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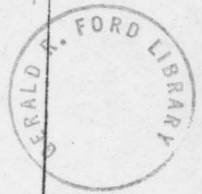
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Health

THE WHITE HOUSE
WASHINGTON

5/1/76



Art -

Very good

charts -

We ought to
begin preparing
a briefing on
health, somewhat
like Parsons'
briefing on Drugs.

Jim



The Size and Shape of the Medical Care Dollar



May 5, 1976

Office of the White House Press Secretary

THE WHITE HOUSE

TO THE CONGRESS OF THE UNITED STATES:

I am pleased to transmit to the Congress the Third Annual Report on the Administration of the National Sickle Cell Anemia Control Act (P.L. 92-294) in accordance with the requirements of Section 1106 of the Public Health Service Act.

Sickle cell anemia is the most common genetic blood disorder in the United States. It is found predominantly, but not exclusively, in the black population where it affects nearly 50,000 persons. The individual cost of sickle cell anemia is tremendous; in addition to medical care and loss of time from school or employment, the resulting psychosocial and educational problems makes advancement against this disorder of highest priority.

This year's report highlights the progress made in the implementation of the National Sickle Cell Disease Program and other related activities of the Public Health Service carried out by the National Institutes of Health, the Center for Disease Control, and the Health Services Administration. We have continued to move ahead in the areas of research, education and public awareness, screening and counseling, and rehabilitation.

Fifteen comprehensive Sickle Cell Centers have been established, bringing together all aspects of research -- basic, clinical, clinical application, and clinical trials. Continuing education and community demonstration programs have been included as integral parts of this important effort. This combination will permit the Centers to develop new and innovative approaches to education, testing, counseling and rehabilitation.

Also, last year 25 Sickle Cell Screening and Education Clinics provided information to more than one million persons, screened approximately 233,000 individuals, counselled more than 16,000 and referred many for appropriate medical care.

This activity is extremely important because the sickle cell trait is found in approximately two and one-half million black people. Although the sickle cell trait is primarily a healthy state wherein one carries genes for both sickle hemoglobin and normal hemoglobin, the blood disorder occurs as a result of the presence of genes for sickle hemoglobin inherited from both parents.

The National Institutes of Health is conducting intense investigations into the mechanisms of sickling in sickle cell anemia and subsequent complications, as well as carrying out therapy trials to alter the sickling process.

more



We must continue to push ahead for new knowledge and methodologies for the diagnosis, control and treatment of sickle cell anemia, as well as carrying on and improving existing screening and counseling, information, and education and training activities.

The progress made in the last year is heartening and sickle cell anemia program activities will continue to be of the highest priority. I am pleased to present this report to the Congress.

GERALD R. FORD

THE WHITE HOUSE,
May 5, 1976

#



RED TAG

THE WHITE HOUSE
WASHINGTON

May 13, 1976

MEMORANDUM FOR: JIM CANNON

THROUGH: MAX FRIEDERSDORF *m.b.*
CHARLES LEPPERT, JR. *CLJ*

FROM: PATRICK ROWLAND *PR*

SUBJECT: Rep. Paul Rogers (D-Fla.)

Rep. Rogers had requested the information regarding the Administration's stand on his drug bill, H.R.12391. Attached is a copy of that bill.

The proposals in his bill should not be confused with the Administration's bill which was sent up two weeks ago and introduced by Rep. Robert McClory (H.R.13577).

Roger's bill deals with the labeling of drugs and significant health hazards of pharmaceuticals, while the Administration proposals deal with illegal drug trafficking.



THE WHITE HOUSE

WASHINGTON

May 24, 1976

MEMORANDUM FOR: JIM CANNON

FROM: SARAH MASSENGALE *SM*

Attached is a letter for your signature to Senator Frank Moss who wrote the President concerning the transfer of the National Institute for Occupational Safety and Health functions and staff from the Western Area Laboratory in Salt Lake City.



THE WHITE HOUSE
WASHINGTON

May 24, 1976

file
Health
Gen.

Dear Senator Moss:

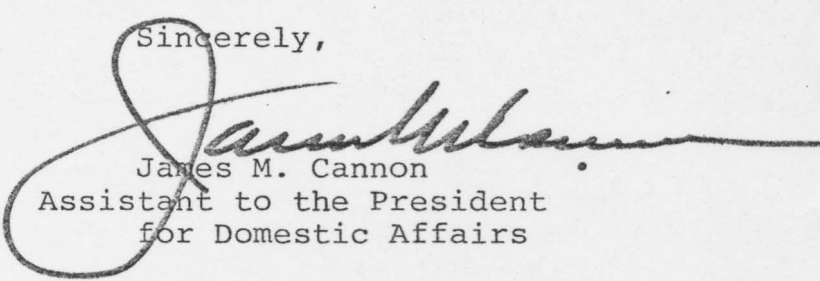
The President has asked me to respond to your letter about the transfer of the National Institute for Occupational Safety and Health (NIOSH) functions and staff from the Western Area Laboratory in Salt Lake City.

Because of the concern that you and others have expressed in this matter, Secretary Mathews has assured me that he will examine the proposal very carefully before making a final decision. I appreciate your concern; let me assure you that this decision will not be made arbitrarily, but on the basis of whether operations will be more efficient and whether NIOSH will be better able to accomplish its mission.

Each concerned member of Congress will be notified. There was no intent to forego this courtesy. As a matter of fairness, the 21 affected persons were informed without delay of the proposed transfer of functions.

As soon as Secretary Mathews has reviewed this matter, he will be getting back in touch with you.

Sincerely,


James M. Cannon
Assistant to the President
for Domestic Affairs

Honorable Frank E. Moss
United States Senate
Washington, D.C. 20510



file

THE WHITE HOUSE

WASHINGTON

May 25, 1976

Dear Mr. Parfet:

Thank you for your letter to the President expressing concern about the Maximum Allowable Cost (MAC) drug regulations proposed by the Department of Health, Education and Welfare.

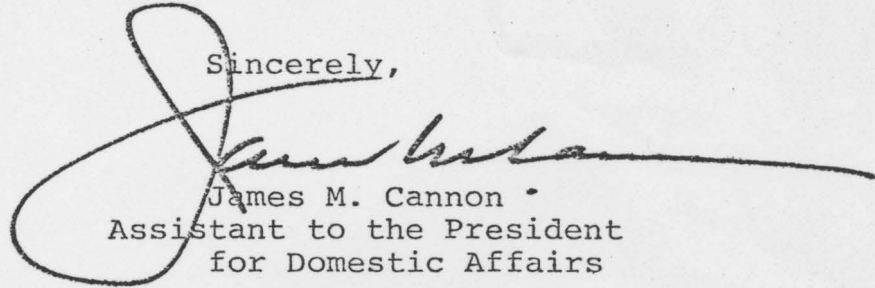
As you are probably aware, on April 5, 1976, Secretary Mathews announced his decision to delay implementation of the regulations from April 26 until August 26, 1976. This decision was made solely by the Secretary on the recommendation of the Pharmaceutical Reimbursement Board, which oversees the drug cost control program and which is chaired by Dr. Theodore Cooper, HEW Assistant Secretary of Health.

The purpose of the four month delay is to allow additional time for State Medicaid programs to become familiar with cost guidelines being prepared by HEW and to conduct studies of pharmacy operating costs.

I have sent a copy of your letter to the Department for their information.

If I may be of further assistance, please do not hesitate to contact me.

Sincerely,



James M. Cannon
Assistant to the President
for Domestic Affairs

Mr. R. T. Parfet, Jr.
Chairman of the Board
The Upjohn Company
Kalamazoo, Michigan 49001



RECEIVED
JUL 29 1976

CENTRAL FILE

THE WHITE HOUSE

WASHINGTON

SIGNING CEREMONY
MEDICAL DEVICE AMENDMENTS OF 1976
(Enrolled Bill S. 510)

Friday, May 28, 1976
12:00 p.m. (10 minutes)
The Oval Office

From: Jim Cannon



I. PURPOSE

To sign into law Enrolled Bill S. 510, Medical Device Amendments of 1976 which provides new authority to the Secretary of Health, Education, and Welfare to assure the safety and effectiveness of medical devices intended for human use.

II. BACKGROUND, PARTICIPANTS, PRESS PLAN

A. Background: S. 510 would amend the Federal Food, Drug and Cosmetic (FDC) Act of 1938 to provide the Food and Drug Administration (FDA) in the Department of Health, Education and Welfare (HEW) with significant new authority to regulate the safety and effectiveness of medical devices. The enrolled bill is the first amendment to the FDC Act since 1938 dealing with medical devices and represents several years of work by the Executive branch and the Congress to develop acceptable legislation to assure that modern medical devices are safe and effective.

B. Participants:

Secretary David Mathews
Dr. Theodore Cooper, Assistant Secretary of Health
Dr. Alexander Schmidt, Commissioner, FDA
Sylvester Jones, Intern for Secretary Mathews



- C. Press Plan: No announcement. White House photo opportunity.

III. TALKING POINTS

1. I am pleased to sign into law the Medical Device Amendments of 1976 which will give the Secretary of Health, Education and Welfare new authority to assure safe and effective medical devices for America's medical system.
2. These amendments will give the Food and Drug Administration the ability to do for the individual citizen what he or she cannot do for themselves -- prevent the sale or use of unsafe or ineffective medical devices.
3. The FDA faces a most difficult task that requires determination, scientific skills, judgement, and most of all, compassion for the hopes and needs of our fellow man.
4. I commend the Congress, HEW, and the FDA for their fine work and cooperation.

[June 1976]



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

EYES ONLY

THE HONORABLE RICHARD B. CHENEY
✓ THE HONORABLE JAMES M. CANNON

This note is to alert you to the fact that I will be bringing to the President's attention (for information unless he feels otherwise) a guideline from the National Institutes of Health to control research in the very sensitive field of genetic engineering. Biological scientists can now actually change the basic building blocks of all life, genes, and are themselves suggesting controls on this research.

We will have our materials on this subject ready by the end of the month.


Secretary

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

OFFICIAL BUSINESS

POSTAGE AND FEES PAID
U.S. DEPARTMENT OF H.E.W.

File
Health

EYES ONLY

1976 JUN 4 AM 9 25

REC'D AND SECURITY UNIT
THE WHITE HOUSE
WASHINGTON

The Honorable James M. Cannon
The White House

EYES ONLY

Cannon fye

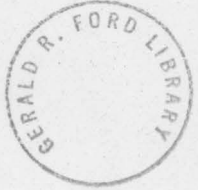
THE WHITE HOUSE

WASHINGTON

DECISION

Last Day: June 5, 1976

June 3, 1976



MEMORANDUM FOR: THE PRESIDENT
FROM: JIM CANNON *s by JHC*
SUBJECT: Enrolled Bill H.R. 12132 - Extension
of District of Columbia Medical and
Dental Manpower Act of 1970

Attached for your decision is H.R. 12132, a one-year extension of the District of Columbia Medical and Dental Manpower Act of 1970.

Background

H.R. 12132 authorizes \$9 million to continue financial support for one year to Georgetown and George Washington Universities Schools of Medicine and Dentistry. Grants of \$5,000 per medical student and \$3,000 per dental student would be authorized.

When you signed an extension of the D.C. Medical and Dental Manpower Act of 1970 in 1974, you indicated that both universities should seek other alternatives, such as the District of Columbia Government, for a long-term solution to their medical school financing needs.

The schools are making this effort. The District government, however, has refused financial support.

The medical schools are in the process of implementing a guaranteed student loan program to be financed by private funds through local and national banking institutions. This long-term solution, however, will not be established until FY 1978. The medical schools have indicated that they have exhausted every possible funding alternative during the last six months and failure to approve H.R. 12132, as an emergency measure, would have serious consequences to their fiscal viability as well as creating undue financial hardships for their students.

Arguments for Approval

1. Your statement of two years ago is having the desired effect; the schools are moving toward other sources of funding.
2. Although you suggested that the District government assume some of the financial responsibility, it has refused because of its financial position.
3. Proponents say that the schools are a "national resource" and deserve special national support, since the student population is drawn from all 50 States and the District of Columbia. Nearly 11,000 graduates are located throughout the United States.
4. Each of the schools has assured the Administration that loans will be available to students beginning in FY 78 and that this will be the last time that either will seek preferential Federal funding.
5. Additionally, the denial of funds would have the most deleterious effect on minority and low income students. The sizeable tuition increases could cause a significant number of these individuals to be unable to continue their medical studies.

Arguments Against Approval

1. In August 1974, when signing the last extension of the 1970 Act, you stated that this would be the last time you intended to sign legislation singling out medical and dental schools for favored treatment simply because of their geographic location. This statement was repeated before both the House and Senate Committees by HEW in testimony on H.R. 12132.
2. Opponents say that these institutions should not receive preferential funding treatment solely on the basis of their location in the District of Columbia.
3. Opponents say that the arguments that other private medical and dental schools receive State financial support and that these schools are "national resources" are not valid. Not all private medical schools receive State funds.

4. In addition to capitation funds, these schools have received special financial distress awards for several years but still have not corrected administrative and management deficiencies that contributed to their current fiscal conditions.

Staff and Agency Recommendations

HEW	Disapproval. "The bill would provide for unjustified special funding for medical and dental schools in the District of Columbia."
OMB	Disapproval. "Enactment of such preferential legislation would be bad public policy." (Jim Lynn's memo is attached at Tab A.)
Buchen (Lazarus)	Approval (without signing statement). "It would be unnecessarily harsh to refuse to tide them over the next year, especially in view of the President's support over the years for the efforts of both universities."
Friedersdorf	Approval. "Senator Beall called personally to request bill be signed. He regards signing as very important. . . . Veto would be extremely difficult to sustain in either House."
Hartmann	Approval.

Recommendation

Because the Universities are arranging other sources of financial support and because the financial burden of the tuition increase would fall most heavily on minority and low income students now enrolled,

I recommend that you sign H.R. 12132 approving a final one-year extension of financial support.

I also recommend that no signing statement be issued.



Decision

1. _____ Approve H.R. 12132
(Buchen, Hartmann, Friedersdorf, Cannon)
2. _____ Approve H.R. 12132 and issue signing statement
(attached at Tab B; to be approved by Robert T.
Hartmann)
3. _____ Disapprove H.R. 12132 and issue veto statement
(attached at Tab C; text approved by Robert T.
Hartmann)
(HEW, OMB)

The enrolled bill is attached at Tab D.



DRAFT SIGNING STATEMENT

I have reluctantly signed H.R. 12132, a bill to extend for one year the District of Columbia Medical and Dental Manpower Act of 1970.

Two years ago, I extended this Act to avoid disrupting the programs of the George Washington and Georgetown University medical and dental schools during the District of Columbia's interim status with regard to home rule government. At that time I stated that these medical and dental schools should not continue to receive favored treatment by the federal government simply because of their geographic location. Moreover, the Congress agreed and indicated that the best sources for funds in the future would be by the District of Columbia government.

My opinion has not changed. The medical schools, however, have assured the Administration and the Congress that they have undertaken agreements to secure guaranteed student loans for increased tuition costs to meet future funding needs. Although each student will be required to assume additional financial burdens the availability of loans for those who need them will be assured.

Also, the medical schools have pursued the question of funding from the District of Columbia government. The District, however, has indicated to both the schools and the Congress that because of its precarious financial situation no local funds will be available for FY 1977.

Since the medical schools have taken an initiative to secure funding for FY 1978, and since they have been denied funds for support from the District of Columbia for FY 1977, I believe a final one year extension is appropriate.

Additionally, the denial of funds to the George Washington and Georgetown University medical and dental schools, would have the most deleterious effect on minority and low income students currently enrolled. The sizeable tuition increases that would be necessary to absorb the deficit for next fiscal year could cause a significant number of these individuals to be unable to continue their medical studies.

The Congress and I agree that this must be the final instance of special treatment for the George Washington and Georgetown University medical and dental schools. The

District of Columbia government should make arrangements to provide a reasonable amount of assistance to these schools in return for meeting the District's medical manpower needs and medical services requirements. At the same time, the medical schools must fulfill their pledge to secure other non-federal funding for FY 1978 and beyond.

to extend for one year the District of Columbia Medical and Dental Manpower Act of 1970.

H.R. 12132 would continue to single out three schools--the George Washington University medical school and the Georgetown University medical and dental schools--for special Federal subsidies. The bill is designed to provide preferential Federal funding to these schools amounting to \$5,000 for each medical student and \$3,000 for each dental student based solely on the schools' location in the District of Columbia. These subsidies would be available without regard to the ability of the schools to meet the statutory requirements which must be met by all other medical and dental schools in the United States in order to qualify for Federal financial distress grants.

Two years ago, I reluctantly signed into law an extension of this Act--P.L. 93-389. I did so in order to avoid disrupting the services provided by these three institutions during the District of Columbia's interim status with regard to home rule government. I stated, however, that that would be the last time I would sign legislation singling out medical and dental schools for favored treatment simply because of their geographic location. Moreover, the House and Senate reports accompanying P.L. 93-389 indicated that future special funding would come through the budget of the District of Columbia.

The medical and dental schools at Georgetown and George Washington now receive Federal institutional support funds i.e., capitation grants, on the same basis as other medical and dental schools in the United States. They are also

eligible for special project grant support including the "financial distress" grants that help institutions meet special financial problems. Last year, for example, Federal capitation grants alone amounted to \$1.2 million for Georgetown University medical school; \$1 million for George Washington University medical school; and \$804,000 for Georgetown University dental school.

Over the years, these schools have also benefited from financial distress awards which Congress designed as temporary assistance to schools while they reformed their finances. For example, one third of the total funds nationally available for financial distress for all health professions schools in 1974--\$4.9 million--went to Georgetown University and George Washington University.

In 1975, special Federal grants in the amount of \$7.5 million were awarded for the first time to these schools under the District of Columbia Medical and Dental Manpower Act after their applications for financial distress assistance were recommended for disapproval by the National Advisory Council on Health Professions Education. This fiscal year Congress appropriated \$9 million under the District of Columbia Medical and Dental Manpower Act.

I do not believe that there is ^{sufficient} justification ^{on} ~~based upon~~ grounds of either need or equity, to continue to ~~single~~ ^{favor} ~~out~~ these two institutions ^{over} ~~from~~ the entire ^{list} ~~universe~~ of private medical and dental schools in the United States for ^{such a} ~~special~~ preferential subsidy by the general taxpayer.

THE WHITE HOUSE

May , 1976

*Sighted by Smith
WJ 3/3/76*

THE WHITE HOUSE
WASHINGTON

file
Health
INFORMATION

MEMORANDUM FOR THE PRESIDENT

FROM: JIM CANNON

SUBJECT: Flu Program Bi-Weekly Status Report

Attached is Secretary Mathew's bi-weekly report on the National Influenza Immunization Program for the period ending June 15, 1976.

In his report, the Secretary makes reference to the continuing legal problem of indemnifying vaccine manufacturers against claims for injuries arising out of the government's program. On Wednesday of this week, the Secretary sent to the Congress legislation designed to permit the federal government to indemnify vaccine manufacturers against claims related to the inoculation program, except those arising out of the negligence of the manufacturers. The enactment of this proposal would provide the protection that the drug manufacturers are seeking.

In addition, the Secretary makes reference to the problem of sharing vaccine supplies with Canada and Mexico. As directed by your recent decision on this question, Canada has already been informed, through health channels, that the United States is willing to cooperate to the fullest extent possible in helping them meet their needs, depending on our own ability to meet the U.S. demands.

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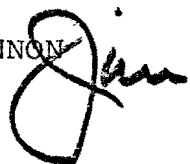
THE WHITE HOUSE

WASHINGTON

June 24, 1976

MEMORANDUM FOR: SECRETARY DAVID MATHEWS

FROM: JIM CANNON



We have your June 18 memorandum to the President requesting authority to create an advisory committee to coordinate among federal agencies policy and action pertaining to the conduct of research involving DNA.

After reviewing the memorandum, we would like to have more information on these questions:

What would be the charter of the Committee?

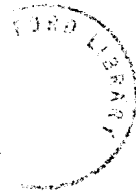
Who would the members be?

What is the relationship of the proposed committee to the requirements of the Federal Advisory Committee Act?

How does this relate to pending Congressional action to change the HEW Commission on the Protection of Human Subjects into a Presidential Commission?

We would appreciate having these and any other points you think appropriate in a proposal for the President's consideration.

Thank you.



THE WHITE HOUSE

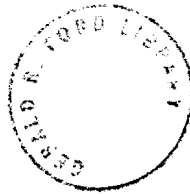
WASHINGTON

June 23, 1976

MEMORANDUM FOR: JIM CANNON

FROM: SARAH MASSENGALE *SM*

Attached is a memorandum for your signature to David Mathews concerning the creation of an advisory committee to coordinate among Federal agencies policy and action pertaining to the conduct of research involving DNA.





JAMES A. RHODES
GOVERNOR

STATE OF OHIO
OFFICE OF THE GOVERNOR
COLUMBUS 43215

cc: Spence Johnson
Steve McConahey

Health

June 29, 1976

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

Dear Jim:

At the urging of my Director of the Ohio Department of Health, I am writing to ask your help in overturning one of the regulations published June 3 with respect to Medicare Coverage of End Stage Renal Disease and the control of facilities providing care to patients suffering from such disease.

The objections of my Director of Health are supported by physicians in Ohio, the Board of Regents (the coordinating agency for our institutions of higher education), the deans of our medical schools, and our planning agencies. The main objection we hear voiced is that the State of Ohio has been split into two parts to which have been attached at one end the State of Kentucky and at the other Western Pennsylvania. This arbitrary cleavage ties Ohio to Regions III and IV although Ohio, itself, is in Region V.

Currently, End Stage Renal Disease affects only 700 to 800 patients in Ohio. By 1980, it is predicted that only 15-20,000 people in the whole nation will be directly affected, but the cost is predicted to be better than \$8 billion per year. Such extravagance need not overtake us if the ESRD program is handled rationally.

Ohio has already formally initiated a request for redesignation of network areas so that Ohio will become one network. I am asking your help in the matter because the present structure of networks neutralizes the possibility of obtaining assistance from the Regional Director of Region V at Chicago. A previous letter from my office to the Secretary of H.E.W. went unanswered for five months.

I am particularly concerned about the ESRD program because of the arbitrary way in which it is being handled, with non-representative administering and advisory bodies being set up to be responsible and accountable to no one but the Social Security Administration. For example, the Secretary chooses

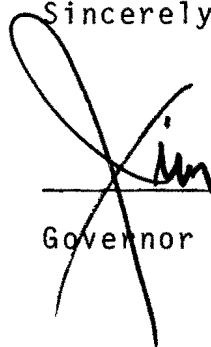
The Honorable James A. Cannon
Page 2
June 29, 1976

network Coordinating Councils for each network. The Councils then, in turn, appoint Medical Review Boards of not more than seven members. Such Boards then set the criteria and standards for care of all the renal patients in the network. This makes a problem because different physicians have different modes of treatment arising from differences in values. For example, some physicians emphasize freedom from pain, freedom from inconvenience, and freedom to pursue a happy life while other physicians emphasize length of life notwithstanding suffering. Patients usually attach themselves to physicians having the same value system as their own. This is the prime argument for an open referral system.

Under the regulations as promulgated, the governing body of each renal disease facility is required to follow the recommendations of the Medical Review Board. The arbitrariness of this arrangement is compounded by the fact that there is no appeal procedure.

As I have indicated, there are people in the Ohio Department of Health who are very much shaken by the total impact of the ESRD regulations. Typical of the bristling response evoked by the June 3 Regulations is a memorandum sent to one of my staff people by a physician who works closely with my Director of Health. I am sending you a copy of the memorandum, but to protect the innocent, I have deleted the name of its author. I have also deleted some observations at the end that do not pertain to the matters I have raised.

Sincerely,



A handwritten signature, appearing to be "Jim", is written over a horizontal line. Below the line, the word "Governor" is printed.

Governor

cc: Dr. Dorrain, Chief
Bureau of Medical Services

Dr. Ackerman, Director
Department of Health

