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MEETING ON SWINE INFLUENZA IMMUNIZATION PROGRAM

Wednesday, March 24, 1976
3:30 p.m. (one hour)
The Cabinet Room

From: Jim Cannon

I. PURPOSE

To discuss with influenza experts, medical professionals, public health officers, pharmaceutical executives, and public officials plans for a Federal initiative to immunize all Americans against swine influenza.

II. BACKGROUND, PARTICIPANTS & PRESS PLAN

A. Background: On Monday, you met with Secretary Mathews, Dr. Ted Cooper, Jim Lynn, Paul O'Neill, Jim Cavanaugh and me about a possible outbreak of swine influenza this coming winter. You directed that a meeting be convened with various experts and public officials to seek their evaluation of the extent of the problem and the appropriate course of action.

B. Participants: See attached list.

Special Note: Included in the participants are Dr. Jonas Salk and Dr. Albert Sabin who both played key roles in developing the two major types of polio vaccine.

C. Press Plan: To be announced. White House photo.

You would go to the press briefing room at the conclusion of the meeting and announce your decisions. (Statement to be provided).
III. TALKING POINTS

1. I have been following with great interest the recent developments concerning a possible outbreak of swine influenza next winter.

2. Monday, I received an update on the situation from Secretary Mathews and Dr. Cooper on the potential seriousness of this matter, and I directed them to convene this meeting.

3. I will ask both Secretary Mathews and Dr. Cooper to comment briefly on the situation that now confronts us. Then Dr. Sencer, Director of the Center for Disease Control, will present the details of our recent activities.

(AT THE CONCLUSION OF DR. SENCER'S REMARKS:)

4. Let me open the discussion by raising three questions of vital concern to me:
   a) I want to ask Dr. Salk, Dr. Sabin and Dr. Stallones if they feel that we have sufficient evidence that a potential epidemic exists to undertake a nationwide program of prevention.
   b) Mr. Hilleman could comment on the capability of the pharmaceutical industry to produce the quantities of vaccine to accomplish this program, and,
   c) I would like Dr. Fowinkle and Dr. Holden to address the question of whether the public and private sectors of medicine can mobilize effectively to achieve this objective.

(AT THE CONCLUSION OF RESPONSES TO THESE QUESTIONS:)

5. At this point, I would like to hear any additional comments or perspectives on these questions.

6. I would like to ask Secretary Mathews and Dr. Cooper to summarize the main points of our discussion and give me their recommendations.
Secretary F. David Mathews.

Dr. Theodore Cooper, Assistant Secretary for Health.

James F. Dickson, M.D., Deputy Assistant Secretary for Health.

Dr. Donald Frederickson, Director, National Institutes of Health.

Richard Krause, Director, National Institutes of Allergies and Infectious Diseases.

Dr. Harry M. Meyer, Director, Bureau of Biologics, Food and Drug Administration.

Dr. Alexander M. Schmidt, Commissioner of Food and Drugs, Food and Drug Administration.

Dr. David Sencer, Director, Center for Disease Control.

Staff

Jim Cannon
Jim Cavanaugh
Jim Lynn
Paul O'Neill
Spencer Johnson
Dick Cheney
Ron Nessen
Jack Marsh
Max Friedersdorf
Sarah Massengale

Dr. Bill Lukash
PARTICIPANTS


George Hardy, M.D., Health Officer, Jefferson County Health Department, Birmingham, Alabama.

Albert G. Randell, M.D., Director of Public Health, City of Houston, Texas.

Charles Hall, M.D., Charleston, West Virginia.

Merritt B. Lowe, M.D., Greenfield, Massachusetts.

Raymond Holden, M.D., Washington, D.C., chairman, A.M.A.

Morton S. Hilbert, MPH, CE, Chairman, Department of Environmental and Industrial Health, School of Public Health, University of Michigan, Ann Arbor.

Maurice R. Hilleman, Ph.D., Vice President, Merck, Sharp and Dohme Research Laboratories, West Point, PA.

John F. Lawlis, Ph.D., Vice President of Biological Operations, Merrell-National Laboratories, Swiftwater, PA.

Eugene A. Timm, Ph.D., Asst. Division Director, Quality Control and Government Regulations, Parke, Davis and Company, Detroit, Michigan.

Alan Gray, Ph.D., Director of Biologics, Merck, Sharp and Dohme, West Point, PA.

Alan Bernstein, Ph.D., Managing Director, Wyeth Laboratories, Inc., Marietta, Pennsylvania.

Dr. Fred M. Davenport, Department of Epidemiology, University of Michigan School of Public Health, Ann Arbor.

Reul A. Stallones, M.D., Dean, University of Texas School of Public Health, Houston.

Dr. Floyd Denny, University of North Carolina Department of Pediatrics, Chapel Hill.

Edwin Kilbourne, M.D., Chairman, Department of Microbiology, Mt. Sinai School of Medicine, City University of New York.

Saul Krugman, M.D., Department of Pediatrics, New York University School of Medicine.
Kenneth McIntosh, M.D., Department of Medicine and Pediatrics, University of Colorado Medical Center, Denver, Colorado.

Mrs. Dale Bumpers, Bethesda, Maryland.

Jasper Williams, M.D., President, National Medical Association, Chicago.

Jonas Salk, M.D., Salk Institute for Biological Studies, San Diego, California.

Albert B. Sabin, M.D., Medical University of South Carolina, Charleston.

Rosalie Abrahms, Senator, National Conference of State Legislatures, Annapolis, Maryland.

Francis Francois, Councilman, Prince Georges County, Upper Marlboro, Maryland.

Governor Philip Noel, Providence, Rhode Island.

Mayor Harvey Sloane, M.D., Louisville, Kentucky.
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MEMORANDUM FOR THE HONORABLE JAMES T. LYNN

Following is the information you requested regarding Federal purchase of vaccine.

1. Salk polio vaccine was licensed in 1955. During FY 1956 and 1957, the Federal Government purchased $53 million worth of vaccine (100% of production). The vaccine was distributed to the States through a grant mechanism on the basis of population (probably school age).

2. Measles vaccine was licensed in March 1963. The first Federal purchase was in the Fall of 1965. This amounted to less than 50% of the amount produced during 1965, 8 million doses. Until Federal purchase only some 100,000 doses had been purchased and used in public clinics. However, practically all the vaccine purchased by the Federal Government in 1965 went to public clinics.

3. Rubella vaccine was licensed in June 1969. The first Federal purchases occurred in July 1969, and during the ensuing 18 months 85% of the vaccine produced was given in the public sector, most purchased with Federal funds. Federal expenditures for vaccines during FY 1970 were approximately $17 million, and for FY 1971, approximately $8-9 million.

Theodore Cooper, M.D.
Assistant Secretary for Health
Congressional Notification of the President’s Program on Swine Influenza Immunization

On Monday the President met with Secretary Mathews and others about a possible outbreak of swine influenza this coming winter. The President, concerned with the potential seriousness of this situation, has convened a panel of influenza experts, medical professionals, public health officials, pharmaceutical executives, and public officials to discuss his plans for a Federal initiative to immunize all Americans against the swine influenza.

The meeting will take place in the Cabinet Room at 3:30 p.m. today. Following his discussion with the group, the President will announce his decision. You may want to notify key members of the Health Authorization and Appropriation Committees of the President’s decision at 4:00 p.m. this afternoon. The members include Congressmen Rogers, Carter, Flood, and Michel, and Senators Kennedy, Schweiker, Magnuson, and Brooke.

TALKING POINTS

1. I am calling to inform you that the President and Secretary Mathews are now meeting with influenza experts, medical professionals, public health officials, pharmaceutical executives, and public officials to discuss a possible swine influenza epidemic next winter.

2. This meeting is a result of a briefing on Monday by HEW detailing the potential seriousness of this situation.

3. The President will announce his decision to give the go-ahead to industry to produce enough vaccine to immunize every American.
4. The President will send up a $134 million supplemental appropriation request for the FY 1976 budget to support this necessary effort.

cc: Jack Marsh
MEMORANDUM FOR THE PRESIDENT

FROM: JIM CANNON

SUBJECT: Message to Congress on Swine Influenza Immunization Program

Attached for your signature are two copies of a special message to the Congress outlining your proposal to inoculate all Americans against a possible swine influenza epidemic.

The messages have been reviewed and approved by OMB (O'Neill), Doug Smith (for Robert T. Hartmann), and Jack Marsh.

RECOMMENDATION

I recommend you sign both copies of the message.
MEMORANDUM FOR THE PRESIDENT
FROM: JIM CANNON
SUBJECT: Proposed Supplemental for HEW Nationwide Influenza Immunization Program

OMB has prepared for your consideration the attached letter to the Speaker of the House transmitting a proposed 1976 supplemental of $135 million for the Department of Health, Education and Welfare's nationwide influenza immunization program.

Additional information is provided in Jim Lynn's memorandum at Tab A.

OMB, Max Friedersdorf, Counsel's Office (Lazarus) and I recommend approval of the letter to the Speaker of the House which has been cleared by Bob Hartmann.

RECOMMENDATION
That you sign the letter to the Speaker of the House at Tab B.
March 25, 1976

Dr. James H. Cavanaugh, Deputy Assistant
Domestic Affairs
The White House - Room 231
Washington, D. C. 20503

Dear Jim:

To follow up on our recent discussion, here is some background material on the final Medicaid Home Health Regulations presently awaiting the Secretary's signature. I will try to highlight those areas germane to the proprietary issue.

1. SRS/MSA developed several drafts of the regulations over the past two years. There has been only one Medicaid regulation (Section 249.10) on home health (copy attached) since passage of the law. Since 1965, there has been only a Policy Information Memo issued to the states (copy attached), which cannot even be called a guideline, since it is marked "For Internal Use Only" and, therefore, carries no weight.

2. On June 9, 1975, SSA issued proposed regs, under mandate from the Federal Courts, (finalized December 4, 1975) to allow non-profit agencies to subcontract for services with proprietary agencies. Otherwise, proprietaries can participate in Medicare only in those fifteen states that license home health agencies. Why all states don't license is beyond me.

3. On July 2, 1975, Secretary Weinberger sent his 1975 Medicare proposals to Congress in letter form (copy attached). These included a statutory change to include proprietaries, but were never put into bill form.

4. On August 8, 1975, Secretary Weinberger signed the proposed Medicaid regs and they were published in the Federal Register on August 21.
MEMORANDUM FOR: JIM CANNON
PAUL O’NEILL
ROBERT HARTMANN
THEODORE COOPER, M.D.
WILLIAM MORILL
FROM: SPENCER JOHNSON
SUBJECT: Presidential Memorandum to Departments and Agencies about the National Swine Influenza Immunization Program.

Attached is a draft memo for your IMMEDIATE comment. Hopefully the President can sign the memorandum and a public release made by noon tomorrow (Tuesday, March 30) before HEW begins a week of testimony on Capitol Hill in the afternoon on the program.

cc: Jim Cavanaugh
Art Quern
Sarah Massengale
Doug Smith
Jim Dickson
Victor Zafra
Memorandum for the Heads of Departments and Agencies

Last week I announced my intention for implementing a national influenza immunization plan to inoculate every American against swine flu.

Prior to 1930, this strain was the predominant cause of human influenza in the U.S. In fact, in 1918-19 it was the cause of an epidemic that killed an estimated 548,000 Americans -- and 20 million people worldwide. Since 1930, the virus has been limited to transmission among swine, with only occasional transmission from swine to man, and no secondary person-to-person transmission.

However, last month an outbreak of swine influenza was isolated among several hundred recruits at Fort Dix, New Jersey, and it was associated with one death. While it is not evident that the flu has spread beyond the Army base, the reappearance of this strain has caused great concern in the medical community. It was based on this concern and broad consultation with members of my Administration, health community leaders and public officials,
that I announced a program of effective countermeasures to prevent an outbreak of swine influenza this winter. Although the facts do not suggest that there is any cause for alarm, they do suggest the need for immediate action.

I have asked the Congress for a supplemental appropriation of $135 million for the manufacture of over 200 million doses of vaccine, additional medical equipment and assistance for the States to develop inoculation program plans. In addition, however, since there are no precedents for an endeavor of this magnitude, I am issuing this directive so that the task can be completed in an appropriate, orderly and timely manner.

The Secretary of HEW, David Mathews, through the Public Health Service, under the direction of Assistant Secretary for Health Dr. Theodore Cooper, will be primarily responsible for the development and implementation of this plan. I direct all federal departments and agency heads to offer full cooperation with HEW in carrying out this program.

The Public Health Service will proceed with the planning and implementation efforts to make the vaccine available to all Americans. This activity will be carried out in close coordination with the Center for Disease Control,
the Bureau of Biologics of the Food and Drug Administration, and the National Institutes of Health.

I expect that this program will take advantage of the strengths and resources of both the public and private sectors. The successful immunization of our population in the brief time available can be accomplished only by such cooperation.

In addition to the necessary Federal responsibilities, the plan will include the expertise of State and local health agencies in conducting immunization programs, and as logical distribution centers for vaccine. Also, the vast resources of professional personnel and facilities of the private sector must be mobilized.

NATIONAL INFLUENZA IMMUNIZATION PLAN OBJECTIVES

A. Production and Evaluation of the Vaccine.

The Federal government will initiate production of sufficient vaccine by pharmaceutical manufacturers to immunize the entire population. This will require an estimated 213 million doses. Testing and field trials will assure quality control and vaccine efficacy and effectiveness.
B. Professional Education.

A continuing information program will be directed at health professionals through direct communication, professional media and a Speakers Bureau for medical and health related meetings. This program of professional education by national health organizations is designed to increase immunization levels. Organizations will be encouraged to support this effort and to urge their state and local units to actively participate.

C. Public Awareness.

A nationwide citizen awareness program will be developed through a multi-media campaign to coincide with the availability of the vaccine. This national mass media campaign will be supported by State, regional and community awareness programs sponsored by local media and organizations.

D. Distribution and Inoculation Program.

In addition to the vaccine, the federal government will arrange for the procurement of additional equipment and supplies, such as jet guns, and cold chests for field transport of vaccine. State health agencies, with the technical assistance of the Center for Disease Control, will develop plans to immunize the people in their
States through a combination of official and voluntary action. Training material and assistance will be provided for those workers carrying out the program. The strategy will be to tailor the approach to the situation or opportunity, using mass immunization techniques where appropriate, but also using delivery points already in place, such as physicians' offices, health department clinics, community health centers, and public facilities.

E. Program Assessment and Evaluation
Since this is the first national mass immunization program undertaken evaluations must be made to assess the effectiveness of this effort in reducing influenza associated morbidity, hospitalization, and mortality in a pandemic period. Epidemiologic and laboratory surveillance of the population will be maintained to determine immediately disease trends and outbreaks in order to direct any necessary additional immunization and health efforts toward epidemic control.

These efforts are ongoing at this time by HEW and the Public Health Service. As I indicated, full interagency cooperation and preparedness will be expected so that we meet our goal of inoculating every man, woman, and child.
in the three month period from September through November. The Department of Defense is beginning its efforts to immunize 2.7 million persons around the world. Also, the Veterans Administration and the Indian Health Service are developing plans to meet the special needs of their beneficiaries.

I expect to be kept informed, and where necessary, personally involved as the program proceeds. The Secretary of HEW, working with the Director of OMB and the Executive Director of the Domestic Council will assure the availability of timely information on our progress toward this goal and presentation of any issue requiring my immediate attention.

I shall expect departments and agencies other than HEW, with a role to play, to give Secretary Mathews and Assistant Secretary Cooper full assistance and cooperation.

Looking ahead, it is my expectation that we will, in fact, be able to meet our vaccination needs in a manner that will match the ability of the public and private sector of American medicine to distribute it. At this time it is likely that, as the vaccine becomes available, initial inoculation could begin during the late summer and be continued through the fall and early winter.
It is my belief that we have the science, technology and the will, both in the public and the private sector, to undertake this unprecedented action and be successful with it. Our success in the end, however, will depend on each and every American making certain that he or she receives the vaccine when it is made available at public health facilities, hospitals, schools and physicians' offices. As I have indicated, this matter will have my direct, continuous and personal attention, and I intend to do all I can to insure its success.
MEMORANDUM FOR THE HEADS OF DEPARTMENTS AND AGENCIES

Last week I announced plans for a national immunization program to inoculate Americans against a swine-type influenza virus. Because of the serious nature of this virus, it is my hope that every man, woman, and child in the country can be inoculated before the end of this calendar year.

Since there are no precedents for an endeavor of this magnitude, I am issuing this directive to assure completion of the task in an appropriate, orderly, and timely manner. The Secretary of Health, Education and Welfare, David Mathews, will take the lead in this effort, but it is essential that all federal department and agency heads give him their full cooperation in carrying out this program.

I have asked the Congress for a supplemental appropriation of $135 million for this program. The Public Health Service, under the direction of HEW Assistant Secretary for Health, Dr. Theodore Cooper, will proceed with the planning and implementation efforts to make the vaccine available to all Americans. This activity will be carried out in close coordination with the Center for Disease Control, the Bureau of Biologics of the Food and Drug Administration, and the National Institutes of Health.

These efforts will include utilization of State and local health agencies in conducting immunization programs, and as distribution centers for vaccine. It will be necessary to have the full cooperation and participation of the private sector, as well as government, to assure the immunization of the total population in the brief time available. In particular, we will need to mobilize the vast resources of private sector health professionals and facilities.
NATIONAL INFLUENZA IMMUNIZATION PLAN OBJECTIVES

-- The vaccine must be tested in field trials for efficacy and effectiveness, and 215 million doses produced to immunize the entire population.

-- The nation's health professionals must be encouraged to fully support this effort to increase the effectiveness of the immunization program.

-- The public must be made aware of the importance of inoculation against this type of influenza virus through a nationwide citizen awareness program.

-- The vaccine, along with sufficient medical supplies and equipment, must be distributed through the State agencies. Every opportunity for inoculation must be maximized including mass immunization and the utilization of delivery points already in place, such as physicians' offices, health department clinics, community health centers, and public facilities.

-- Epidemiologic and laboratory surveillance will be maintained to evaluate the effectiveness of this effort and to determine disease trends and outbreaks so that any necessary additional immunization and health efforts may be directed toward epidemic control.

Initial efforts are now underway by the Public Health Service.

Our goal is to ensure that the flu vaccine is available at public health facilities, hospitals, schools, and physicians' offices throughout the country and that a maximum number of Americans avail themselves of it. Clearly we have the scientific and medical resources to undertake this action. We will only succeed, however, by effectively mobilizing all units of government, including Federal, State, and local officials, the medical profession, hospitals, clinics, and the manufacturers of the vaccine.

Because the health of our nation is at stake, I intend to give this matter my direct and continuous attention, and I am asking each of you to make a similar commitment within your own organization.
MEMORANDUM FOR THE PRESIDENT

FROM: JIM CANNON

SUBJECT: Presidential Statement On Swine Flu

Attached for your approval is a statement that we would like to release this afternoon on swine flu after your meeting with the scientists.

It has been reviewed and approved by Secretary Mathews, Assistant Secretary Ted Cooper, and Paul O'Neill. Bob Orben has approved the text.

RECOMMENDATION

I recommend that you approve the attached statement for release this afternoon.

_______ Approve

_______ Disapprove
PRESIDENTIAL STATEMENT ON SWINE FLU

WEDNESDAY, MARCH 24, 1976

-1-

WE HAVE JUST CONCLUDED A MEETING ON A SUBJECT THAT IS OF IMPORTANCE TO ALL AMERICANS, AND I WANT TO REPORT TO YOU ON THE RESULTS.
ONE MONTH AGO, A STRAIN OF INFLUENZA --  
SOMETIMES KNOWN AS SWINE FLU -- WAS DISCOVERED AND ISOLATED AMONG ARMY RECRUITS AT FORT DIX, NEW JERSEY.

THE APPEARANCE OF THIS STRAIN HAS CAUSED CONCERN WITHIN THE MEDICAL COMMUNITY, BECAUSE THIS VIRUS IS SIMILAR TO ONE THAT CAUSED A WIDESPREAD AND VERY DEADLY FLU EPIDEMIC LATE IN THE FIRST WORLD WAR. SOME OLDER AMERICANS TODAY WILL REMEMBER THAT 450 THOUSAND PEOPLE DIED IN THIS COUNTRY DURING THAT TRAGIC PERIOD.
DURING THE LAST FEW DAYS, I HAVE CONSULTED WITH MEMBERS OF MY ADMINISTRATION AND LEADING MEMBERS OF THE HEALTH COMMUNITY AND PUBLIC OFFICIALS ABOUT THE IMPLICATIONS OF THIS NEW APPEARANCE OF SWINE FLU.

I HAVE BEEN ADVISED THAT THERE IS A REAL POSSIBILITY THAT UNLESS WE TAKE EFFECTIVE COUNTER-ACTIONS, THERE COULD BE A NEW EPIDEMIC OF THIS DANGEROUS DISEASE NEXT FALL AND WINTER HERE IN THE UNITED STATES.
LET ME STATE CLEARLY THAT AT THIS TIME,

NO ONE KNOWS EXACTLY HOW SERIOUS THIS THREAT COULD BECOME.

NEVERTHELESS, WE CANNOT AFFORD TO TAKE A CHANCE WITH

THE HEALTH OF OUR NATION.

ACCORDINGLY, I AM ANNOUNCING TODAY THE

FOLLOWING ACTIONS:

-- FIRST, I AM ASKING THE CONGRESS TO APPROPRIATE

135 MILLION DOLLARS PRIOR TO THEIR APRIL RECESS FOR THE

PRODUCTION OF SUFFICIENT VACCINE TO INOCULATE EVERY MAN,

WOMAN, AND CHILD IN THE UNITED STATES.
-- SECONDLY, I AM DIRECTING H.E.W. SECRETARY DAVID MATHEWS AND ASSISTANT SECRETARY COOPER, TO DEVELOP PLANS THAT WOULD MAKE THIS VACCINE AVAILABLE TO ALL AMERICANS DURING THE THREE MONTH PERIOD FROM SEPTEMBER TO NOVEMBER OF THIS YEAR.

-- FINALLY, I AM ASKING EACH AND EVERY AMERICAN TO MAKE CERTAIN HE OR SHE RECEIVES AN INOCULATION THIS FALL.
INOCULATIONS ARE TO BE AVAILABLE AT SCHOOLS,
HOSPITALS, PHYSICIANS' OFFICES, AND PUBLIC HEALTH FACILITIES.

THE REACTION TO THE SHOT, I AM TOLD, MAY MEAN A SORE ARM
FOR A DAY OR TWO -- A VERY SMALL PRICE TO PAY FOR THIS

VITAL PROTECTION.

THE FACTS THAT HAVE BEEN PRESENTED TO ME
IN THE LAST FEW DAYS HAVE COME FROM MANY OF THE BEST
MEDICAL MINDS IN THE COUNTRY. THESE FACTS DO NOT
SUGGEST THERE IS ANY CAUSE FOR ALARM.
THE SCIENTIFIC COMMUNITY ESSENTIALLY UNDERSTANDS WHAT WE ARE DEALING WITH, AND THEY WILL DEVELOP A VACCINE THAT WILL BE EFFECTIVE IN COMBATTING IT.

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THE FACTS DO SUGGEST, HOWEVER, THAT THERE IS A NEED FOR ACTION NOW -- ACTION BY THE GOVERNMENT, ACTION BY INDUSTRY AND THE MEDICAL COMMUNITY, AND MOST IMPORTANTLY, ACTION BY OUR CITIZENRY.
WE ARE TAKING THE FIRST STEPS THIS AFTERNOON --

AND BEFORE NEXT WINTER, I HOPE WE WILL HAVE PUT THIS THREAT BEHIND US.

THANK YOU.

END OF TEXT