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MEMORANDUM OF INFORMATION FOR THE FILE

DATE *3/22/76*

EXECUTIVE

HE 1

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PR 7-1

FG 23

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FG 6-11-1/Cheney

FG 6-11-1/Cannon

LETTER, MEMO, ETC.

Agenda

TO:

FROM:

James T. Lynn

SUBJECT:

Swine Influenza Program Meeting

*Cooper, Ted
Dickson, Jim
O'Neill, Paul*

CORRESPONDENCE FILED CENTRAL FILES - CONFIDENTIAL FILE



BPM



THE PRESIDENT HAS SEEN....
EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

C.F.
HEI

SWINE INFLUENZA PROGRAM MEETING
Monday, March 22, 1976
11:00 to 11:30 a.m. (30 minutes)
Cabinet Room

From: James T. Lynn

I. PURPOSE

To discuss a possible Federal initiative to immunize all Americans against swine influenza.

II. BACKGROUND PARTICIPANTS AND PRESS PLAN

A. Background: HEW is concerned about a possible "out-break" of swine influenza during the winter of 1976-1977 and recommends a \$134 million Federal program to immunize every American. If this is to be done, drug companies must be given the go-ahead to produce the necessary vaccine within the next two weeks. The decision to give the go-ahead to vaccine manufacturers and to seek a 1976 budget supplemental is complicated by both uncertainties and its precedential implications.

-- Attachment A outlines some of the uncertainties within which this decision must be made.

-- Attachment B is an HEW memorandum on the subject.

B. Participants: Secretary Mathews; HEW Assistant Secretary Ted Cooper and his deputy, Jim Dickson; Richard Cheney, James Lynn, James Cannon and Paul O'Neill.

C. Press Plan: None

III. TALKING POINTS

A. Mr. Secretary, would you please start off by explaining:

1. What swine influenza is and how it can be distinguished from other types of flu in terms of its severity?



2. What is the probability of an occurrence of an epidemic in the winter of 1976-1977, given the 10-year cycle of epidemics, the last of which occurred in the 1968/1969 winter?
3. Why do we believe that the very same swine influenza virus that was recently identified in New Jersey will cause a nationwide epidemic this coming winter as opposed to say, a mutant form of this virus or another virus?



Uncertainties Surrounding a Federal
Mass Swine Influenza Immunization Program

- Scientific Evidence on Likelihood and Success of Immunization: Person-to-person transmission of the swine virus has been proven in only one location, Fort Dix in New Jersey. Further scientific evidence on the probability of an occurrence of swine flu virus next year may or may not become available before the current flu season is over. HEW epidemiologists have stated that the probability is "unknown."
- The swine virus is a different strain entirely from the flus of the past few years. The swine flu vaccine will have no effect whatever on preventing these more conventional flus. Moreover, there remains a possibility that mutated swine virus may occur -- against which the vaccine to be developed would not be effective.
- Seriousness of Swine Influenza: The number of Americans that would be seriously ill or killed if an epidemic did occur may not be analogous to the 1919 experience of 500,000 deaths because of the absence in 1919 of antibiotics. We cannot be certain that there have been no person-to-person transmission of swine influenza since 1930.
- Implications of a Federal Initiative: Will it be necessary to mount another massive Federal effort in each succeeding year (1) if the swine influenza epidemic does not occur in the winter of 1976/1977 or (2) in order to protect every American against mutating versions of swine virus?
- Press Attention: The national press is already aware of a possible swine influenza occurrence through weekly HEW press conferences on the flu morbidity.
- Views of the Scientific Community: HEW is now in the process of trying to obtain consensus from all important members of the virology scientific community on the advisability of a nationwide immunization drive against the swine flu virus. Nevertheless, what is the contrary virology argument against the massive immunizations?



TAB B

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE ASSISTANT SECRETARY FOR HEALTHTO : The Secretary
Through: ES _____

DATE:

FROM : Assistant Secretary for Health

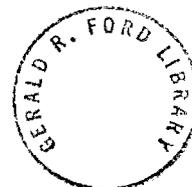
SUBJECT: Swine Influenza--ACTION

ISSUE

How should the Federal Government respond to the influenza problem caused by a new virus?

FACTS

1. In February 1976 a new strain of influenza virus, designated as influenza A/New Jersey/76 (Hsw1N1), was isolated from an outbreak of disease among recruits in training at Fort Dix, New Jersey.
2. The virus is antigenically related to the influenza virus which has been implicated as the cause of the 1918-1919 pandemic which killed 450,000 people--more than 400 of every 100,000 Americans.
3. The entire U.S. population under the age of 50 is probably susceptible to this new strain.
4. Prior to 1930, this strain was the predominate cause of human influenza in the U.S. Since 1930, the virus has been limited to transmission among swine with only occasional transmission from swine to man--with no secondary person-to-person transmission.
5. In an average year, influenza causes about 17,000 deaths (9 per 100,000 population) and costs the nation approximately \$500 million.
6. Severe epidemics, or pandemics, of influenza occur at approximately 10 year intervals. In 1968-69, influenza struck 20 percent of our population, causing more than 33,000 deaths (14 per 100,000) and cost an estimated \$3.2 billion.
7. A vaccine to protect against swine influenza can be developed before the next flu season; however, the production of large quantities would require extraordinary efforts by drug manufacturers.



ASSUMPTIONS

1. Although there has been only one outbreak of A/swine influenza, person-to-person spread has been proven and additional outbreaks cannot be ruled out. Present evidence and past experience indicate a strong possibility that this country will experience widespread A/swine influenza in 1976-77. Swine flu represents a major antigenic shift from recent viruses and the population under 50 is almost universally susceptible. These are the ingredients for a pandemic.
2. Routine public health influenza recommendations (immunization of the population at high risk--elderly and chronically ill persons) would not forestall a flu pandemic. Routine actions would have to be supplemented.
3. The situation is one of "go or no go". If extraordinary measures are to be undertaken there is barely enough time to assure adequate vaccine production and to mobilize the nation's health care delivery system. Any extensive immunization program would have to be in full scale operation by the beginning of September and should not last beyond the end of November 1976. A decision must be made now.
4. There is no medical epidemiologic basis for excluding any part of the population--swine flu vaccine will be recommended for the total population except in individual cases. Similarly there is no public health or epidemiologic rationale for narrowing down the targeted population. Further, it is assumed that it would be socially and politically unacceptable to plan for less than 100 percent coverage. Therefore, it is assumed that any recommendations for action must be directed toward the goal of immunizing 213 million people in three months (September through November 1976). The nation has never attempted an immunization program of such scope and intensity.
5. A public health undertaking of this magnitude cannot succeed without Federal leadership, sponsorship, and some level of financial support.
6. The vaccine when purchased in large quantities will cost around 50 cents per dose. Nationally, the vaccine will cost in excess of \$100 million. To this total must be added delivery costs, as well as costs related to surveillance and monitoring. Part, but not all, of the costs can be considered sunk costs, or as non-additive. Regardless of what strategy is adopted, it will be extremely difficult to estimate the amount of additional costs that will result from a crash influenza immunization program.



7. The Advisory Committee on Immunization Practices will recommend formally and publicly, the immunization of the total U.S. population against A/swine influenza.

8. Any recommended course of action, other than no action, must assure:
- that a supply of vaccine is produced which is adequate to immunize the whole population.
 - that adequate supplies of vaccine are available as needed at health care delivery points.
 - that the American people are made aware of the need for immunization against this flu virus.
 - that the population systematically reach or be reached by the health system.
 - that the Public Health Service maintain epidemiologic, laboratory, and immunization surveillance of the population for complications of vaccination, for influenza morbidity and mortality, and for vaccine effectiveness and efficacy.
 - that the unique research opportunities be maximized.
 - that evaluation of the effectiveness of the efforts is conducted.

ALTERNATIVE COURSES OF ACTION

1. No Action

An argument can be made for taking no extraordinary action beyond what would normally be recommended. To date there has been only one outbreak. The swine flu virus has been around, but has not caused a problem among humans since 1930.

Pro:

- The market place would prevail--private industry (drug manufacturers) would produce in accordance with its estimate of demand and the consumers would make their own decisions. Similarly, States would respond in accordance with their own sets of priorities.
- The "pandemic" might not occur and the Department would have avoided unnecessary health expenditures.
- Any real action would require direct Federal intervention which is contrary to current administration philosophy.



Con:

- Congress, the media, and the American people will expect some action.
- The Administration can tolerate unnecessary health expenditures better than unnecessary death and illness, particularly if a flu pandemic should occur.
- In all likelihood, Congress will act on its own initiative.

2. Minimum Response

Under this option there would be a limited Federal role with primary reliance on delivery systems now in place and on spontaneous, non-governmental action.

- a. The Federal Government would advise the drug industry to develop and produce A/swine vaccine sufficient to immunize the general population. The Federal Government would underwrite this effort by promising to purchase vaccine for the 58 million Federal beneficiaries.
- b. A nationwide public awareness program would be undertaken to serve as general backdrop for local programs.
- c. The Public Health Service would stimulate community programs sponsored by local organizations (medical societies, associations, industries, etc.)
- d. The Center for Disease Control would maintain epidemiologic and laboratory surveillance of the population.
- e. The National Institutes of Health would conduct studies and investigations, particularly on new and improved vaccines.

Pro:

- The approach is characterized by high visibility, minimum Federal intervention, and diffused liability and responsibility. It is a partnership with the private sector that relies on Federal stimulation of nongovernmental action.
- The burden on the Federal budget would be minimal. Assuming purchase of vaccines for 58 million beneficiaries, plus additional costs related to c., d., and e., above the total new obligational authority requirement would not exceed \$40 million (\$32 million for vaccine; plus 8 million for surveillance, monitoring, evaluation, and research).



--Success would depend upon widespread voluntary action--in terms of individual choice to seek immunization and in terms of voluntary community programs not unlike the polio programs of the past.

Con:

--There is little assurance that vaccine manufacturers will undertake the massive production effort that would be required to assure availability of vaccine for the entire nation.

--There would be no control over the distribution of vaccines to the extent that they are available; the poor, the near poor, and the aging usually get left out. Even under routine flu recommendations in which the elderly are a primary target, only about half the high risk population gets immunized against flu.

--Probably only about half the population would get immunized.

3. Government Program

This alternative is based on virtually total government responsibility for the nationwide immunization program.

- a. The Federal Government would advise vaccine manufacturers to embark on full scale production of vaccine with the expectation of Federal purchase of up to 200 million doses.
- b. The Public Health Service, through the CDC would purchase the vaccines for distribution to State Health Departments.
- c. In each State the health department would organize and carry out an immunization program designed to reach 100 percent of the State's population. Vaccine would be available only through programs carried out under the aegis of the State health department (or the Federal Government for direct Federal beneficiaries).
- d. Primary reliance would be placed on systematic, planned delivery of vaccine in such a way as to make maximum use of intensive, high volume immunization techniques and procedures--particularly the use of jet-injector guns.
- e. In addition to a general nationwide awareness program, intensive promotion and outreach activities would be carried out at the local level. Maximum use would be made of temporary employment of unemployed workers, high school and college students, housewives, and retired people as outreach workers and for jobs requiring no special health skills.



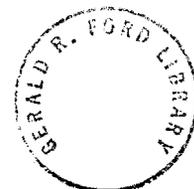
- f. The Center for Disease Control would maintain epidemiologic and laboratory surveillance of the population.
- g. The National Institutes of Health would conduct studies and investigations, particularly on new and improved vaccines.
- h. The program would be evaluated to assess the effectiveness of the effort in reducing influenza associated morbidity, hospitalization, and mortality in a pandemic period.

Pro:

- Under this alternative adequate availability of vaccine would be closest to certainty, and the vaccine would be distributed throughout the nation most equitably.
- There would be greater certainty of participation of all States as well as a predictably more uniform level of intensity across the nation.
- Accessibility to immunization services would not depend upon economic status:
- This approach would provide the framework for better planning - for example, the use of travelling immunization teams which could take the vaccine to the people; and greater use of the jet injector, and other mass immunization techniques.
- The Federal and State governments traditionally have been responsible for the control of communicable diseases; therefore, the strategy relies upon government action in an area of public health where the States are strong and where basic operating mechanisms exist.

Con:

- This alternative would be very costly and given the timing, the magnitude of the problem, and the status of State fiscal health, the costs would have to be borne by the Federal Government. The impact on the Federal budget would be an increase of \$190 million in new obligational authority.
- The approach is inefficient to the extent that it fails to take advantage of the private sector health delivery system, placing too much reliance on public clinics and government action.



--While this approach would undoubtedly result in a higher percentage of the population being immunized than would be the case with the Minimum Response strategy (alternative 2), it is unlikely that the public sector could achieve uniform high levels of protection. Although socioeconomic barriers to immunization services would be virtually eliminated, breakdowns would occur because the program is beyond the scope of official agencies.

--A totally "public" program is contrary to the spirit and custom of health care delivery in this country and should only be considered if it is clearly the most effective approach.

4. Combined Approach

A program based on this strategy would take advantage of the strengths and resources of both the public and private sectors. Successful immunization of our population in three months' time can be accomplished only in this manner in this country. In essence, the plan would rely on: the Federal Government for its technical leadership and coordination, and its purchase power; State health agencies for their experience in conducting immunization programs and as logical distribution centers for vaccine; and on the private sector for its medical and other resources which must be mobilized.

- a. The Federal Government would advise vaccine manufacturers to embark on full scale production of enough vaccine to immunize the American people. The Public Health Service would contract for 200 million doses of vaccine which would be made available at no cost through State health agencies.
- b. State health agencies would develop plans to immunize the people in their States through a combination of official and voluntary action - travelling immunization teams, community programs, private physician practices, as examples.
- c. The strategy would 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--any place with the competence to perform immunization services.
- d. Awareness campaigns would be carried out at the local level against a broader, generalized nationwide effort. Use would be made of unemployed workers, students, etc., for certain jobs.
- e. The Center for Disease Control would maintain epidemiologic and laboratory surveillance of the population.



- f. The National Institutes of Health would conduct studies and investigations of vaccine effectiveness and efficacy.
- g. The program would be evaluated to assess the effectiveness of the effort in reducing influenza associated morbidity, hospitalization, and mortality in a pandemic period.

Pro:

- Under this alternative adequate availability of vaccine would be closest to certainty, and the vaccine would be distributed throughout the nation most equitably.
- There would be greater certainty of participation of all States as well as a predictably more uniform level of intensity across the nation.
- Accessibility to immunization services would not depend upon socioeconomic factors.
- Making use of all delivery points better assures that the vaccine will get to more people.
- The approach provides the framework for planning and expands the scope of resources which can be applied.
- Undertaking the program in this manner provides a practical, contemporary example of government, industry, and private citizens cooperating to serve a common cause--an ideal way to celebrate the nation's 200th birthday.

Con:

- This strategy would require substantial Federal expenditures. A supplemental request of approximately \$134 million would be needed.
- Under this alternative there is the greatest possibility of some people being needlessly reimmunized.

DISCUSSION

Any of the courses of action would raise budgetary and authorization questions and these will be discussed later. More important is the question of what the Federal Government is willing to invest if some action is deemed necessary to avert a possible influenza pandemic. We have not undertaken a health program of this scope and intensity before in our history. There are no precedents, nor mechanisms in place that are suited



SWINE INFLUENZA PROGRAM
MEETING

Monday, March 22, 1976

11:00 A.M.
(30 minutes)

THE PRESIDENT HAS SEEN....

