or to the Governor's Office if you believe that is more appropriate.

Following the termination of Mr. Donovan from the assignment to the Department of Public Welfare, it is my understanding that he wishes to be assigned to the Ohio branch office of the HEW audit agency, or an alternative location acceptable to him. I know that Mr. Donovan is interested in maintaining his Federal Civil Service status during his detached special assignment to the State of Ohio.

We are attempting to move quickly and effectively in assuring that the Ohio Medicaid Program is free of the abuses that have troubled some such programs. Your early response to our request would help us achieve that goal.

Sincerely,

Thomas J. Moyer,
Executive Assistant
to the Governor

TJM:pmj

bc: James M. Cannon

THE WHITE HOUSE

WASHINGTON

Rle
Health

September 16, 1976

MEMORANDUM FOR: PAUL O'NEILL

FROM: JIM CANNON JMC

SUBJECT: Senate Black Lung Bill, S. 3183

Here is our staff evaluation of the Black Lung Bill.

attachment

THE WHITE HOUSE

WASHINGTON

September 15, 1976

MEMORANDUM FOR: JIM CANNON

FROM: BILL DIEFENDERFER

SUBJECT: SENATE BLACK LUNG BILL, S. 3183

The Senate Committee on Labor and Public Welfare reported out yesterday S. 3183 -- the Black Lung Bill. The Committee Report is expected to be filed this Friday or Monday of next week.

Although quite a few changes were made to the Bill, the reasons for Administration opposition have not decreased. In fact, some changes were made to the Bill which may increase our opposition:

- The medical term describing Black Lung, pneumoconiosis, has been omitted from the Bill. DOL fears this means a miner suffering from respiratory illness or heart disease, which is not related to coal mining, would be eligible for "Black Lung" benefits as long as he has 25 years or more service in the coal mines.

- In Subcommittee Senator Javits managed to have adopted a 1981 cut-off date for the Bill's effectiveness. Senator Schweiker was successful in having that cut-off date eliminated in full Committee.

It had been hoped that the Senate Finance and Appropriations Committees would exert jurisdiction over the Bill for at least a few weeks. Now DOL feels those Committees will only ask to look at the Bill for one or two days at most.

If Senator Mansfield can find a place on the Senate calendar for consideration of S. 3183, it could conceivably be before the Senate late next week or early the following week.

Normally the House-Senate Conference on such a Bill would be lengthy, but if the House and Senate leadership are determined to forward this Bill to the President matters

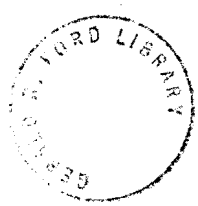
could be settled well before the scheduled October 2, 1976, adjournment of Congress.

Informed observers in the House and Senate feel the Bill will be forwarded to the President for action before Congress adjourns.

The House equivalent of S. 3183, H.R. 10760, passed the House by 210-183, which indicates a veto could be sustained.

cc:

Art Quern
Allen Moore



THE WHITE HOUSE
WASHINGTON

Allen: Eliska is not doing message. HEW told her it would be inappropriate since Fair was being sponsored by only one doctor. She would like a copy of the Cooper telegram, which I am sending her. Should someone acknowledge the Wills telegram?

NO

Judy 9/17

Close out

Kable

TELEGRAPHIC MESSAGE

NAME OF AGENCY	PRECEDENCE	SECURITY CLASSIFICATION
HEW-PHS-OASH-OPA	ACTION: INFO:	
ACCOUNTING CLASSIFICATION 7561101 CAN # 6-A730010	DATE PREPARED 9/16/76	TYPE OF MESSAGE [x] SINGLE [ ] BOOK [ ] MULTIPLE-ADDRESS
FOR INFORMATION CALL		
NAME John M. Blamphin	PHONE NUMBER 245-6867	

THIS SPACE FOR USE OF COMMUNICATION UNIT

MESSAGE TO BE TRANSMITTED *(Use double spacing and all capital letters)*

TO:

REV. ALLAN R. MILLER AND DR. STAN GOLDEN
ORDER OF THE HOLY FELLOWSHIP
10100 Culver Blvd.
Culver City, California 90230

ON BEHALF OF PRESIDENT FORD I WISH TO CONVEY OUR BEST WISHES FOR A SUCCESSFUL HEALTH FAIR. YOU, THE ORDER OF THE HOLY FELLOWSHIP AND CIVIC LEADERS OF CULVER CITY, CALIFORNIA ARE TO BE CONGRATULATED FOR ORGANIZING THIS EVENT WHICH WILL, I AM SURE, HAVE A SIGNIFICANT IMPACT ON THE HEALTH OF THE PEOPLE WHO LIVE IN AND AROUND CULVER CITY. THE FAIR WILL AID IN THE DETECTION OF DISEASE AT AN EARLY AND TREATABLE STAGE. BUT MORE IMPORTANT, IT WILL SERVE AS A SYMBOL TO THE COMMUNITY OF THE IMPORTANCE OF DISEASE PREVENTION, AND THE NEED FOR GREATER INDIVIDUAL RESPONSIBILITY FOR THE MAINTENANCE OF GOOD HEALTH.

WE WISH YOU WELL IN THIS IMPORTANT ENDEAVOR.

Theodore Cooper

THEODORE COOPER, M.D.
ASSISTANT SECRETARY FOR HEALTH

SECURITY CLASSIFICATION		
	PAGE NO.	NO. OF PGS.
	1	1

STANDARD FORM 14
REVISED AUGUST 1967
GSA FPMR (41 CFR) 101-35.306

U.S. GOVERNMENT PRINTING OFFICE: 1974-535-402

14-306

THE WHITE HOUSE

WASHINGTON

September 14, 1976

MEMORANDUM TO: JAMES DIXON M.D.

FROM: SPENCER JOHNSON SJ

SUBJECT: Special Message Concerning Health Fair Week

Attached is a telegram from Maury Wills of Los Angeles, to President Ford concerning the designation of Health Fair Week.

Although there is merit in the idea the timing would not permit the maximum nationwide participation by interested groups. It would be appropriate however for Dr. Cooper to send a message of encouragement on behalf of the President.

WHB014(1216)(2-022035E251)PD 09/07/76 1216
ICS IPMRNCZ CSP
1976 SEP 7 PM 1 38
21387034 17 TDRN LOS ANGELES CA 126 09-07 1216P EST
PMS PRESIDENT FORD
WHITE HOUSE DC 20500
DEAR PRESIDENT FORD: I JOIN WITH THE ORDER OF THE HOLY FELLOWSHIP IN REQUESTING YOU TO DECLARE THE WEEK OF SEPTEMBER 19TH AS NATIONAL HEALTH FAIR WEEK
THE ORDER, AS WELL AS CULVER CITY CALIFORNIA, AND THE SURROUNDING AREA, ARE SPONSORING A HEALTH FAIR WHERE FREE MEDICAL, DENTAL, AND COUNSELING SERVICES WILL BE PROVIDED, AS WELL AS FREE GIFTS, DONATED BY CONCERNED BUSINESSMEN.
AS YOU KNOW, I HAVE ALWAYS BEEN INVOLVED IN PHYSICAL FITNESS AND HEALTH, AND WHOLEHEARTEDLY SUPPORT THIS UNIQUE PREVENTIVE CONCEPT OF INCREASING HEALTH AWARENESS ON A COMMUNITY LEVEL.
IN MY OPINION THIS IDEA OF COMMUNITY SELF RELIANCE IS DESERVING OF THE WIDEST POSSIBLE ENCOURAGEMENT AND SUPPORT. THE DIGNITY OF YOUR OFFICE WOULD LEAD TO THE ACTUALIZATION OF THIS CONCEPT. SINCERELY
MAURY WILLS
LA DODGERS
NBC SPORTS NETWORK
NNNN

THE WHITE HOUSE
WASHINGTON

Date 9/17

To: Aaron Moore

From: Spencer C. Johnson

____FYI

____For Appropriate Action

Comments:

Here is the Mary Wells package on health fair week -- the message has already gone out from HEW.

Spence

090821

File

Health

THE WHITE HOUSE

WASHINGTON

ACTION

September 18, 1976

MEMORANDUM FOR THE PRESIDENT

FROM: JIM CANNON

SUBJECT: Guidelines for Conducting Genetic Research

On June 23 the National Institutes of Health published guidelines for the conduct of genetic research. The guidelines are specifically directed at experimentation involving the creation of new forms of life. They establish carefully controlled conditions for such experiments.

In order to monitor developments in this sensitive area, Secretary Mathews has proposed the creation of an interagency committee to review all Federal activities related to this scientific field (often referred to as recombinant DNA experiments).

Attached for your signature is a memorandum to the heads of departments and agencies urging their cooperation and participation in naming representatives to serve on this proposed committee.

In addition, there are two letters for your signature to Senators Kennedy and Javits. These two jointly wrote to you congratulating the Administration for the issuance of research guidelines. However, they expressed their concern that the guidelines are only binding on Federally funded research and have no effect on other domestic and international research.

The letters to the Senators indicate your shared concern about this problem and your intention that the issue be carefully studied by the interagency committee.

The letters and memorandum have been approved by Robert T. Hartmann, OMB, the Counsel's Office, Jack Marsh and the Office of Science and Technology.

I recommend you sign the attached memorandum and letters.

THE WHITE HOUSE

WASHINGTON

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.

THE WHITE HOUSE

WASHINGTON

Dear Senator Javits:

I am writing in response to your and Senator Kennedy's letter of July 19 concerning the National Institutes of Health (NIH) Guidelines on Recombinant Deoxyribonucleic Acid (DNA) Research. As you note in your letter, the Guidelines were developed over an 18-month period and involved the participation not only of the scientific community but of the public as well.

I am advised by the Secretary of Health, Education, and Welfare that the potential scientific and medical benefits in this research area are promising and that support for the research is merited with appropriate safeguards against possible hazards. The material accompanying the release of the Guidelines explained in great detail the care and consideration given stated public concerns for safety.

The application of these Guidelines beyond the NIH to the public and private sectors merits further consideration. To consider this and other issues further Secretary Mathews has proposed 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. The committee could also coordinate activities with non-Federal institutions. I have written to all Department Secretaries urging their cooperation and participation in naming representatives to serve on this proposed committee.

By this means I believe the concerns you address in your letter will receive careful attention. I am asking Secretary Mathews to keep you apprised of the deliberations of this committee and any recommendations that may be forthcoming.

Thank you very much for your thoughtful letter.

Sincerely yours,

The Honorable Jacob K. Javits
Ranking Minority Member
Committee on Labor and
Public Welfare
United States Senate
Washington, D.C. 20510

THE WHITE HOUSE

WASHINGTON

Dear Mr. Chairman:

I am writing in response to your and Senator Javits' letter of July 19 concerning the National Institutes of Health (NIH) Guidelines on Recombinant Deoxyribonucleic Acid (DNA) Research. As you note in your letter, the Guidelines were developed over an 18-month period and involved the participation not only of the scientific community but of the public as well.

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Thank you very much for your thoughtful letter.

Sincerely yours,

The Honorable Edward M. Kennedy
Chairman, Subcommittee on Health
Committee on Labor and Public Welfare
United States Senate
Washington, D.C. 20510

United States Senate
COMMITTEE ON
LABOR AND PUBLIC WELFARE
WASHINGTON, D.C. 20510

July 19, 1976

The President
The White House
Washington, D.C.

MF

Dear Mr. President:

For several years, the biomedical research community has been engaged in an extremely important debate over the safety of certain types of genetic research. The research involves combining genetic material from different organisms. The technology that permits this type of genetic experimentation, called recombinant DNA research, is revolutionary, and holds the promise of enormous benefits in our understanding of disease processes, and could lead us to ways of controlling or treating complex diseases such as cancer and hereditary defects. It could conceivably lead to improved ways of producing such important hormones as insulin, clotting factors, and enzymes important to treatment of many diseases. The technology also has conceivable applications in agriculture and industry. Clearly, it is a research area of enormous promise.

However, recombinant DNA research also entails unknown but potentially enormous risks due to the possibility that micro-organisms with transplanted genes might prove hazardous to human and other forms of life--and might escape from the laboratory. Indeed, scientists engaged in such research declared a voluntary moratorium on recombinant DNA research in 1974 when they foresaw the possibility, for example, of creating in the laboratory self-propagating infectious bacteria that contain genes from cancer-causing viruses. The moratorium was lifted in 1975, but maintained, again by the researchers themselves, for the specific types of experiment which might produce cancer-causing bacteria, raise the resistance of antibiotics of known bacteria, or have other dangerous results.

On June 23rd of this year, the National Institutes of Health issued comprehensive guidelines for recombinant DNA research which specify more stringent safety and containment measures than are currently required or practiced in many areas. They specifically prohibit the most potentially dangerous types of experiments. In addition, the guidelines prohibit the release into the air or water or environment of any of the genetic materials created by the research.

We appreciate the great care NIH has taken, in the formulation of these strict guidelines, in obtaining the best scientific advice as well as advice from experts in law and ethics. Opportunity was also given for the public to comment on the guidelines. The environmental impact assessment of the guidelines currently being prepared by NIH will offer further opportunities for such comment.

The guidelines will be widely discussed and debated with regard to their ultimate adequacy in safeguarding the public, and they will no doubt further evolve and develop during this debate and as our understanding of recombinant DNA advances. Based on the process by which NIH produced the present guidelines, we are confident they are a responsible and major step forward and reflect a sense of social responsibility on the part of the research community and the NIH.

However, we are gravely concerned that these relatively stringent guidelines may not be implemented in all sectors of the domestic and international research communities and that the public will therefore be subjected to undue risks. The National Institutes of Health has the authority to require adherence to the guidelines as a condition of their grants and contracts for research, but they cannot enforce the guidelines with respect to other Federal agencies, with respect to research in the private sector in this country, and with respect to research done in other nations.

In particular, it is clear that recombinant DNA research has great potential in the private sector, such as pharmaceutical manufacture, the oil industry and agricultural products. It is also clear that some elements of the guidelines, such as limitations on the size of experiments, public disclosure, and non-release of materials into the environment, may be contrary to the interest and practice of research in private industry, and may therefore be ignored. In addition, since private sector research will lead to industrial application, guidelines must be extended beyond research into application and production stages. If the NIH guidelines are necessary to protect the public in Federally funded research, it is clear they are necessary for privately funded research and application as well.

Given the high potential risks of this research, it seems imperative that every possible measure be explored for assuring that the NIH guidelines are adhered to in all sectors of the research community. We urge you to implement these guidelines immediately wherever possible by executive directive and/or rulemaking, and to explore every possible mechanism to assure compliance with the guidelines in all sectors of the research community, including the private sector and the international community. If legislation is required to these ends, we urge you to expedite proposals to Congress.

This is an unprecedented issue in the area of biomedical research. It has been likened in importance to the discovery of nuclear fission. In the interest of public safety, and in the interest of permitting this beneficial research to continue with the blessing of a reassured public, we must act expeditiously on these matters.

Sincerely,

Jacob K. Javits
Ranking Minority Member
Committee on Labor and
Public Welfare

Edward M. Kennedy
Chairman
Subcommittee on Health

file
Health
Medicaid

THE WHITE HOUSE

WASHINGTON

September 20, 1976 PM 5 23

MEMORANDUM FOR: JIM CANNON
JIM CAVANAUGH
PAUL O'NEILL
MIKE DUVAL
DAVE GERGEN
AGNES WALDRON

FROM: ART QUERN

SUBJECT: Carter Comments on Medicaid

In the News Summary of September 14, Carter is quoted as criticising the President's position on Medicaid. Among other things, he claimed "the Republican Administration hasn't enforced the laws or listened to the GAO that said there are 59 things you can do to cut down on fraud."

The GAO report in question lists 59 recommendations and points out that 55 of the recommendations had been fully or partially implemented. The report itself indicates that only 4 of the 59 recommendations had not been implemented.

This simply reinforces the point that tinkering with and policing the current system is not the answer. A complete overhaul of the system such as is recommended in the President's $10 billion block grant is the only lasting answer.

But - what on the 4 - do we can we Do Then?

Jimmy Carter said Tuesday he will confront President Ford during their debates with charges that waste and fraud cost the nation up to half of its Medicaid funds.

Calling the problem "a national disgrace," Carter told a senior citizens rally in Phoenix: "The Republican administration has not provided tough, competent management to make our scarce health dollars go to help patients or to prevent disease."

Asked whether he would raise problems of the aged in his debate with Ford on Sept. 23 Carter declared: "Yes, I will... I'd like to know why President Ford voted against Medicare. I'd like to know why, after eight years of a Republican administration we're still losing 25 to 50 percent of all the Medicaid money that's supposed to be for good health care and why HEW in the Republican administration hasn't enforced the laws or listened to the GAO that said there are 59 things you can do to cut down on fraud."

Carter's remark about the President's opposition to Medicare apparently was a reference to Ford's voting record against Medicare when he was in the House.

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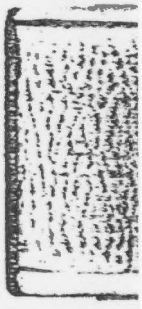

STATUS AS OF DECEMBER 1, 1975, OF IMPLEMENTATION OF SELECTED GAO RECOMMENDATIONS TO CONTROL UNNECESSARY MEDICAID COSTS

Summary Table

Purpose of recommendation	Recommendation number (note a)		
	Fully or substantially implemented	Partially implemented	Not implemented
Modify method of reimbursing providers	M-1	K-1, M-2, S-3	None
Increase share of cost borne by beneficiary	None	None	None
Reduce unneeded utilization	U-1	K-2, L-2, M-3, N-1, P-1, P-2, U-8	Q-1, U-9
Change benefits or eligibility criteria	None	None	None
Emphasize use of more cost effective providers	R-1, R-2, R-3, S-1, S-2	R-4, R-5, R-6, R-7, R-8, S-4, S-5, S-6, S-9, T-5	None
Improve management to control overpayments, abuses, and fraud	U-2	L-3, U-3, U-4	L-4
Reduce administrative costs	None	O-3	None
Strengthen Federal administration	T-1	K-3, N-2, S-7, S-8, T-8, U-5, U-6, V-1	None
Other	L-1, T-2	O-1, O-2, O-4, O-5, O-6, T-3, T-4, T-6, T-7, U-7, V-2, V-3	N-3

a/The letter indicates the report and the number indicates the recommendation.

FYI

cc: Johnson

Health file

September 20, 1976

1976 SEP 20 PM 3 10

MEMORANDUM FOR: JACK MARSH
JIM CANNON
JIM LYNN

FROM: MAX FRIEDERSDORF

John Rhodes and the AMA have called in support of the Indian Health bill.

cc Johnson

MFC

092019

C

cc: Massengale, Quern

THE WHITE HOUSE

WASHINGTON

September 21, 1976

MEMORANDUM FOR: JAMES E. CANNON

FROM: JAMES E. CONNOR JEC

SUBJECT: Guidelines for Conducting Genetic Research

The President reviewed your memorandum of September 18 on the above subject and signed the attached memorandum and letters.

The Signed documents have been forwarded to Robert Linder for appropriate handling.

cc: Dick Cheney
Robert Linder

THE WHITE HOUSE

WASHINGTON

September 9, 1976

MEMORANDUM FOR: PHIL BUCHEN
ROBERT T. HARTMANN
JACK MARSH
MAX FRIEDERSDORF
JIM LYNN
GUY STEVER

FROM: JIM CANNON

SUBJECT: PRESIDENTIAL LETTERS TO SENATORS KENNEDY AND JAVITS

Attached for your comments and recommendations are two drafts for the President's signature.

The first is a memorandum to all Department and Agency heads concerning their participation in an interagency committee formed to coordinate federal action in recombinant DNA experiments. Scientists had declared a self-imposed moratorium on such experiments for two years while they awaited guidelines from NIH. These guidelines were issued in June. The President's memo is to assure the cooperation and participation of each Department and Agency conducting or supporting recombinant DNA experiments with the interagency committee and the guidelines.

The second is a draft response to Senators Kennedy and Javits. Their letter to the President is also attached. They are concerned that the NIH guidelines are not sufficient and suggest further action. Senator Kennedy has also scheduled hearings on recombinant DNA experimentation for October 22.

Because we would like to present these to the President for his action as soon as possible, I would appreciate having your comments and recommendations sent to Sarah Massengale, Room 220, Ext. 6776 by 3:00 p.m., Thursday, September 9.

Thank you.

THE WHITE HOUSE

WASHINGTON

September 9, 1976

MEMORANDUM FOR: PHIL BUCHEN
ROBERT T. HARTMANN
JACK MARSH
MAX FRIEDERSDORF
JIM LYNN
GUY STEVER

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Thank you.

THE WHITE HOUSE

WASHINGTON

DRAFT

MEMORANDUM FOR FOR THE HEADS OF DEPARTMENTS AND AGENCIES

On June 23 the Department of Health Education and Welfare 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 object 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. Recombinant DNA research has strong potential in medicine as well as in science and technology generally. There are risks, however. The NIH guidelines prohibit certain types of experiments; other experiments will go forward under special safety conditions. The provisions will afford protection with a wide margin of safety to workers and the environment while permitting research to proceed.

HEW 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. Of special concern to the public is the extension of these guidelines beyond the purview of NIH.

In light of the great public concern, Secretary Mathews will be convening an interagency committee. The purpose of the committee will be to review Federal policies on the conduct of research involving recombinant DNA.

Since there are no precedents for an endeavor of this sort, I am issuing this directive to assure the participation of each department and agency conducting or supporting recombinant DNA experiments. Secretary Mathews will take the lead in this, but it is essential that all Federal Department and Agency Heads give him their full cooperation.

Thank you.

Gerald R. Ford

The Honorable Edward M. Kennedy
Chairman, Subcommittee on Health
Committee on Labor and Public Welfare
United States Senate
Washington, D. C. 20510

DRAFT

Dear Mr. Chairman:

I am writing in response to your and Senator Javits' letter of July 19 concerning the National Institutes of Health (NIH) Guidelines on Recombinant Deoxyribonucleic Acid (DNA) Research. As you note in your letter, the Guidelines were developed over an 18-month period and involved the participation not only of the scientific community but of the public as well.

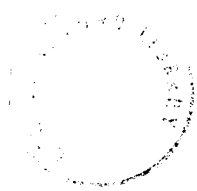
The potential scientific and medical benefits in this research area are promising. Support for the research is merited with appropriate safeguards against possible hazards. The decision of the Director, NIH, that accompanied the release of the Guidelines explained in great detail the care and consideration given stated public concerns for safety.

The application of these Guidelines beyond the NIH to the public and private sectors indeed merits further consideration. In order to provide this review, Secretary Mathews has proposed 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. The committee could also coordinate activities with non-Federal institutions. I have written to all Department Secretaries urging their cooperation and participation in naming representatives to serve on this proposed committee.

The committee will perform a number of duties. It will answer questions; facilitate compliance with the Guidelines in the public and possibly private sectors; and provide coordination among several Government agencies that support and conduct this research. Further, the committee will report to Secretary Mathews and my office on appropriate executive or legislative actions that might be required as a result of their policy review. By this means I believe the concerns you address in your letter will receive careful attention. You will be apprised of the deliberations of this committee and any recommendations that may be forthcoming.

I want to thank you very much for your thoughtful letter.

Sincerely yours,



Same reply to Senator Javits

Perpich, NIH/OD, 496-3152

7-22

United States Senate
COMMITTEE ON
LABOR AND PUBLIC WELFARE
WASHINGTON, D.C. 20510

July 19, 1976

The President
The White House
Washington, D.C.

MF

Dear Mr. President:

For several years, the biomedical research community has been engaged in an extremely important debate over the safety of certain types of genetic research. The research involves combining genetic material from different organisms. The technology that permits this type of genetic experimentation, called recombinant DNA research, is revolutionary, and holds the promise of enormous benefits in our understanding of disease processes, and could lead us to ways of controlling or treating complex diseases such as cancer and hereditary defects. It could conceivably lead to improved ways of producing such important hormones as insulin, clotting factors, and enzymes important to treatment of many diseases. The technology also has conceivable applications in agriculture and industry. Clearly, it is a research area of enormous promise.

However, recombinant DNA research also entails unknown but potentially enormous risks due to the possibility that micro-organisms with transplanted genes might prove hazardous to human and other forms of life--and might escape from the laboratory. Indeed, scientists engaged in such research declared a voluntary moratorium on recombinant DNA research in 1974 when they foresaw the possibility, for example, of creating in the laboratory self-propagating infectious bacteria that contain genes from cancer-causing viruses. The moratorium was lifted in 1975, but maintained, again by the researchers themselves, for the specific types of experiment which might produce cancer-causing bacteria, raise the resistance of antibiotics of known bacteria, or have other dangerous results.

On June 23rd of this year, the National Institutes of Health issued comprehensive guidelines for recombinant DNA research which specify more stringent safety and containment measures than are currently required or practiced in many areas. They specifically prohibit the most potentially dangerous types of experiments. In addition, the guidelines prohibit the release into the air or water or environment of any of the genetic materials created by the research.

We appreciate the great care NIH has taken, in the formulation of these strict guidelines, in obtaining the best scientific advice as well as advice from experts in law and ethics. Opportunity was also given for the public to comment on the guidelines. The environmental impact assessment of the guidelines currently being prepared by NIH will offer further opportunities for such comment.

The guidelines will be widely discussed and debated with regard to their ultimate adequacy in safeguarding the public, and they will no doubt further evolve and develop during this debate and as our understanding of recombinant DNA advances. Based on the process by which NIH produced the present guidelines, we are confident they are a responsible and major step forward and reflect a sense of social responsibility on the part of the research community and the NIH.

However, we are gravely concerned that these relatively stringent guidelines may not be implemented in all sectors of the domestic and international research communities and that the public will therefore be subjected to undue risks. The National Institutes of Health has the authority to require adherence to the guidelines as a condition of their grants and contracts for research, but they cannot enforce the guidelines with respect to other Federal agencies, with respect to research in the private sector in this country, and with respect to research done in other nations.

In particular, it is clear that recombinant DNA research has great potential in the private sector, such as pharmaceutical manufacture, the oil industry and agricultural products. It is also clear that some elements of the guidelines, such as limitations on the size of experiments, public disclosure, and non-release of materials into the environment, may be contrary to the interest and practice of research in private industry, and may therefore be ignored. In addition, since private sector research will lead to industrial application, guidelines must be extended beyond research into application and production stages. If the NIH guidelines are necessary to protect the public in Federally funded research, it is clear they are necessary for privately funded research and application as well.

Given the high potential risks of this research, it seems imperative that every possible measure be explored for assuring that the NIH guidelines are adhered to in all sectors of the research community. We urge you to implement these guidelines immediately wherever possible by executive directive and/or rulemaking, and to explore every possible mechanism to assure compliance with the guidelines in all sectors of the research community, including the private sector and the international community. If legislation is required to these ends, we urge you to expedite proposals to Congress.

This is an unprecedented issue in the area of biomedical research. It has been likened in importance to the discovery of nuclear fission. In the interest of public safety, and in the interest of permitting this beneficial research to continue with the blessing of a reassured public, we must act expeditiously on these matters.

Sincerely,

Jacob K. Javits
Ranking Minority Member
Committee on Labor and
Public Welfare

Edward M. Kennedy
Chairman
Subcommittee on Health

Health

THE WHITE HOUSE

WASHINGTON

September 21, 1976

Dear Mr. Bolger:

Thank you for your letter of August 19 enclosing a copy of the resolution recently passed by the NACDS Board of Directors. I am interested in the establishment of effective Federal health care programs and appreciate your help in keeping me informed.

Again, thank you.

Sincerely,

James M. Cannon
Assistant to the President
for Domestic Affairs

Robert J. Bolger
President
National Association of Chain
Drug Stores, Inc.
1911 Jefferson Davis Highway
Arlington, Virginia 22202

cc: Spence Johnson

NATIONAL ASSOCIATION OF CHAIN DRUG STORES, INC.
1911 JEFFERSON DAVIS HIGHWAY, ARLINGTON, VIRGINIA 22202, Telephone 703-521-1144

JEROME A. WEINBERGER, CHAIRMAN OF THE BOARD
ROBERT J. BOLGER, PRESIDENT

August 19, 1976

Mr. James A. Cannon
Assistant for Domestic Affairs
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear Mr. Cannon,

Enclosed is a copy of a resolution recently approved by the NACDS Board of Directors which urges a postponement of at least six months of the Department of Health, Education and Welfare's (HEW) Maximum Allowable Cost/Estimated Acquisition Cost (MAC/EAC) regulations.

We are bringing this matter to your attention because of your interest in the establishment of effective, efficient Federal health care programs.

If you have any questions regarding this matter, we would welcome the opportunity to discuss them with you.

Sincerely yours,

Robert J. Bolger
President

ch

August 19, 1976

The Honorable Gerald Ford
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear Mr. President:

We, the National Association of Chain Drug Stores' (NACDS) Board of Directors, approved the following resolution at a special meeting on Tuesday, August 17, 1976. NACDS represents 10,000 retail pharmacies throughout the United States, and a 68.8% share of the retail drugstore market. We request your immediate attention and strongly urge a minimum six month postponement of the Department of Health, Education and Welfare's (HEW) Maximum Allowable Cost/Estimated Acquisition Cost (MAC/EAC) program. The importance and timeliness of the situation is critical to our industry and the entire health care delivery system.

RESOLUTION

WHEREAS, the Department's MAC/EAC program is inherently arbitrary, discriminatory and inequitable; and

WHEREAS, the program is without adequate scientific and technological data to support implementation of it; and

WHEREAS, the implementation of the program has created extreme confusion among the state programs; and

WHEREAS, the health care industry support of the program is totally absent; and

WHEREAS, above all, total costs and projected savings of the MAC/EAC program have not been determined; and

WHEREAS, the critical question of availability of state funds for this program has not been answered; and

WHEREAS, the EAC provisions under the MAC program have been severely damaged by an industry document which was not formally submitted to HEW;

BE IT THEREFORE RESOLVED, that in the interest of providing efficient quality health care services to recipients and providing acceptable cost controls for drug products, the National Association of Chain Drug Stores strongly urges that the Secretary of Health, Education and Welfare postpone the implementation of the MAC/EAC program for a minimum period of six months.

BE IT FURTHER RESOLVED, that NACDS is extremely willing to work with the Department toward the development of alternative approaches which would make the MAC/EAC regulations a realistic and efficient Federal drug reimbursement program.

NACDS Board of Directors:

Robert B. Begley
Begley Drug Company
Richmond, Kentucky

S.H. Ashcraft
Craft's Drug Stores
Spartanburg, South Carolina

Ray A. Shapero
Cunningham Drug Stores, Inc.
Detroit, Michigan

Milton L. Elsberg
Drug Fair, Inc.
Alexandria, Virginia

David H. Rankin
Eckerd Drugs, Inc.
Charlotte, North Carolina

Henry A. Pansaci, Jr.
Fay's Drug Co., Inc.
Liverpool, New York

J.A. Weinberger
Gray Drug Stores, Inc.
Cleveland, Ohio

A.F. Hook
Hook Drugs, Inc.
Indianapolis, Indiana

Stewart Turley
Jack Eckerd Corporation
Clearwater, Florida

Sydney J. Besthoff, III
Katz & Besthoff, Inc.
New Orleans, Louisiana

Joseph M. Long
Longs Drug Stores, Inc.
Walnut Creek, California

Richard C. Hilden
Osco Drugs, Inc.
Oak Brook, Illinois

E.B. Hart
Pay Less Drug Stores N.W., Inc.
Beaverton, Oregon

Sheldon W. Fantle
Peoples Drug Stores, Inc.
Alexandria, Virginia

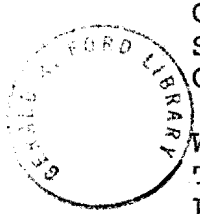
Roger H. Nattans
Read's, Inc.
Baltimore, Maryland

Sidney Dworkin
Revco D.S., Inc.
Twinsburg, Ohio

Alex Grass
Rite Aid Corporation
Harrisburg, Pennsylvania

Walter N. Corrigan
The Sommers Drug Stores Company
San Antonio, Texas

George W. Keith
SupeRx Drugs Corporation
Cincinnati, Ohio



William H. Harrison
Taylor Drug Stores, Inc.
Louisville, Kentucky

Louis L. Avner
Thrift Drug Company
Pittsburgh, Pennsylvania

C.R. Walgreen, III
Walgreen Drug Stores
Deerfield, Illinois

Robert J. Bolger
President
NACDS
1911 Jefferson Davis Highway
Arlington, Virginia 22202