1976 SWINE FLU OUTBREAK
FORD ADMISTRATION PAPERS

BACM RESEARCH
WWW.PAPERLESSARCHIVES.COM

In early February 1976, two recruits stationed at Fort Dix in New Jersey, had an influenza-like illness. One of the soldiers died. Isolates of virus taken from them included A/New Jersey/76 (Hsw1n1), a strain similar to the virus believed at the time to be the cause of the 1918 pandemic, commonly known as swine flu. Serologic studies at Fort Dix suggested that fewer than 200 soldiers had been infected and that person-to-person transmission had occurred.

At the urging of the Center for Disease Control and several well-known and respected scientists, the Ford administration moved quickly to initiate a program to inoculate every American against this perceived threat.

After approximately 40 million Americans were vaccinated fears of the possibility of severe side effects from the vaccine emerged. Some blamed the vaccine for the deaths of Thirty-two people who received the swine flu vaccine from Guillain-Barre Syndrome.

The vaccination program was officially halted on December 16, 1976.

BP

110

MEMORANDUM OF INFORMATION FOR THE FILE

EXECUTIVE
HE1
HE5
PR7-1
FG23
FG6-16
FG6-11-1/Cheney
FG6-11-1/Cannon

DATE 3/22/76

LETTER, MEMO, ETC. Agenda

TO:

FROM: James T. Lynn

SUBJECT: Swine Influenza Program Meeting

Cooper, Jed
Dickson, Jim
O'Neill, Paul

CORRESPONDENCE FILED CENTRAL FILES – CONFIDENTIAL FILE

THE PRESIDENT HAS SEEN....

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

C. F.
HE1

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 "outbreak" 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?

TAB A

Attachment A

Uncertainties Surrounding a Federal Mass Swine Influenza Immunization Program

-- Scientifice 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 occurence 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

Attachment B

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

TO : 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 (HswlNl), 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 visability, 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

to an endeavor of this magnitude. Given this situation, can we afford the administrative and programmatic inflexibility that would result from normal considerations about duplicative costs, third party reimbursements, and Federal-State or public-private relationships and responsibilities? The magnitude of the challenge suggests that the Department must either be willing to take extraordinary steps or be willing to accept an approach to the problem that cannot succeed.

It is recommended that the Department, through the Public Health Service and the Center for Disease Control, undertake an influenza immunization campaign as outlined in alternative 4, Combined Approach. This alternative best satisfies all of the minimum program requirements outlined earlier and more importantly, it is the most likely to succeed--more people would be protected.

The question of legislative authorization is not entirely clear. It would appear that Section 311 a. of the Public Health Service Act contains adequate authority to implement the recommended program. If 311 a. cannot be used, then it will be necessary to seek "point of order" authority in the supplemental appropriation act. It is anticipated that Congress would be receptive to "point of order" language in this instance.

It will be necessary to seek a supplemental appropriation so that all parties can begin to mobilize for the big push in the fall. It will also be necessary for the funds to be available until expended because the program, although time-limited, falls into fiscal year 1976, the transition quarter, and fiscal year 1977. In general terms the request would be for approximately $134 million made up as follows:

Immunization Programs (vaccines, supplies, temporary personnel, awareness)	$126 million
Surveillance and Research	8 million

RECOMMENDATION

It is recommended that the Secretary adopt alternative 4 as the Department's strategy and that the Public Health Service be given responsibility for the program and be directed to begin immediate implementation.

Theodore Cooper, M.D.

CONCURRENCES

C, Young: Concur_____ Nonconcur_____ Date_____
See tab_____

Prepared by: CDC, SENCER, 3/13/76, (404) 633-3311, x3291

SWINE INFLUENZA PROGRAM
MEETING

Monday, March 22, 1976
11:00 A.M.
(30 minutes)

THE PRESIDENT HAS SEEN....

President Gerald R. Ford's Remarks
Announcing the National Swine Flu Immunization Program

March 24, 1976

I have just concluded a meeting on a subject of vast importance to all Americans, and let me report to you the results of that meeting.

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 very 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 548,000 people died in this country during that tragic period.

During the last few days, I have consulted with members of my administration, Secretary Mathews and Dr. Cooper, 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 very real possibility that unless we take effective counteractions, there could be an epidemic of this dangerous disease next fall and winter here in the United States.

Let me state clearly at this time, no one knows exactly how serious this threat could be. Nevertheless, we cannot afford to take a chance with the health of our Nation. Accordingly, I am today announcing the following actions.

First, I am asking the Congress to appropriate $135 million, 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 the Secretary of HEW David Mathews, and Assistant Secretary, Dr. Cooper, to develop plans that would make this vaccine available to all Americans during the 3-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 few sore arms 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 this country. These facts do not suggest there is any cause for alarm. The scientific community essentially understands what we are dealing with, and they have developed a vaccine that will be effective in combatting it.

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 all of our citizens.

We are taking the first steps this afternoon, and before next winter I hope we will have put this threat behind us.

I would like to thank the very outstanding group of technicians who came in and met with me for an hour or so this afternoon -- Dr. Salk, Dr. Sabin, and others here who have convinced me beyond any doubt whatsoever, that this is the right course of action. And tomorrow, I will submit to the Congress a message and a budget supplement, so that this money will be available, and available as promptly as possible.

We discussed how the supplemental should be handled, whether it should be a part of the supplemental that is now going through the Congress or a separate supplemental that would be identified only for this purpose and passed by both the House and the Senate for this purpose and this purpose alone. It is my recommendation that the Congress take this item for $135 million, act promptly on it, and not tie it up with a broader supplemental appropriation bill.

And now, it is my pleasure to ask Dr. Mathews, Secretary of HEW, and Dr. Cooper and the other distinguished scientists who are here who can answer your technical questions.

Thank you very much.

Note: The President spoke at 4:50 p.m. to reporters assembled in the Briefing Room at the White House.

Following the President's remarks, a news briefing on the subject was held by David Mathews, Secretary, Dr. Theodore Cooper, Assistant Secretary for Health, Dr. David J. Sencer, Director, Center for Disease Control, Department of Health, Education, and Welfare; and Dr. Jonas Salk and Dr. Albert B. Sabin, pioneers in the development of the polio vaccine.

FOR IMMEDIATE RELEASE MARCH 24, 1976

OFFICE OF THE WHITE HOUSE PRESS SECRETARY

THE WHITE HOUSE

PRESS CONFERENCE
OF
FORREST DAVID MATHEWS
SECRETARY OF THE DEPARTMENT OF
HEALTH, EDUCATION AND WELFARE
JONAS SALK
SALK INSTITUTE FOR BIOLOGICAL STUDIES
ALBERT B. SABIN
MEDICAL UNIVERSITY OF SOUTH CAROLINA
THEODORE COOPER
ASSISTANT SECRETARY FOR HEALTH
DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
AND
DAVID SENCER
DIRECTOR, CENTER FOR DISEASE CONTROL
DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

THE BRIEFING ROOM

4:57 P.M. EST

SECRETARY MATHEWS: I will discuss the history of virology and Dr. Cooper will discuss its current effects.

We have no additional statements. We are ready for any questions you may have.

Q Dr. Mathews, the President said flatly that he is asking each and every American to receive an innoculation of this this fall. If this is grown on an egg substrain, what are you going to do about people who are allergic to that and cannot handle it?

SECRETARY MATHEWS: Dr. Cooper, Dr. Sabin and Dr. Salk are experts in that field. I shouldn't answer that question in their presence.

DR. SALK: The only caution that should be exercised is to inquire whether or not a person is sufficiently allergic to eggs to develop asthma or hives.

Q And if so?

MORE

DR. SALK: If so, they should avoid being vaccinated and they will be protected as part of the effect by virtue of the beneficial vaccination of the rest of the population. The purpose of vaccinating on a mass scale is to offer community protection, nationwide protection, as well as individual protection.

DR. COOPER: I would add to that that it is part of our intention in the campaign, therefore, as part of the necessary awareness activity, to make a full disclosure of the sensitivities, what the expected adverse reaction would be, including the sore arms that the President talked about, since it is inevitable as we deal with 207 odd million injections that we have to alert the public to this in a responsible way. This also is the proper way to deal with the question of liability.

Q One other question, to follow up, if I may. Do you have any rough estimates of how many people are sufficiently allergic to egg to make this an unwise procedure for them?

DR. COOPER: When I asked about this, the best estimate I could get on this was about one per 100,000 --

DR. SALK: And they know it.

DR. COOPER: -- and usually they know it, as Dr. Salk points out.

Q Are you going to recommend a monovalent vaccine, what CC level and how many doses?

DR. COOPER: We are recommending monovalent vaccine for this particular activity, one dose.

Q How many doses totally are you going to tell the drug companies to manufacture, 215 million?

DR. COOPER: Enough for every citizen until we have completely covered the population.

Q Dr. Cooper, are there going to be monies available so that people who could otherwise not afford it will have it available? Will there be outreach, in other words?

DR. COOPER: Yes. As part of our proposed activity, there are three main parts. One is the production and certification of high quality vaccine. We have been assured by the experts it is efficacious.

Secondly is the organization of the system so that the capability of delivering it is present in any setting, including the financial barrier system that you just described, and thirdly is having the capability there, without the public awareness and willingness to participate, would not be as successful campaign and, as was pointed out to the President, I believe by Dr. Sabin earlier, the previous campaigns that did not include an important awareness activity of this type were only 50 or 60 percent effective. So, the program that is proposed has all three elements.

Q Can I follow up, if I may. I understand that this means--this will mean the holding of the vaccines for the present strain of flu so that the entire production effort can be devoted to this.

DR. COOPER: No, this is not to be done at the expense of all other production of vaccines.

Q Other production of flu vaccines?

DR. COOPER: Even other flu vaccines because there is a need -- particularly for certain high-risk groups -- to have the other flu vaccines that are being produced all the time, even now. That would not be set aside. This will continue.

Dr. Sencer might want to comment.

DR. SENCER: The production cycle for the Victoria strain, which is going to be in the vaccine, recommended for high-risk has already been completed, as has the production of the B virus, so that we are not displacing any of that.

SECRETARY MATHEWS: I think this might be a good point to make this observation. It was made several times in the meeting. There are many different kinds of flu. Even though we will inoculate, hope to inoculate, 200 million people to protect them against this particular kind of flu, that does not mean that they are protected from flu in general.

I think all of us have a difficult problem before us even conveying to the public the seriousness of the problem and yet, with some precision about what we are doing, as both Dr. Salk and Dr. Sabin will tell you. Flu is almost a generic disease. It is a term for a disease that covers many varieties, and I think we need to be very precise because we would not want to have 200 million people inoculated feeling they were protected from flu and then come down with some other form of it and be surprised.

Q Was there anything said at the meeting by the representatives of organized medicine about their cooperation in keeping down the cost of injections? Did they say they would give them for nothing or cut their office visit charges in half or anything like that?

DR. COOPER: We did not discuss that specific question specifically, but there was discussed the previous experience where the people were mobilized, physicians did donate their time and capability. The representatives of organized medicine did offer full cooperation from both the American Medical Association, the National Medical Association, the pediatricians, the family practice physicians, the State and territorial health officers and the American Public Health Association.

They all described with great enthusiasm their willingness to participate, as they have in previous campaigns.

Q What is this likely to cost a patient?

DR. COOPER: In many cases it will not be much at all. It depends on what locus that he eventually elects to have his inoculation. Some people will choose to go to their own physician's office, and although he will not have to bear the cost of the vaccine, it is their, maybe, Administration cost.

Others who go to public facilities may not have to pay, depending on what the arrangement is in a selected area. All this has not been worked out.

Q The Government is paying for the vaccine.

DR. COOPER: The vaccine. It is not a completely federalized campaign in which the Administration costs in totality are being borne by the Federal Government.

Q Mr. Secretary, are you aware that some scientists and public health officials oppose this program on the basis that with only one death and only a few hundred cases, that it may not be an epidemic and may never become one,and if you are aware of it, what is your answer to that?

SECRETARY MATHEWS: We had the advice of our own scientific advisory committees on this point. We explored this question with them. It was their firm recommendation to us that even though they could not give us a probability description, they felt that the possibility was such that they could do nothing other than recommend to us in the strongest terms that we proceed with the action that the President just announced. Moreover, the purpose of the meeting today which involved a wide range of people from the scientific community, including the two eminent, distinguished gentlemen who are on the platform with me today, reviewed that evidence just as we received it and came to the same unanimous conclusion to the President.

DR. SABIN: This is a very important thing for the public to understand and I would like to have an opportunity to comment.

It is very important to realize that this is a most difficult decision that has an aspect of your damned if you do and you're damned if you don't. Let me explain this. Supposing you do nothing and along comes Labor Day and schools are open and you have one of those big forest fires that can take place with a virus for which most of the population has no immunity. You have done nothing. You have done nothing because you can't be sure -- and nobody can be sure -- that it will really produce an epidemic.

Now then, you decide, well,we have got to do something. Then it is going to cost a tremendous amount of money. It is going to take a tremendous amount of effort. And then nothing happens,or what is even worse, there is going to be a lot of influenza-like disease and other acute respiratory disease because every year now over 400 million days of bed disability are due to acute respiratory disease of all kinds.

So you can visualize the situation in which this vaccine is administered and people are getting influenza and they will say, "What good was all this, we are getting sick anyway." Influenza represents this difficult situation.

What then is the crux of the disease. This particular virus has raised up an image of potential seriousness that was not created,for example, by this in influenza that caused a lot of disease this year.

It has a bad history. Now just because it was bad in 1918, 1919, 1920, doesn't mean that it is going to be bad again,as was brought out during the meeting by Dr. Kilbourne. We don't know. But the point is can we take a chance. And this is the important thing to realize. It is a very difficult thing.

Q Doctor, what about the people that might possibly get the illness from the inoculation? Is there no risk there?

DR. SABIN: It is not a question of getting the illness from the innoculation in this particular case. They may get some reactions, although this is a highly purified vaccine that is now being used by zymosthenigation which most of the egg material has cleared out.

I think the experience in large numbers of people have shown that reactions, perhaps in younger children -- a fever and things like that -- may be encountered, but again they are not all that serious if one keeps in mind the potential.

In other words, you are preparing for a potential attack that might never happen. This is what the Defense Department is doing, too. We are spending a lot of money and a lot of effort against something that may never happen. But should we do it?

DR. COOPER: In the common parlance it would be called a dead virus so it is really not active to cause the disease.

Q Dr. Cooper, the drug companies have said if they have to manufacture high potency vaccine they would have a very difficult time in manufacturing 200,000,000 doses. Here you are talking about 600 CCA. What are you going to make a recommendation for, a less potent vaccine, something a little below that?

DR. SABIN: Absolutely not.

DR. SENCER: The formulation has not been determined. There is another workshop tomorrow at the Department of Biologics to get to the full formulation of the vaccine, but we would not sacrifice potency.

I think the problem is going to be a production problem rather than changing the potency.

Q Dr. Cooper, the President mentioned a vaccination period from September to November of this year. But the 1918-19 flu was very unusual in that it appeared in this country in August and peaked in October.

Now if you should have a replay of that at this time, what would be the effect of a September-November vaccination period, and by the same token, is there any possibility of getting 215 million doses of this vaccine ready to put into people as early as July so it would be effective for an August appearance?

DR. COOPER: Let me take the last first. After the workshop and the potency questions and the production questions are addressed, the lead time for production of the vaccine and its testing and certification, as was discussed with the President, takes six or so weeks. Some, of course -- depending on how much is available, how much could be done -- could be ready in the summer.

It is true that the reporting of the 1918 pandemic did peak somewhat earlier than recent experience. But as reviewed with the President by people from the Armed Forces as well as other recent epidemiological history inoculation early in the fall usually has been quite effective in completely warding off expected activities by November.

Q For a typical virus, but this is not a typical virus and that is the whole point of my question.

DR. COOPER: We do not know that it is a completely atypical virus.

Q Excuse me, I will amend that. The 1918-1919 was not a typical virus, and I ask if you were to have a replay of 1918, what would be the effect of having a vaccine ready for mass use in September?

DR. COOPER: I think we would obviously miss some people and we would begin our innoculation on the high-risk groups as early as possible and continue until we have covered the population.

SECRETARY MATHEWS: I might say at this point this is one of the reasons the President is asking Congress for a most expeditious handling of this matter because time is of the essence and the decision about the time frame and when the inoculation begins, of course, is conditioned on when the industry gets the charge to go ahead.

Q Did Dr. Salk agree with the decision that was made, and did all the others agree, and havewe ever had an immunization program of this size before?

SECRETARY MATHEWS: On the question of agreement, the President paused in about the middle of the conversation and looked around the room and asked if there was anybody in the room who disagreed with the recommendation that was before them. No one disagreed. As a matter of fact, everyone there, including Dr. Salk and Dr. Sabin, pointedly subscribed to the decision.

Q You are not saying there is also agreement outside of that group, are you? Not full agreement, are you?

SECRETARY MATHEWS: We have polled, one, the regular advisory group to the scientific organization within the Government. We secondly polled outside of that group, prior to this meeting, to check for concurrence. Third, we have taken this additional step of polling the principals, both in the medical profession, in the pharmaceutical profession and in this particular field, and in all of those cases we have not found anyone who would recommend any course of action other than that the President is taking.

Q Secretary Mathews, are you asking the pharmaceutical houses which will be making this large amount of vaccine -- ten times the normal supply for a year -- to make any sort of financial concessions or sacrifices in terms of the amount of profit they will get out of the product?

SECRETARY MATHEWS: We made no specific recommendations to them. The President I think made it clear this was the kind of effort that would take the cooperation of everybody in the country. The Federal Government, the Administration, by asking Congress for $135 million, we are prepared to pay for the serum that we are asking for.

Q How much do you normally pay for flu vaccines in the course of a normal year when you don't have something like this?

DR. SENCER: We have not purchased influenza vaccine as a Federal effort, so we don't have any comparable figures. I think the going retail price is around 75 to 90 cents a dose, but that is with a bivalent vaccine.

Q Dr. Sencer, how long does it take to get the full, up to speed, on your titer? If you get a vaccine on a Monday, how long is it before you have immunity?

DR. SENCER: You begin to have protective antibodies within two weeks. We have not had any experience with this particular strain of virus in human trials. We will be getting that within the next few weeks and can give you a better answer then.

Q Dr. Sencer, are you going to be using Edwin Kilbourne's strain, and have you produced any vaccine at all yet?

DR. SENCER: There are production lots that are derived from the recombatant that Dr. Kilbourne has made. I don't think any of those have been put into human subjects as yet.

Q Mr. Secretary, have we ever had as large an immunization program as this in the country before?

SECRETARY MATHEWS: Not to my knowledge. The closest I guess you would be most familiar with.

DR. SABIN: One hundred million people received oral polio vaccine within a matter of about a year and a half. But, that provided a form of volunteer participation by the community, by the medical profession, by lay people, which made it possible to do this in the shortest possible time with the minimum of cost because if you are going to have to pay for administering every dose of this vaccine, you are going to end up with a bill that is going to be much larger than the cost of the vaccine.

Q What year was that, Dr. Sabin?

DR. SABIN: It began in 1962 and went on to 1963. This was the special vaccine -- on Sunday when people didn't go to work, the people came to school, the vaccine was brought to them. It was a remarkable organization which I think may have some value.

Q Would you like to see that done this time, and do you think it is feasible to do it this time?

DR. SABIN: You see, the problem here is that we are faced with something for which we don't have enough knowledge,and the only reason it is being done now and was not done a year ago or was not done, let's say, in 1968 is a double one. One is the potential danger of this particular strain,and secondly, that because of new knowledge which makes it possible to develop more quickly a recombatant that will grow enough in eggs, now there is a possibility of making vaccine well in advance.

I must go along with the fact that if that vaccine is not going to be ready by the time the schools open -- if it is going to be ready only for one part of the country, and if that virus does spread and is as bad an actor as it was in 1918, we are going to have an awful lot of bad influenza and you will have a control.

Q Dr. Sabin, what I was really trying to ask was whether you would advocate doctors and nurses volunteering their services, turn out in schoolyards and parking lots the way they did in 1962 and 1963 and get this done? Do you think that is feasible?

DR. SABIN: I would certainly recommend it because I think if this is not done, merely encouraging people to go to their doctor or go to the Health Department and get it will get a very limited response,as done in the past.

Q Dr. Sabin, are you thinking of doing anything about prevention? For instance, how is this passed on to someone?

DR. SABIN: What we know at the present time is that the most important way in which influenza virus and other respiratory viruses is transmitted is by way of the hands rather than droplets, and I have a particular kind of handshake for people with common colds. Give me your hand, Ted. Don't clasp the hand. (Laughter)

This is the acute respiratory disease handshake and it may be as important as anything else because you don't put that part in your nose or mouth.

Now the reason school children spread so much is because they have it on their hands, and then another thing, too many people you see -- watch the President or King or anybody -- when he coughs he goes (gesturing) and then he shakes your hand. (Laughter)

MR. NESSEN: Why don't we knock it off there and the more technical questions I think Sandy will help you with over at HEW.

END (AT 5:25 P.M. EST)

EMBARGOED FOR RELEASE
UNTIL 5:00 P.M., (EST)

March 24, 1976

Office of the White House Press Secretary

THE WHITE HOUSE

FACT SHEET

SWINE INFLUENZA IMMUNIZATION PROGRAM

BACKGROUND

Last month an outbreak of swine influenza was isolated among recruits in training at Fort Dix, New Jersey. Although only 12 cases were confirmed, extensive blood testing has indicated that several hundred recruits were probably infected during this outbreak, and it was associated with the one death.

This flu strain, which had been dormant for almost half a century, was the cause of an epidemic in 1918-19 that killed an estimated 548,000 Americans.

The entire U.S. population under the age of 50 is susceptible. Hundreds of blood samples of individuals tested from various parts of the country show that approximately 80% of people over the age of 50 have swine-like virus antibodies in their blood from exposure to the influenza which circulated until 1930. However, the presence of these antibodies does not insure protection against the disease if it returns.

Prior to 1930, this strain was the predominant 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.

Although there has been only one outbreak of 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 could experience widespread 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 severe epidemic, or pandemic. 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.

While there is no evidence that the flu has spread beyond the Army base, the reemergence of this strain has caused great concern in the medical community. Over the last few days the President has consulted with members of the Administration, health community leaders and public officials. On the basis of these consultations, the President believes that it is important to take effective counter-measures to avoid an outbreak similar to the one in 1918.

more

DESCRIPTION

In view of these facts, the President has announced the following actions:

-- He is asking the Congress to appropriate $135 million prior to their April recess so that orders can be placed with the pharmaceutical industry to ensure the production of enough vaccine to inoculate every man, woman, and child in the United States.

-- He is directing HEW Secretary David Mathews, to develop plans that would make this vaccine available to all Americans during the three-month period from September to November of this year.

-- He is asking each and every American to receive an inoculation this fall.

Extraordinary measures are necessary because of the short time period available to assure adequate vaccine production and to mobilize the nation's health care delivery system. An extensive immunization program must be in full-scale operation by the beginning of September and should be completed by the end of November, 1976.

# # # # #

White House Photograph

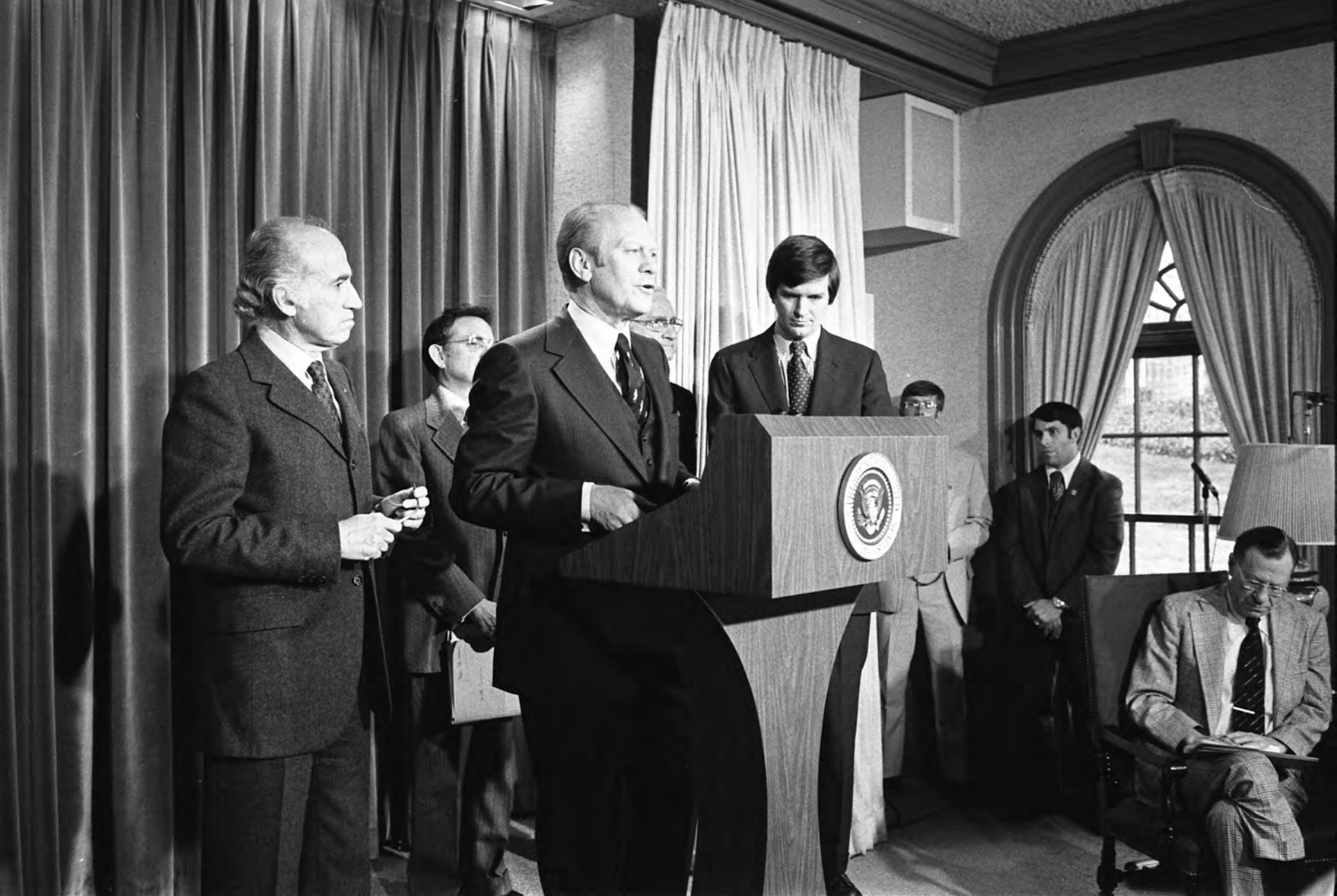
Event: Swine Flu Program

Location: Press Briefing Room

Description: President Ford makes remarks to the press announcing the National Swine Flu Immunization Program. Also shown are Dr. Jonas Salk (to Ford's left) and Secretary of Health, Education and Welfare F. David Mathews (to Ford's right).

Photographer: Ricardo Thomas

Date: March 24, 1976



White House Photograph

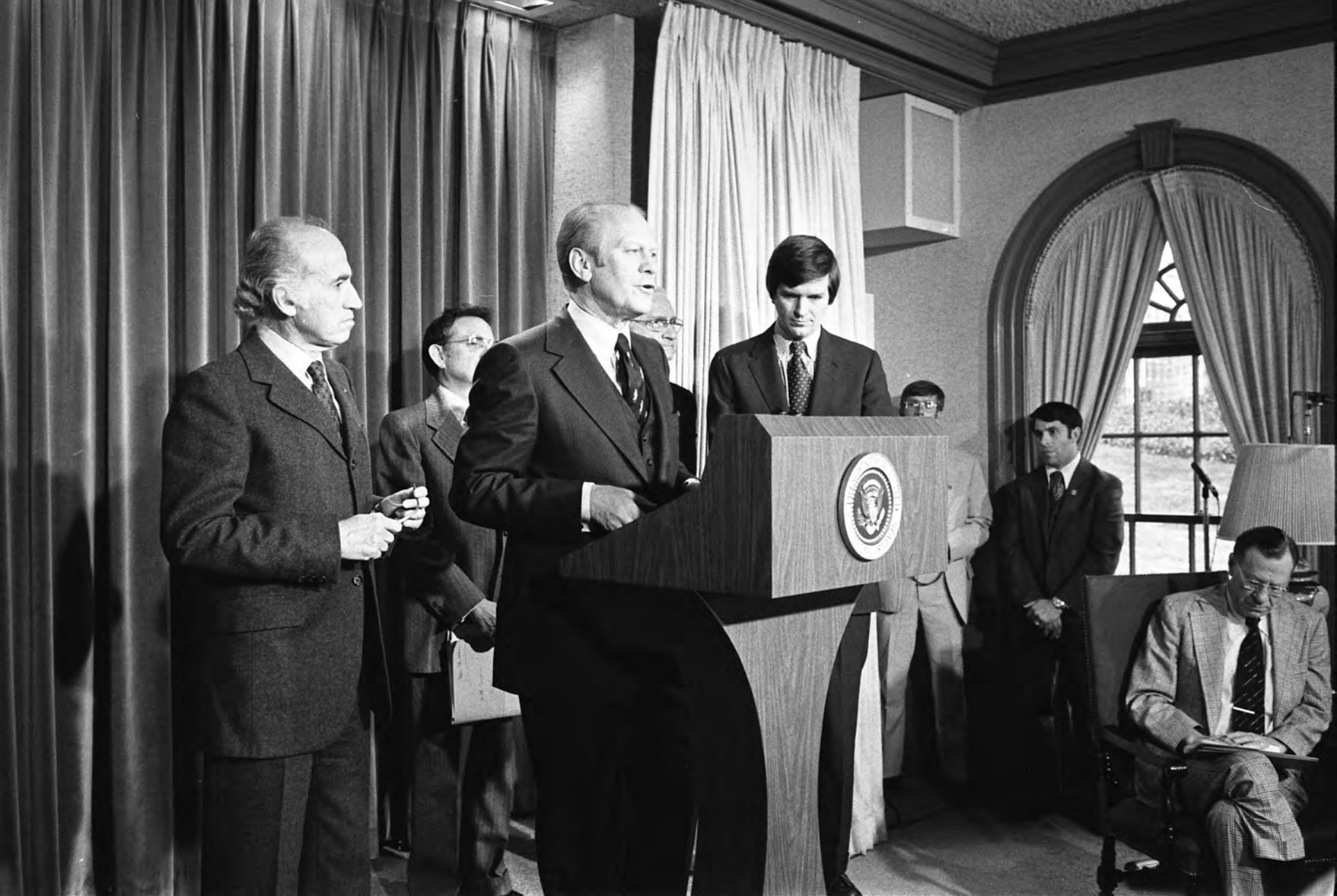
Event: Swine flu program meeting

Location: Cabinet Room

Description: President Ford conducts a meeting to discuss a Federal initiative to immunize all Americans against the swine flu influenza. [l-r: Dr. Jonas Salk, President Ford, HEW Secretary F. David Mathews, Dr. Albert B. Sabin]

Photographer: Karl Schumacher

Date: March 24, 1976



THE PRESIDENT HAS SEEN.

THE AMERICAN NATIONAL RED CROSS
NATIONAL HEADQUARTERS
WASHINGTON, D. C. 20006

OFFICE OF THE CHAIRMAN

March 26, 1976

My dear Mr. President:

The American Red Cross applauds your plan to provide every American with vaccine to help protect against real possibility of epidemic of swine flu.

We have always sought to help our citizens to avoid emergencies if possible -- prepare for those that are unavoidable--and cope with crises when they occur.

I assure you our three thousand chapters and a million volunteers stand ready in all parts of this country to assist you to protect the health and lives of our people. We await your directions as to how we may help.

Faithfully yours,

Frank Stanton

The President
The White House
Washington, D. C.

(3)

EXECUTIVE
3P2-3-94
FG74
PR3

April 8, 1976

Dear Dr. Stanton:

Thank you for your letter of March 26. I am delighted to have the commitment of the American Red Cross to provide volunteers to assist in the national influenza immunization program.

The cooperation of private health professionals and volunteers is critical if we are to ensure that the maximum number of Americans avail themselves of the vaccine.

I commend the Red Cross for its foresight and dedication and look to you and your volunteers for assistance in this vital program during the weeks ahead.

With personal best wishes,

JERRY FORD

The Honorable Frank Stanton
Chairman
The American National Red Cross
National Headquarters
Washington, D. C. 20006

bcc: Spencer Johnson, FYI
GRF:SJohnson:JHH:aby
Cleared in final with Spencer Johnson.

THE WHITE HOUSE

WASHINGTON

April 1, 1976

MEMORANDUM FOR: DICK PARSONS

FROM: SPENCE JOHNSON

SUBJECT: Legal Questions raised by the PMA regarding the production of influenza vaccine.

Attached is the testimony of the Pharmaceutical Manufacturers Association, on the President's influenza immunization program, as presented before the House Health Subcommittee yesterday.

The testimony raises two policy issues: product liability immunity and antitrust immunity.

Committee staff has requested policy guidance in this area and I would appreciate any suggestions you might have as soon as possible.

TESTIMONY OF

C. JOSEPH STETLER, PRESIDENT
PHARMACEUTICAL MANUFACTURERS ASSOCIATION

BEFORE THE

SUBCOMMITTEE ON HEALTH AND ENVIRONMENT
HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

PRESIDENT'S VACCINATION PROGRAM

MARCH 31, 1976

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE:

I AM C. JOSEPH STETLER, PRESIDENT OF THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION. TESTIFYING WITH ME TODAY ARE BRUCE J. BRENNAN, PMA VICE PRESIDENT AND GENERAL COUNSEL, AND JOHN G. ADAMS, PH.D., PMA VICE PRESIDENT FOR SCIENTIFIC AND PROFESSIONAL RELATIONS.

WE ARE PLEASED TO APPEAR BEFORE YOU TODAY TO DISCUSS THE PROPOSED PROGRAM TO INOCULATE ALL AMERICANS AGAINST AN EXPECTED EPIDEMIC INFLUENZA. WE ARE NOT IN A POSITION TO, NOR WOULD WE, ATTEMPT TO QUESTION THE SCIENTIFIC DECISION THAT THE COUNTRY IS THREATENED WITH A SERIOUS EPIDEMIC. OUR MISSION IS TO OUTLINE AS ACCURATELY AS POSSIBLE THE ESTIMATED CAPACITY OF THE PHARMACEUTICAL INDUSTRY TO PRODUCE AND DELIVER THE VACCINE NEEDED FOR A TOTAL IMMUNIZATION PROGRAM. WE ALSO WANT TO RAISE SOME EXTREMELY IMPORTANT QUESTIONS WHICH HAVE NOT BEEN CONSIDERED AND WHICH MUST BE FACED UP TO BY THE GOVERNMENT BEFORE THE MANUFACTURERS CAN PROCEED FULLY.

BEARING IN MIND THAT, GIVEN THE NUMBER OF UNANSWERED QUESTIONS THAT REMAIN, NO ONE CAN PROVIDE ABSOLUTELY RELIABLE DATA ON THESE MATTERS. LET ME DESCRIBE THE SITUATION AS WE SEE IT TODAY.

THERE ARE FOUR PHARMACEUTICAL COMPANIES IN THIS COUNTRY WHICH ARE PRESENTLY PRODUCING INFLUENZA VACCINES. TWO OTHER FIRMS ARE LICENSED, BUT THEY HAVE NOT BEEN PRODUCING VACCINES RECENTLY, AND IT IS UNLIKELY THAT THEY COULD GET INTO PRODUCTION QUICKLY ENOUGH TO PARTICIPATE IN THE PROGRAM. IF THERE IS ANYTHING FORTUNATE ABOUT THE PRESENT SITUATION, IT IS THAT THE FOUR PRIMARY PRODUCERS HAVE JUST COMPLETED PRODUCTION OF REGULAR VACCINES. THE FIRMS HAVE ALREADY BEGUN PRODUCTION OF EXPERIMENTAL BATCHES OF THE A-SWINE STRAIN, AND CAN BE PRODUCING SOON ON AN AROUND-THE-CLOCK BASIS.

IT IS ESTIMATED THAT INITIAL BATCHES WILL BE TURNED OVER TO THE GOVERNMENT FOR CLINICAL EVALUATION BEFORE APRIL 15. THOSE STUDIES WILL DETERMINE THE POTENCY OF THE VACCINE, AND ENABLE THE GOVERNMENT TO SET THE NECESSARY STANDARDS. ONLY WHEN THAT INFORMATION IS IN HAND, PROBABLY BY THE FIRST OF MAY, WILL IT BE POSSIBLE TO ESTIMATE THE PRODUCTION YIELD WITH ACCURACY, AND PREDICT THE TOTAL NUMBER OF DOSES THAT CAN BE PRODUCED. IT MUST BE UNDERSTOOD THAT DESPITE OUR EXPERIENCE WITH OTHER KINDS OF INFLUENZA VACCINE, WE DO NOT KNOW, AND CANNOT KNOW UNTIL MAY, HOW MUCH YIELD WE CAN EXPECT OF A STRAIN WE HAVE NEVER PRODUCED BEFORE.

WE ARE HOPEFUL THAT THE FIRST BATCHES OF THE SPECIFIED VACCINE WILL BECOME AVAILABLE FOR TESTING AND DISTRIBUTION IN JULY OR AUGUST AND OF COURSE PRODUCTION WILL CONTINUE THROUGH THE FALL. AT THIS MOMENT, IT IS IMPOSSIBLE TO GIVE ASSURANCE THAT SUFFICIENT VACCINE TO INOCULATE ALL AMERICANS (213 MILLION DOSES) CAN BE PRODUCED BY THE TARGET DATE OF OCTOBER OR NOVEMBER. THE PROBABILITIES ARE THAT IT CANNOT. HOWEVER, THERE IS ALSO NO ASSURANCE OR LIKELIHOOD THAT EVERYONE WILL WANT TO BE INOCULATED OR THAT THE PROCESS

FOR COUNTRY-WIDE ADMINISTRATION CAN BE FULLY ESTABLISHED. WE CAN PROMISE OUR MOST DILIGENT EFFORTS. IT IS OUR PRESENT BELIEF THAT IF THE ABOVE SCIENTIFIC ISSUES ARE SOLVED WITHOUT UNANTICIPATED DELAYS, AND IF THE REMAINING LEGAL PROBLEMS ARE SOLVED, WE CAN SUPPLY THE VOLUME OF VACCINE NEEDED ON SCHEDULE.

IT SHOULD BE EMPHASIZED AS WELL THAT THE SWINE FLU IS NOT THE ONLY INFLUENZA STRAIN THAT MAY STRIKE THIS YEAR. FEDERAL OFFICIALS HAD PREVIOUSLY AUTHORIZED A VACCINE FORMULA FOR THE 1976-77 FLU SEASON COMPOSED OF "A-VICTORIA" AND "B-HONG-KONG" STRAINS, AND THE PRODUCTION OF THOSE VACCINES HAS BEEN COMPLETED. MANY INDIVIDUALS IN OLDER AGE GROUPS WHO MAY HAVE PARTIAL IMMUNITY TO THE SWINE VIRUS, WILL BE VULNERABLE TO THE HONG KONG VIRUS, WHICH HAS ALREADY HIT IN SOME EUROPEAN COUNTRIES. THE GOVERNMENT IS PRESENTLY AUTHORIZING THE PRODUCTION OF "A-VICTORIA" VACCINES ALONE, OR IN COMBINATION WITH THE NEW SWINE VIRUS. THIS LEAVES A QUESTION AS TO WHETHER THE MASS INOCULATION PROGRAM OUGHT TO INCLUDE VACCINATION AGAINST THE HONG KONG STRAIN AMONG SUSCEPTIBLE GROUPS. HAVING AUTHORIZED AND ENCOURAGED ITS PRODUCTION AND GIVEN THE REMAINING THREAT OF AN INFLUENZA PROBLEM FROM THIS STRAIN, THE GOVERNMENT MUST GIVE EARLY CONSIDERATION TO THIS QUESTION.

IN ADDITION TO THE ABOVE SCIENTIFIC AND PRODUCTION PROBLEMS, THERE ARE MAJOR LEGAL QUESTIONS WHICH MUST BE ANSWERED NOW. WE KNOW FROM EXPERIENCE THAT THEY CANNOT BE LEFT HOPEFULLY FOR LATER CONSIDERATION. ANY IMPLEMENTING OR APPROPRIATIONS LEGISLATION

SHOULD PROVIDE A LIMITED EXEMPTION FOR PARTICIPATING MANUFACTURERS FROM APPLICABLE ANTITRUST LAWS. THIS LIMITED EXEMPTION IS NECESSARY NOW DUE TO THE BASIC NATURE OF THE PROPOSED PRODUCTION PROGRAM AND THE LIMITED NUMBER OF MANUFACTURERS THAT WILL PARTICIPATE. IF A LIMITED STATUTORY EXEMPTION IS NOT PROVIDED FOR PARTICIPATING COMPANIES, THEY WILL BE UNABLE TO JOINTLY DISCUSS MATTERS SUCH AS OPTIMUM ALLOCATION OF PRODUCTION QUOTAS, MATTERS RELATING TO PRODUCTION AND FORMULATION TECHNIQUES, JOINT RESEARCH AND TESTING AND RELATED MATTERS. WE UNDERSTAND THAT THE APPROPRIATION STATUTE IS LIKELY TO AUTHORIZE THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE TO ESTABLISH PRODUCTION QUOTAS AND PRICES. UNDER SUCH CIRCUMSTANCES, THE STATUTE SHOULD FURTHER PROVIDE A LIMITED EXEMPTION TO PARTICIPATING MANUFACTURERS FROM THE ANTITRUST LAWS IN CONNECTION WITH PRODUCTION, FORMULATION, SALE AND DISTRIBUTION OF THE SWINE INFLUENZA VACCINE, ALONE OR IN COMBINATION WITH THE OTHER STRAINS.

ALSO, SINCE THE MANUFACTURERS WILL PRODUCE THE VACCINE IN ACCORDANCE WITH GOVERNMENT SPECIFICATIONS, SELL IT TO THE GOVERNMENT WHO WILL DICTATE AND COORDINATE ITS METHOD OF DISTRIBUTION IT IS REASONABLE THAT THE GOVERNMENT SHOULD INDEMNIFY THE MANUFACTURER FOR LIABILITIES EMANATING FROM OR ASSOCIATED WITH THE USE OF THE VACCINE. WE ARE NOT SUGGESTING THAT THE MANUFACTURER BE INDEMNIFIED AGAINST FAILURE TO PRODUCE A QUALITY VACCINE MEETING STRICT GOVERNMENT SPECIFICATION.

THERE ARE MAJOR PRODUCT LIABILITY PROBLEMS ASSOCIATED WITH MASS IMMUNIZATION PROGRAMS, PARTICULARLY IN LIGHT OF A RECENT DECISION INVOLVING ONE OF OUR MEMBER FIRMS. THAT DECISION HELD THE MANUFACTURER LIABLE FOR AN ALLEGED INJURY IN A COMMUNITY IMMUNIZATION PROGRAM, EVEN THOUGH THE FIRM HAD HAD NO CONNECTION WITH THE PROGRAM OTHER THAN SUPPLYING THE VACCINE AND PROVIDING FULL PRESCRIBING INFORMATION. YET THE SUIT HELD THAT THE COMPANY SHOULD HAVE ADVISED EACH PERSON BEING IMMUNIZED OF THE POTENTIAL HARM THE VACCINE MIGHT CAUSE. CLEARLY, MANUFACTURERS MUST HAVE PROTECTION AGAINST SUCH AN EXAGGERATED INTERPRETATION OF THEIR RESPONSIBILITY IN ANY MASS INOCULATION PROGRAM, AND PARTICULARLY IN ONE OF THE DIMENSIONS WE ARE CONTEMPLATING HERE.

WE HAVE SUPPLIED WITH OUR STATEMENT, SUGGESTED LEGISLATIVE LANGUAGE TO IMPLEMENT THESE RECOMMENDATIONS.

TO CONCLUDE, THE PHARMACEUTICAL INDUSTRY WILL DO EVERYTHING POSSIBLE TO DEVELOP THE NEEDED VACCINES IN THE UNPRECEDENTED QUANTITIES AND IN THE TIME NECESSARY TO MEET THIS PUBLIC HEALTH THREAT, IF THE CONGRESS DECIDES TO PROCEED WITH THIS PROGRAM. WE ARE GIVING THE GOVERNMENT OUR FULL COOPERATION, AND WILL ASSIST THE MEDICAL, PHARMACY AND PUBLIC HEALTH PROFESSIONS IN ASSURING THAT VACCINES ARE AVAILABLE ON AS TIMELY A BASIS AS POSSIBLE. THESE TASKS ARE AMONG THE MOST DEMANDING THAT ANY HEALTH COMPLEX HAS ATTEMPTED. WITH CAREFUL ORGANIZATION, PLANNING, AND <u>IMMEDIATE</u> ATTENTION TO SOME OF THE PROBLEMS I HAVE OUTLINED, WE FEEL THAT THEY CAN BE ACCOMPLISHED.

IF MEMBERS OF THE SUBCOMMITTEE HAVE SPECIFIC QUESTIONS OR A LATER NEED FOR ADDITIONAL INFORMATION ABOUT PHARMACEUTICAL FIRMS'

OPERATIONS IN REGARD TO THIS EFFORT, PMA WILL BE PLEASED TO ACT AS A CONDUIT IN OBTAINING ANSWERS OR SUCH ADDITIONAL INFORMATION.

THAT CONCLUDES OUR STATEMENT, MR. CHAIRMAN. MY ASSOCIATES AND I WELCOME YOUR QUESTIONS.

PRODUCT LIABILITY - IMMUNITY

If any action is brought in any state or federal court based upon any claim that the manufacturer, distributor, or supplier of any vaccine or drug product purchased with or made available through any funds authorized or appropriated under this act is liable for any loss or injury suffered by any person in connection with or as a result of the administration or use of any such vaccine or drug product, the United States shall indemnify such manufacturer, distributor, or supplier against any liability and other costs incurred in connection with any such claim. Provided, that such indemnification shall be made only if such vaccine or drug product was manufactured and labeled in accordance with the specifications and requirements issued by the Secretary of Health, Education, and Welfare. Provided further, that the United States shall have a right to intervene in any such action, and that such manufacturer, distributor, or supplier shall provide the Secretary of Health, Education, and Welfare with timely notice of any such action and shall cooperate fully with the United States in the defense of the action.

Claims for indemnification under this provision shall be submitted to the Secretary of Health, Education, and Welfare, who shall, upon determining that indemnification is due and the amount to be paid, refer such claims to the Secretary of the Treasury. The Secretary of the Treasury shall pay out of moneys in the Treasury not otherwise appropriated the claims referred to him for payment by the Secretary of Health, Education, and Welfare.

ANTI TRUST - IMMUNITY

No person shall be liable for damages, penalties, or other sanctions under the Federal Trade Commission Act (15 U.S.C. 41-77)), or the Antitrust Acts (as defined in section 4 of the Federal Trade Commission Act (15 U.S.C. 44), or under any similar State law, on account of his negotiating, entering into, participating in, or implementing an arrangement providing for the research, development, formulation, manufacture, sale, distribution, or supply of vaccines or drug products purchased with, or made available through, any funds authorized or appropriated under this Act, provided that such activity is undertaken at the request of the Secretary of Health, Education, and Welfare or his delegate.

Letter from citizen who survived the 1918 epidemic, April 15

PUBLIC DOCUMENT
OFFICIAL BUSINESS

Lou Frey Jr. M.C.

My constituent requested that his letter to President Ford be delivered to him personally.

Lou Frey, Jr.

APR 27 1976

FLORIDA.

April 15, 1976

President Gerald R. Ford

Dear Mr. President:

I wish to say "Thank You" for your efforts to preserve and protect the lives of my family and myself from the horrible ravaging effects of the "SWINE FLU".

Those persons who attempt to make a political football of your efforts, should all be made to stand last in line for their shots.

I had a personal experience at the age of eleven. I laid next to my mother, in bed, in 1918, with this horrible disease. Both of us nearly choked to death. God in his mercy, helped us to survive. However, my wife's mother was not so fortunate. She died and left my wife motherless, at six months of age, to be raised by Grandparents.

Again, I say "MANY THANKS" and may God protect and bless you, and all your family.

Your grateful constituent

Richard S.M. Mitchell jr.

Richard S.M. Mitchell jr.
C.Mfg.E.
6476 Colony Park Dr.
Merritt Island, Florida 32952

EXECUTIVE

(3)

HE1
HE5
Swine Flu
Frey, Loug (Corrg)

May 18, 1976

Dear Mr. Mitchell:

President Ford has asked me to thank you for your letter of April 15 in which you expressed your gratitude to him for launching a program to protect Americans against a possible swine influenza epidemic. The President appreciates your kind remarks and good wishes.

The decision to initiate an unprecedented immunization campaign was based on the advice of the most noted health authorities in the field of influenza. The possibility of an epidemic this fall, based on available scientific evidence, is too real to ignore. A virus similar to that of the swine-like virus is believed to be the cause of the 1918-19 world-wide epidemic which resulted in over a half-million deaths in the United States alone.

The effort to immunize almost all Americans this fall will require the marshalling of many resources, both public and private. The involvement of concerned citizens, such as yourself, will also be crucial to the success of this program.

Again, on behalf of the President I would like to thank you for your support and understahding.

Sincerely,

Roland L. Elliott
Director of Correspondence

Mr. Richard S. M. Mitchell, Jr.
6476 Colony Park Drive
Merritt Island, Florida 32952

RLE:HEW:JH:mgs

White House Photograph

Event: Bill signing ceremony

Location: Oval Office

Description: President Ford makes remarks upon signing emergency appropriations legislation for the National Swine Flu Immunization Program. Also present [l-r:]: U.S. Representative Dan Flood (D-PA), Department of Health Education and Welfare Secretary F. David Mathews and U.S. Rep. Paul G. Rogers (D-FL). (H.J. Res 890, Public Law 94-266).

Photographer: William FitzPatrick

Date: April 15, 1976

17

Spencer Johnson

WHD011 253P EDT JUN 15 76 A WU TELTEX WSHA037 (1348) 3 09

1976 JUN 16 AM 8 39

WARNLAM MOPS B
GOVT TELTEX PD MORRIS PLAINS NJ
THE HONORABLE GERALD R FORD
THE WHITE HOUSE
1600 PENNSYLVANIA AVENUE
WASHINGTON D C

AS CHAIRMAN OF WARNER-LAMBERT COMPANY, PARENT COMPANY OF PARKE-DAVIS, ONE OF THE MAJOR PRODUCERS OF NEW JERSEY SWIN-FLU VACCINE, I MUST CALL YOUR ATTENTION TO AN IMPOSSIBLE SITUATION THAT HAS BEEN CREATED BY THE SUDDEN WITHDRAWAL YESTERDAY BY OUR INSURANCE CARRIER OF OUR LIABILITY INSURANCE ON VACCINES TO BE PRODUCED FOR YOUR SWINE FLU KPROGRAM.

OUR COMPANY IS MORE THAN WILLING TO PRODUCE THE VACCINE FOR THE

GOVERNMENT PROGRAM. HOWEVER, WE ARE PLACED IN AN UNTENABLE POSITION WHEN WE ARE REQUESTED TO SUPPLY INFLUENZA VACCINE TO BE USED IN A MASS IMMUNIZATION PROGRAM WITHOUT ANY INSURANCE COVERAGE OR OTHER LIABILITY PROTECTION.

PARKE-DAVIS HAS PRODUCED QUALITY VACCINE FOR YEARS AND WILL CONTINUE TO DO SO. HOWEVER, IT IS RECOGNIZED BY MEDICAL EXPERTS THAT IN A MASS IMMUNIZATION PROGRAM COVERING ALL SEGMENTS OF THE POLULATION--YOUNG, OLD, SICK AND WELL--THAT DIFFERENT REACTIONS MAY BE EXPECTED. FOR THE VAST MAJORITY IT CANN BE ANTICIPATED WITH CERTAINTY THAT COMPLETE PROTECTION WITH MINOR OR NO SIDE EFFECTS WILL RESULT. OTHERS, HOWEVER, MAY OBTAIN LESS THAN FULL PROTECTION AND OTHERS MAY HAVE MORE SEVERE SIDE EFFECTS.

AS YOU KNOW, VACCINATIONS ARE USUALLY GIVEN IN A DOCTORS'S OFFICE WHERE THE PERSON AND HIS OR HER GENERAL HEALTH SITUATION IS KNOWN TO THE DOCTOR AND THE CONDITIONS UNDER WHICH IT IS GIVEN ARE CONTROLLED. IN ADDITION, EACH PERSON CAN BE FULLY INFORMED OF ALL ASPECTS OF THE INNOCULATION AND IN GENERAL WHAT TO EXPECT.

IN A MASS IMMUNIZATION PROGRAM THIS IS HIGHLY IMPROBABLE OR IMPOSSIBLE OF ACCOMPLISHMENT. AS A RESULT LESS THAN FULLY PROTECTION FROM ILLNESS, GREATER SIDE EFFECTS THAN ANTICIPATED OR EVEN A SUBSEQUENT UNRELATED ILLNESS MAY BE CONSIDERED IN THE MINDS OF SOME AS A BASIS FOR A LIABILITY SUIT AGAINST THE COMPANY. SUCH SUITS WOULD BE EXTREMELY COSTLY EVEN IF SUCCESSFULLY DEFENDED AND COULD HAVE UNCERTAIN OUTCOMES FOR YEARS.

N KEEPING WITH THE AMERICAN SENSE OF FAIR PLAY, WE ARE SURE THAT YOU WILL RECOGNIZE THAT THE COMPANY AND ITS STOCKHOLDERS SHOULD NOT BE LEFT WITH THIS SUBSTANTIAL RISK ALONE WITH NO LIABILITY PROTECTION--PRIVATE OR GOVERNMENT--TO SHARE THIS MASSIVE POTENTIAL BURDEN WHICH COULD COMPLETELY UNDERMINE THE COMPANY'S FINANCIAL POSITION.

SINCE THERE NOW APPEARS TO BE NO OTHER SOURCE FOR SUCH SPREADING OF THE RISK AS IS ACCOMPLISHED BY INSURANCE, WE EARNESTLY REQUEST YOU TO SUPPORT OR SPONSOR LEGISLATION WILL ENABLE HEW OR ANY OTHER APPROPRIATE ARM OF THE GOVERNMENT TO PROMPTLY REPLACE OUR INSURANCE COVERAGE THAT WILL BE CANCELLED JULY 1.

AGAIN WE WANT TO ASSURE YOU THAT OUR COMPANY IS MOST DESIROUS OF SUPPORTING YOUR PROGRAM AND THAT WE ARE CONTINUING TO PRODUCE VACCINE AND HAVE TODAY SUBMITTED A BID AS REQUESTED BY HEW, SUBJECT TO RESOLUTION OF THIS PROBLEM BEFORE OUR INSURANCE COVERAGE IS WITHDRAWN ON JULY1.

WE ARE CONFIDENT THAT YOU AND THE CONGRESS AND THE AMERICAN PEOPLE WILL RECOGNIZE AND RESOLVE THIS DIFFICULT SITUATION IN WHICH OUR COMPANY AND ITS STOCKHOLDERS HAVE BEEN PLACED DUE TO CIRCUMSTANCES BEYOND OUR CONTROL

E.BURKE GIBLIN

Dq

(5)

GENERAL
HE 5
HE D
I91

June 28, 1976

Dear Mr. Giblin:

I am writing on behalf of the President about your communication to provide indemnification against claims for injury related to inoculation with vaccine under a comprehensive nationwide influenza immunization program.

As you know the Secretary of Health, Education and Welfare has submitted legislation to agree, in contracts for the purchase of vaccine in connection with the National Influenza Immunization Program to indemnify the vaccine manufacturers against claims attributable to inoculation with the vaccine, except claims arising out of the negligence of the manufacturers. Hearings are being held by the Congress and final action is expected soon by both bodies.

Sincerely,

SPENCER C. JOHNSON
Associate Director of the
Domestic Council

Mr. E. Burke Giblin
Chairman
Warner-Lambert Company
Morris Plains, New Jersey

15.

Steve McClintock

COMMONWEALTH OF PENNSYLVANIA
OFFICE OF THE GOVERNOR
HARRISBURG

MILTON J. SHAPP
GOVERNOR

July 8, 1976

The Honorable Gerald R. Ford
President of the United States
1600 Pennsylvania Avenue
Washington, D. C. 20500

Dear President Ford:

It is with grave concern that I call upon you to provide immediate direction to the mass influenza immunization program which you announced in a news conference on March 24, 1976.

At that time, many of the nation's top medical and scientific experts met with you and concurred that we needed a massive influenza immunization program as a preventive public health measure against a strain of virus, defined as A-New Jersey-76 (Swine Flu). It was feared then that this new strain of influenza might be as virulent as the 1917-1918 worldwide epidemic which claimed more American lives than World War I.

Your recommendation led to the unprecedented appropriation by Congress of $135 million for this massive preventive health program. Pennsylvania public health officials joined with most of their counterparts in other states in applauding your action, noting that "an ounce of prevention was indeed worth a pound of cure." However, since that time, the entire Swine Flu Program has been engulfed in controversy involving the legal and scientific interests across the nation.

The American public is bewildered and confused by the conflicting reports emanating from the Federal government.

For example:

-- One pharmaceutical company made the wrong type vaccine.

-- Federal testing of the Swine Flu vaccine by the Center for Disease Control in Atlanta, Georgia, was inconclusive as to the vaccination of children.

-- There has been no administrative or congressional action taken on granting indemnification to vaccine manufacturers against claims for injury related to inoculation.

-- We have no assurance, because of the conflicting reports, whether Americans will indeed roll up their sleeves for shots this fall against a flu virus which may not come this winter.

-- Most states are hardpressed by their share of the $135 million to deliver vaccine and the required administrative support to 80 percent of their populations.

Here in Pennsylvania, our Department of Health has been prepared since early May to administer your immunization program. Dr. Theodore Cooper, Assistant Secretary for Health, U. S. Department of Health, Education and Welfare, has referred to Pennsylvania's proposed immunization program as one of the most ambitious in the nation. Just this week, I signed a special $1,390,000 appropriation to help administer the program throughout the Commonwealth.

Unfortunately, with each passing day, lack of Federal guidelines and direction on the legal issues have seriously jeopardized public confidence in this preventive health program. Our deadlines for inoculating high risk groups and the mass population have been pushed back several times by Federal indecision.

Throughout this entire four-month period, you have remained silent. I now urge you to step in personally and direct your administration to resolve the scientific, and, particularly, the legal differences which have sidetracked this program and confused the American public.

Should this program fail, we may never again be able to mount the type of preventive health programs so necessary to save thousands of lives in any given year.

If in fact, Swine Flu can be expected to take thousands of American lives this fall and winter, your administration should move the mass influenza immunization program off dead-center.

If not, the truth should be told now.

Pennsylvania continues to be greatly concerned about the outcome of this dilemma and you have my assurances we will do all we can to promote and implement a genuine preventive immunization program.

Sincerely,

MILTON J. SHAPP
Governor

cc: Pennsylvania Members of Congress
Dr. Leonard Bachman, Pa. Health Secretary

August 5, 1976

Dear Governor Shapp:

This is in further response to your letter of July 8, concerning the national influenza immunization campaign which the President announced last March.

The President has taken a personal interest in seeing that this needed program overcomes the obstacles which it now faces, and that immunization against this new type of influenza virus is made available to all Americans.

The Congress has begun favorable action on our proposal to provide Federal indemnification for the manufacturers of the vaccine, and thus break the deadlock between manufacturers and the insurance industry on the question of liability. This will enable the program to proceed as planned.

The remaining scientific questions which prevent us from making firm vaccination recommendations for those under age 25 are also being addressed at the present time. Data from additional field trials will permit us to answer these questions by early September.

I appreciate your support of this unprecedented effort and assure you that I will do everything in my power to see that it succeeds.

Sincerely,

Stephen G. McConahey
Special Assistant to the President
for Intergovernmental Affairs

The Honorable Milton J. Shapp
Governor of Pennsylvania
Harrisburg, Pennsylvania 17120

cc: Spencer Johnson

114

MEMORANDUM OF INFORMATION FOR THE FILE

DATE 7/22/76

EXECUTIVE
HE1
PR7-1
HE5
IS
BE4
BE4-28
FG23
FG6-16
FG6-11-1/Cavanaugh
FG6-11-1/Khatican
PR7

LETTER, MEMO, ETC. Agenda

TO:

FROM: Jim Cannon

SUBJECT: Meeting with Sec. Mathews on Swine Flu

Cooper, Ted
Taft, William H.
O'Neill, Paul
NIIP

CORRESPONDENCE FILED CENTRAL FILES – CONFIDENTIAL FILE

THE PRESIDENT HAS SEEN

C.F.

THE WHITE HOUSE

WASHINGTON

July 22, 1976

MEETING WITH SECRETARY MATHEWS ON SWINE FLU

Thursday, July 22, 1976
2:30 p.m. (30 minutes)
The Cabinet Room

From: Jim Cannon

I. PURPOSE

To receive a status report on the swine flu vaccine program and to obtain the Secretary's specific recommendations on next steps.

II. BACKGROUND, PARTICIPANTS & PRESS PLAN

A. Background: On Tuesday, Secretary Mathews reported on the flu vaccine program at the Cabinet meeting. Following that, the Secretary sent you a memorandum, Tab A, outlining 10 options, including the recommendation that you meet with the Congressional leadership to urge their reconsideration of proposed legislation to relieve the manufacturers of responsibility for any government negligence in carrying out this program. The Secretary also recommended that you meet with representatives from the drug manufacturers and the insurance companies.

Since that time, the Secretary has sent you a memorandum, Tab B, recommending that you meet with representatives of the 18 major insurance carriers involved in the program.

The soundings that we have taken in the last 72 hours from people across the country reveal the following:

1. There is widespread scientific-medical evidence and support for the national swine flu vaccination program.

2. The drug manufacturers are on the verge of stopping production of additional flu vaccine pending resolution of their liability problem.

3. The insurance carriers do not appear to have as a motive making unreasonable profits, but are concerned about the cost of defending "nuisance" claims.

4. The Congressional committees, particularly Paul Rogers' health subcommittee in the House, are uneasy about the possibility of swine flu being found in Australia and are trying to shift the burden for not enacting your legislation to the White House. Rogers has issued a press release calling for you to meet with the drug companies and the insurance industry to bring about a "resolution" of the problem.

5. An increasing number of states are beginning to experience difficulty in securing liability insurance for their part of the vaccination program.

6. Because of concern about being exposed to potential liability, the Advertising Council this morning decided to withdraw from the advertising portion of the program.

B. Participants: Secretary David Mathews
Dr. Ted Cooper, Assistant Secretary for Health, HEW
William H. Taft, General Counsel, HEW
Jim Cavanaugh
Bill Rhatican
Paul O'Neill

C. Press Plan: To be determined.

III. TALKING POINTS

1. David, where are we and where do we go from here?

2. I have no objection to meeting with the insurance companies and perhaps the drug industry as well, but I would like to know specifically what positively could result from such a meeting.

3. My feeling is that it is the Congress that is delaying this program now with their failure to enact the legislation that we asked them to move four weeks ago. Do you think that it would be helpful at this point for me to issue a statement hitting the Congress for not moving our legislation?

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

JUL 20 1976

MEMORANDUM FOR THE PRESIDENT

Recent notification by the four vaccine manufacturers that they will be unable to obtain product liability insurance has created a crisis for the National Influenza Immunization Program (NIIP). Without resolution of the liability issue, manufacturers are expected to stop vaccine production within a matter of days. Merrell-National has notified us that they will not purchase any more eggs after Tuesday, July 20, and, therefore, will be going out of influenza vaccine production. Parke-Davis has also notified us that they will be making an "imminent decision" within the next few days as to the termination of their production. Finally, none of these manufacturers will enter into contracts to sell existing stocks of 76 million doses to the government for use in NIIP.

The liability problem, the underlying issue of the cost of baseless suits for supposed government negligence, and the immediate problem of keeping production going are the three issues we need to address.

As a result of meetings over the weekend, we have developed an evaluative paper on the issue (a revised copy with the latest information is attached). From that analysis and my sense of the situation from being in the direct negotiations for the last week, I would offer the following recommendations:

- That in our public statements we not minimize the seriousness of the inability of the manufacturers to find liability support but announce that the government and manufacturers are still in contract negotiations.

- That we take whatever steps are necessary to see that the vaccine manufacturers continue producing influenza vaccine. Unless there is a legal prohibition, the Department should, from its recent appropriation, make an advance payment to cover production costs while negotiations are in process.

- That you meet with the Congressional leadership as soon as possible to capitalize on their recent expressions of support and to urge reconsideration of our existing proposed legislation.

- That the Administration, under this legislation, make a new proposal to set a limit on the liability for baseless suits which imply government fault so that the liability is insurable. Under this proposal the government then pays the attorneys' fees if the suits exceed reasonable projections. (The government would, in most of these cases, already be a party.) With this position we would then try to unlock the impasse with the insurance companies, even though they are now insisting on full coverage by the government, even for the negligence of the manufacturers.

- That we begin now to prepare a long-range answer to a question that we will get asked even before August on what we recommend to solve this same liability problem which may now reappear with all public immunization programs. This is one facet of a form of national health insurance that will become more and more central to the debate.

Secretary

Attachment

National Influenza Immunization Program
Status Report
July 20, 1976

A. ISSUE: In view of the likelihood that insurance coverage will be denied to vaccine manufacturers, where do we go from here?

B. BACKGROUND
1. Justification and Scientific Rationale for the National Influenza Immunization Program (NIIP)
2. Delivery Aspects of NIIP
3. Clinical Trials and Vaccine Safety
4. Vaccine Production Capacity

C. MAJOR PROBLEMS
1. Contract Negotiations
2. Insurance Coverage
3. Other Liability Problems

D. OPTIONS
1. Modify or Abandon The Program
   - Option 1: Partial Program: Adopt a Federally-supported Influenza Immunization Program of Limited Size--e.g. High-risk or "First Come, First Serve"
   - Option 2: No Program: Abandon Current Attempts to have a Federal Influenza Program of Any Size
2. Continue Negotiations Without Further Legislation
   - Option 3: Presidential Discussions with the Insurance Industry
   - Option 4: Indemnification Fund, from Current Program Appropriations
   - Option 5: Formal Contract with Two or Three of the Vaccine Manufacturers, In an Effort to Effect Agreement With Hold-out Company(ies).
3. Seek New Legislation
   - Option 6: Consultation With Congressional Leadership by President and Reconsideration of Existing Proposed Legislation
   - Option 7: Federal Indemnification to Provide "Top-dollar" Coverage
   - Option 8: Federal Compensation for Persons Injured as a Result of Receiving Nationally Recommended, Licensed Vaccine
4. Other Options
   - Option 9: Government Manufacture of Vaccine Under the Authority of Section 352 of the U.S. Public Health Service Act which Presently Authorizes the Production of Vaccine, Otherwise Unavailable.
   - Option 10: Miscellaneous Options

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

TO : The Secretary

DATE: July 20, 1976

FROM : Assistant Secretary for Health

SUBJECT: The National Influenza Immunization Program: Status Report, July 20, 1976--ACTION

ISSUE:

Recent notification by vaccine manufacturers that they will be unable to obtain product liability insurance has created a crisis for the National Influenza Immunization Program (NIIP). Without resolution of the liability issue, manufacturers are expected to terminate vaccine production within a matter of days, and furthermore not enter into contracts to sell existing stocks of vaccine to the government. How should we proceed?

BACKGROUND

Program Justification: The original scientific rationale for NIIP has not been seriously questioned, and remains sound:

-The infectiousness of the A/New Jersey/76 (swine influenza-type) virus and its Human-to-Human spread at Fort Dix, New Jersey, involved several hundred military recruits, in February of this year.

-Since this virus is new to the majority of people, the potential for pandemic spread exists.

-Influenza remains a serious public health and economic problem.

-We have the capacity to produce quality vaccine in sufficient quantities and deliver it to the public, thereby thwarting the threat of an epidemic.

Delivery Aspects of NIIP: Organizational activities at the State and local levels are well advanced. Voluntary groups have been identified, briefed, and organized. Training of volunteers by health department personnel has begun. The private medical community is involved in the planning of programs in many States; some State and local medical societies have already endorsed the program and pledged their support.

Clinical Trials and Vaccine Safety: Results of the first phase of clinical trials which involved 5,200 volunteers in the largest pre-certification field trials ever performed, have been very encouraging. The trials demonstrate that vaccine preparations from each of the four manufacturers were effective in immunizing persons over age 24, at as low as 200 CCA units. The effectiveness was particularly pronounced in individuals over the age of 53, since they have been primed by exposure to swine influenza-type virus during the period between 1918-1929.

Reactions to vaccine at the 200 CCA dosage level among all recipients over the age 24 were minimal. For example, only 1.9 percent of recipients experienced any fever during the 48-hour observation, a frequency not significantly different from that observed in the placebo control group where 1.7 percent had fevers.

Persons below the age of 25 years were less successfully immunized. In these younger adults and children, larger doses of vaccine were required to induce a protective antibody response. A second phase of clinical trials, which is expected to end in September, will provide sufficient data on which to make recommendations for use of A/New Jersey/76 vaccine in children and young adults. One possibility may be to give a primary injection to initiate antibody production, and follow at a later time with a booster shot to raise the antibodies to the proper level. Like the first phase, the current phase of studies is going well. Participants have not experienced any unexpected or severe reactions that have required hospitalization.

These studies confirm the long-standing safety record for influenza vaccines. More than 250 million doses of influenza vaccine have been administered in this country during the 40-year history of the use of influenza vaccine. We are aware of no case in the medical literature of a fatality clearly attributable to killed-virus influenza vaccine.

Based on other experience to date, there is no known vaccine that is safer than A/New Jersey/76 vaccine when given in the 200 CCA unit dosage, to adults over age 24.

Vaccine Production Capacity: Seventy-six million doses of A/New Jersey/76 vaccine (200 CCA units) are available in final bulk form in company freezers, as of Friday, July 16, 1976.

An additional 15 to 20 million doses are in the production pipeline.

On July 15, 1976, we were verbally notified that Merrell-National will not purchase any more eggs after Tuesday, July 20, and therefore, will be going out of influenza vaccine production. We also learned that Parke-Davis will be making an "imminent decision" within the next few days as to the termination of their production.

MAJOR PROBLEM

Contract Negotiations: Since the emergency appropriations for the program were enacted, the Department and representatives of the four manufacturers have endeavored to negotiate a suitable contract clause on liability question. From the outset, the manufacturers expressed their concern that they might be held liable in suits for injuries resulting from failure in aspects of the program over which they had no control.

A liability clause was developed by mid-May which was tentatively acceptable to three of the companies; they indicated that they thought that it would reduce their risks to an acceptable level. One company balked at participating in the program unless all risks--other than those incurred as a result of their own negligence--were assumed by the government. Shortly thereafter, all companies were informed that their liability insurance was going to be either cancelled or severely reduced.

In light of these developments, the Department sought legislation to indemnify the manufacturers against losses resulting from the government's failure to carry out its responsibilities under the program. On July 1, the House Subcommittee on Health and the Environment refused to take action on legislation and urged all parties to resolve the liability problem through agreement and contract language.

The Department then resumed intensive negotiations with the manufacturers and a new contract clause was developed which, in our judgement and that of the manufacturers' counsel, goes to the very limit of our authority to meet the manufacturers' concerns on the liability question. Among other provisions, the clause would make the government liable for losses incurred by the manufacturers in personal injury suits (including attorney's fees), arising out of failure of the government to discharge its responsibilities under the contract. At the request of the manufacturers, we obtained a legal opinion from the Department of Justice that the contract clause would not contravene the provisions of the Anti-Deficiency Act. Any general undertaking to indemnify the manufacturers would require legislation, such as that proposed by the Department last month.

The attitude of the insurors has not been helped by testimony from their association asserting the possibility of enormous litigation costs resulting from the program. While ill-informed and exaggerated, this perception plus the more general problems in liability insurance have made the insurors unwilling to insure most of the drug manufacturers even for "baseless" suits and manufacturer negligence.

Current situation. Although we provide a full range of options below, it now appears (mid-day on Monday) that: (1) some manufacturers will be unable to get any insurance, even for their own negligence; (2) our previous proposed legislation will not resolve the problem alone; and (3) the manufacturers are understandably unwilling to sign contracts without some protection.

Other Liability Problems: Almost two-dozen States and municipalities anticipate difficulty in obtaining normal liability insurance for the participation of their employees in NIIP.

In addition, the liability issue has stalled our efforts to obtain an advertising agency, through a contract with the Advertising Council, to develop a needed mass-media public awareness campaign.

Finally, negotiations between manufacturers of split-virus vaccines and their insurors were recently complicated by news reports of the military's decision to purchase only whole-virus vaccine, which erroneously implied that there was something inferior or undesirable about the split-virus vaccine.

OPTIONS:

The available options can be divided into three categories: (1) options which would decide now to abandon or substantially revise the program; (2) options which continue to assume no new legislation but undertake to continue a full national program; and (3) options which assume new legislation in order to continue the national program.

In light of most recent developments, some of the options are no longer viable as the manufacturer's position has been made clear. They have been retained, however, to give you the full range of our review. In addition, several options from the second and third category could be selected in combination. For example, one could decide to consult with the Congressional leadership without finally deciding to pursue new legislation.

Category I: Modify or Abandon the Program

Option 1: Partial program. Under this option, the Federal government would seek to acquire some or all of the stocks currently in the possession of the manufacturers and would develop a program to vaccinate some fraction of the population. Possibilities for a limited or partial program include vaccination of the high-risk members of the population or a "first come, first serve" program.

PRO

-Would provide Federal monies to protect some Americans

-Would place Federal government in position of trying to protect the health of our citizens.

CON

-Would reverse the basic thrust of our public position in behalf of the national program

-Would force a highly undesirable set of Federal choices:

--Selection of high risk group raises undesirable scientific, ethical and economic consequences for those left out.

--A "first come, first serve" program virtually guarantees geographic and socio-economic discrimination.

-Manufacturers are likely to be unwilling to release the vaccine to the Federal government on the grounds that they would be still subject to suit.

Option 2: Abandon the Program. Under this option, the Executive branch would announce the failure of insurors to underwrite on reasonable terms, thus causing us to abandon our program. Flu shots would still be recommended, if obtainable, and the scientific element would continue. Manufacturers would presumably sell their current 96 million doses in normal markets, including foreign markets.

PRO

- Would probably result in some coverage of Americans, mainly middle- and upper-income.

- Might permit manufacturers to obtain some insurance (higher priced), since risks in purely private undertakings are considered somewhat less.

CON

-Excludes much of population and raises price of protection

-Could be regarded as a failure of the Administration

-Could provoke a negative and unpredictable Congressional or public reaction.

Category II: Continue Negotiations without Further Legislation

Option 3: Presidential Discussions With the Insurance Industry. The President could intercede personally and urge the leadership of the largest insurors to provide adequate insurance coverage to the manufacturers of the vaccine.

PRO

-This action would carry the weight of the Presidency and demonstrate the importance of preserving the health of the American people. It would represent the ultimate attempt on the part of the Executive branch to encourage the insurance carriers to provide coverage.

-Might be necessary, as a prerequisite, to persuade Congress to reconsider its negative view of our existing, proposed legislation.

CON

-Should the insurance industry refuse to provide adequate coverage, this could be construed as a defeat for the Administration.

Option 4: Indemnification Fund, from Current Program Appropriations. A portion of current appropriations might be made available as an "indemnification fund" to reimburse manufacturers for costs of defending third party law suits arising out of actions other than their own negligence. Vaccine manufacturers might then be persuaded to remain in the program. An "indemnification fund" could be created in one of two ways: (1) a portion of the excess funds in the program could be set aside by the government in each contract (the amount to be determined by negotiation) and be available as needed to reimburse the contractor for

costs of defending suits, up to the maximum amount set aside, or (2) by inclusion of an additional, fixed amount in the vaccine contract purchase price. Such an "indemnification fund" could be justified on the grounds that it is "a part of the contractors' costs of doing business"--a program cost which we have the authority to pay.

PRO

-This provision might meet the manufacturers' professed greatest concern--the cost of defending a large number of baseless law suits. Assuming an "indemnification fund" of about $5 to $10 million for each contract, manufacturers might be able to obtain insurance to cover the cost of defending claims above the amount available in the "indemnification fund".

-If the "indemnification fund" were created under government control (method 1), the government would be paying only for costs actually incurred by the manufacturers for defending such suits.

CON

-The Government would be taking a step further than we have been prepared to go so far by bearing the cost of defending law suits against the manufacturer even though the government fully discharged its responsibilities under the contract.

-If method 2 were used, the manufacturers could receive a windfall if the number of suits are smaller than they expect (we believe that they will be).

-Other participants in the program, including public units, non-profit organizations, volunteers, and health care providers might demand that an "indemnification fund" be made available for claims against them.

-The manufacturers may not feel that the amounts the government can commit are adequate.

-The Congress could question our authority to proceed in this manner.

Option 5: Formal Contract with Two or Three of the Vaccine Manufacturers In an Effort to Effect Agreement With Hold-out Company(ies). Convincing two or three of the vaccine producers to enter into contract could put public pressure on the remaining one or two company(ies) to participate in NIIP.

PRO

-Would have the advantage of allowing the hold-out company(ies) "to bend to public pressure and eventually concede to participate ...in the National interest".

CON

-If unsuccessful, the decision to implement a national program in the absence of assurances of adequate amounts of vaccine could result in a serious over-commitment without a clear recourse to obtain more supplies.

-Not likely to be successful. The least likely companies are the largest manufacturers who have given very little indication of flexibility.

Category III: Seek New Legislation

Option 6: Consultation With Congressional Leadership by the President and Reconsideration of Existing Proposed Legislation. In view of the major role that the Congress has played in authorizing and appropriating monies for NIIP and its present interest in seeing the program continue, the President could meet with both the general and health leadership of the Congress to urge reconsideration of the Administration's previous bill. The Subcommittee's belief that this national program could proceed without additional legislation now appears to be wrong.

PRO

-The Executive branch would be taking a responsible role in informing the Congress as to the status of contract and liability aspects of the NIIP. It would provide an opportunity to discuss the possibility of reconsidering our previous legislation to indemnify manufacturers for liability other than that due to their own negligence.

-Our previous legislative proposal had broad provisions which would permit us to address, if we elected, all of the concerns of the manufacturers, including the issue of baseless suits (but not including manufacturer negligence).

-Informal Congressional "feelers" have indicated a willingness to reconsider the matter.

CON

-This action by the President could be misinterpreted by the Congress, and viewed by the public, as an admission of failure to implement a "Presidential program".

-The bill still lacks the specificity desired by the manufacturers as to whether, and how, the Secretary will exercise his authority to handle the major problem.

-May not meet the concern of some manufacturers about coverage for their own negligence.

Option 7: Federal Indemnification to Provide "Top-dollar" Coverage. The use of Federal dollars to cover legal costs of suits can be approached in two ways. Either the government can pay into an "indemnification fund" to cover costs of suits up to a certain amount (Option 4), leaving to private insurance any larger amounts; or the government could cover any costs of suits above some fixed amount, with regular insurance covering costs up to that fixed point. This option would adopt the latter approach.

PRO

-Would limit outer liability of insurors, thus making their risk limits explicit.

-Could protect Federal dollars from actual use if we are right about the real risks.

CON

-Manufacturers might not accept limits proposed by Federal government

-Insurors might not make primary, "first-dollar" coverage available to manufacturers at all, or make it available only at a prohibitive price, which could in turn be passed back to the government through the price of vaccine.

Option 8: Federal Compensation for Persons Injured as a Result of Receiving Nationally-Recommended, Licensed Vaccine. We could request that Congress authorize the development of a compensation plan for personal injuries incurred as a result of participation in the National Influenza Immunization Program.

PRO

-Would demonstrate Federal acceptance of the responsibility for vaccine-associated disability in that claims would be made directly to the Federal government, by-passing the manufacturer.

-Would indicate a responsible Federal role since the government would license, recommend usage, and support purchase of vaccine and implementation of programs of immunization.

-Would be applicable to other preventive health programs.

-Would improve surveillance of vaccine-associated disability since all claims would be centralized for review and action.

CON

-Could require a new Federal bureaucracy to review, arbitrate, and settle claims--for what may likely be very few cases each year.

-Would require a major legislative effort to develop a compensation plan. Furthermore, the time required to develop and pass legislation would be too long to benefit NIIP.

-Could create some undesirable precedent for other than national immunization programs.

Category IV: Other Options

Option 9: Government Manufacture of Vaccine, Perhaps Under the Authority of Section 352 of the U.S. Public Health Service Act Which Presently Authorizes the Production of Vaccine, Otherwise Unavailable.

PRO

-Would provide technical capability to continue to produce A/New Jersey/76 Vaccine and enable the government to produce influenza and possibly other vaccines in the future.

CON

-Federal government has no experience in managing or directly manufacturing influenza vaccine. The administrative problems would be formidable.

-Authority under provision 352 of the PHS Act does not presently exist since influenza vaccine is not unavailable in the strictest sense. We are simply unable to successfully enter into contract to purchase the millions of A/New Jersey/76 vaccine for use in NIIP.

Option 10: Miscellaneous Options: There are several other options which we have considered, but rejected from significant consideration on grounds of legality, administrative feasibility or time required to implement. These include the following:

A. Purchase of Lease Vaccine Facilities (Administrative Infeasibility and Insufficient Time).
B. Federal Purchase of Vaccine and Re-sale to Recipients at Cost, With Revenue Being Placed in an "Indemnification Fund"; Federal Support Retained for National Plan to Deliver Vaccine, at No Charge (Administrative Infeasibility; Violation of Congressional Intent).
C. Payment of Court Costs by Plaintiffs in Baseless, Frivolous Suits (Legality Problems)

D. Purchase Vaccine from Manufacturer to Relieve their Expenses, With a Commitment by Us Not to Use Vaccine In NIIP, Without Their Consent, Until Liability Issue is Resolved. (Legal Authority Problems).
E. Attempt to Get Those Vaccinated to Waive Right to Sue. (Legally Not Possible)
F. Classic Re-insurance Plan for Insurors. (Inadequate Time to Get Enacted and Implemented)

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

July 20, 1976

MEMORANDUM FOR THE PRESIDENT

In light of your response to my report to you this morning on the flu situation, I would propose that you invite the vaccine manufacturers along with their principal insurance carriers to meet with you immediately to seek a solution to the current impasse over liability coverage.

The insurance companies to be invited should include the following:

Aetna
Prudential Re-insurance
LeBoeuf, Lamb, Leiby & MacCrae (LLOYDS OF LONDON)
Crumm and Foster Insurance
Chubb & Son, Inc. (Federal Insurance)
American Home Assurance
Continental Insurance of New York
Alexander & Alexander Insurance Broker
Insurance Company of North America
American Re-insurance
Northbrook (of All-State Insurance)
Johnson & Higgins Insurance Broker
Home Insurance
Liberty Mutual
Davis-Dorland Insurance Broker
General Re-insurance
Fred S. James Insurance Broker
Patterson & Ross of Chicago (WEAVERS OF LONDON)

I would also suggest that you meet with the Congressional leadership on this matter soon, particularly the health leadership.

Secretary

MEETING WITH
SECRETARY MATHEWS ON SWINE FLU

Thursday, July 22, 1976

2:30 P.M.

THE PRESIDENT HAS SEEN....

EXECUTIVE
HE 1
HE 5

THE PRESIDENT HAS SEEN....

THE WHITE HOUSE

WASHINGTON

August 5, 1976

FACT SHEET

Swine Flu Influenza Immunization Program Legislation

The bill would amend the Public Health Service Act to establish a mechanism to handle claims and if necessary, compensate persons injured as a result of inoculation with vaccine under the Swine Flu National Influenza Immunization Program. It would provide that persons injured as a result of inoculation under the Program would have as their exclusive remedy a suit against the Federal government under the Federal Tort Claims Act.

Under this bill, the Federal government would be liable for claims against "program participants", including the vaccine manufacturers and distributors who participate in the Program, the public and private agencies or organizations that participate in the Program without charge for the vaccine or its administration, and the medical and paramedical personnel who, without charge for the vaccine or its administration, administer or assist in administering inoculations with such vaccine.

At the same time, the government retains the right to recover for any negligent act of a "program participant" that results in a settlement or court judgment.

Physicians who administer the vaccine in their normal practice for a fee would be covered by their regular malpractice insurance and would not be included in this Program.

This approach is similar to the Administration's draft to provide indemnity under the Federal Tort Claims Act which Secretary Mathews presented to the subcommittee. The only amendment made in subcommittee was to change the term "agent of the government" to "program participant".

White House Photograph

Description: In a press briefing President Ford urges congressional enactment of the National Swine Flu Influenza Program.

Photographer: David Hume Kennerly

Date: August 6, 1976

8/12/76

APPROVED
AUG 12 1976
Signed in Ceremony - Cabinet Room - 12:00 Noon.
Statement + Remarks issued
8/12/76

THE WHITE HOUSE

WASHINGTON

August 11, 1976

ACTION

Last Day: August 23

MEMORANDUM FOR THE PRESIDENT

FROM: JIM CANNON

SUBJECT: S. 3735 - National Swine Flu Immunization Program of 1976

Archive
8/12/76

Attached for your consideration is S. 3735, sponsored by Senator Kennedy.

The enrolled bill authorizes the Secretary of Health, Education and Welfare to carry out a national swine flu immunization program until August 1, 1977, and provides legal protection for agencies, organizations and individuals who manufacture, distribute, and administer swine flu vaccine against liability for other than their own negligence to persons alleging personal injury or death arising out of the administration of the vaccine.

Additional information is provided in OMB's enrolled bill report at Tab A.

OMB, Max Friedersdorf, Counsel's Office (Lazarus) and I recommend approval of the enrolled bill and the proposed signing statement which has been cleared by the White House Editorial Office (Smith).

RECOMMENDATION

That you sign S. 3735 at Tab B.

That you approve the signing statement at Tab C.

Approve _____ Disapprove _____

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

AUG 11 1976

MEMORANDUM FOR THE PRESIDENT

Subject: Enrolled Bill S. 3735 - National Swine Flu Immunization Program of 1976
Sponsors - Sen. Kennedy (D) Massachusetts and 6 others

Last Day for Action

August 23, 1976.

Purpose

Authorizes the Secretary of Health, Education, and Welfare (HEW) to carry out a national swine flu immunization program until August 1, 1977, and provides legal protection for agencies, organizations, and individuals who manufacture, distribute, and administer swine flu vaccine against liability for other than their own negligence to persons alleging personal injury or death arising out of the administration of the vaccine.

Agency Recommendations

Office of Management and Budget	Approval (Signing statement attached)
Department of Health, Education, and Welfare	Approval
Department of Justice	No objection
Department of Housing and Urban Development	Approval (informally)

Discussion

S. 3735 is the result of extended negotiations between the Administration and the House and Senate Health Committees to obtain legislation that would enable the Government to provide a comprehensive program of swine flu immunization to protect the American public during the next flu season. You previously recommended funding for this program, and the Congress responded to your request by appropriating

$135 million on April 15, 1976 in P.L. 94-266.

The enrolled bill responds to the concern of the vaccine manufacturers that they might be held liable for negligence or failures in those aspects of the immunization program over which they had no control. This concern stemmed from the trend in court decisions to hold manufacturers of some drugs and vaccines liable to users of the products under principles of strict product liability. Moreover, the insurance carriers refused to provide liability insurance because of the magnitude of the program and the uncertainties regarding the risk involved.

S. 3735 has the following three major features.

Program authorization - The enrolled bill would authorize HEW to conduct activities necessary to carry out the national swine flu immunization program until August 1, 1977. These activities include development, preparation, procurement and distribution of safe and effective vaccine, as well as related personnel training and research activities.

The bill would require HEW to develop, in consultation with the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and to implement a written informed consent form and procedures for assuring that the risks and benefits from the swine flu vaccine are fully explained to each person receiving the vaccine -- including information necessary to advise them with respect to their rights and remedies.

The bill would provide that any contract for procurement by the United States of swine flu vaccine shall be subject to renegotiation to eliminate any profit realized from such procurement. A "reasonable" profit -- to be determined by the Secretary of HEW -- would be allowed, however, with respect to influenza A/Victoria/75 vaccine, which would be administered with the swine flu vaccine to high risk groups.

HEW would be required to submit quarterly reports to the Congress on the administration of the swine flu program. The bill states that no funds are authorized to be appropriated for the swine flu activities specifically enumerated in the bill in addition to the funds already appropriated by P.L. 94-266, except for grants to the States to assist in meeting their costs related to the swine flu program.

The authorized activities summarized above are unnecessary, since HEW already has the statutory authority to conduct the program, and the activities have been underway for some time.

Protection against liability - S. 3735 would establish a procedure under which all claims for injury from inoculation with the swine flu vaccine would be asserted directly against the United States. The filing of claims and actions under the Federal Tort Claims Act would be the exclusive remedy for all eligible claimants. Since the United States is responsible only for negligence under that Act, the enrolled bill would make an exception for this program and permit a claimant to recover under any principle of strict liability in tort or breach of warranty which is applicable in the jurisdiction in which the act or ommission is alleged to have occurred.

The bill would not absolve participants in the program -- drug manufacturers, public and private agencies, medical and paramedical personnel, and the government -- from negligence. In those instances in which payment is made by the Government to a claimant, either by court judgment or administrative settlement, the Government could bring an action to recover any damages awarded which are caused by the negligence of any of the other participants in the program.

The protection provided to all participants in the program would be available to public and private agencies and medical and paramedical personnel only if they administer the vaccine without charge and comply with the consent form and procedures requirements. Provisions are included in the bill for the removal to Federal court of suits filed in State court against participants in the program, and for the substitution of the United States as the sole defendant.

Within one year after enactment of the enrolled bill, and semiannually thereafter, the Secretary of HEW would be required to submit a report to the Congress on the conduct of settlement and litigation activities provided for in the bill.

Study of liability - The enrolled bill would require a study to be conducted or provided for by HEW of the scope and extent of liability for personal injuries or death

arising out of immunization programs, and of alternative approaches to providing protection against liability for such injuries in the future. The Secretary would be required to report to the Congress within one year the findings of the study and any appropriate recommendations for legislation.

In a letter to Chairman Rodino of the House Judiciary Committee on an earlier House version of this legislation, Secretary Mathews stated that it reflected the following four principles:

"1. The public's legal remedies for genuine injuries should not be circumscribed and an efficient method of pursuing them should be assured.

2. All program participants, including the Government, should be responsible for their own negligence.

3. No program participant or other person should make a windfall profit from this public health program.

4. No solution to the difficulties which have developed in this Government-sponsored and administered universal immunization program should be established as a precedent for other programs of smaller scope in which the Government plays a different and significantly smaller role."

With respect to the fourth principle, it should be noted that the "findings" section of S. 3735 refers to the "unique role" of the United States in the initiation, planning, and administration of the swine flu program. The bill as enrolled, however, also finds that the procedure instituted for handling claims in this case is necessary "until Congress develops a permanent approach for handling claims arising under programs of the Public Health Service Act." This latter finding, plus the requirement for a study by the Secretary mentioned above, suggests the possibility that S. 3735 may become a precedent for other programs.

The Department of Justice also sent a letter to Chairman Rodino on August 9 favoring enactment of the earlier House version of this legislation. Justice now states in the attached views letter that the additional requirement included in the enrolled bill that program participants comply with the informed consent form and procedure requirements is troublesome and will likely lead to considerable litigation. Justice believes it would

have been preferable if this program could have been accomplished with the normal insurance coverage usually provided to vaccine manufacturers. The Department notes, however, that extensive efforts to obtain such coverage were unavailing and the desirability of conducting the program was such that the legislation was deemed necessary. Justice concludes that the enrolled bill is technically and administratively acceptable, "in consideration of the strong policy reasons requiring the emergency enactment of the legislation."

In view of the general consensus that liability protection legislation is essential to resolve the impasse in the swine flu immunization program, and since the enrolled bill was worked out in lengthy discussions between the various concerned groups, your approval of S. 3735 is recommended. A draft signing statement is attached for your consideration.

James M. Frey
Assistant Director for
Legislative Reference

Enclosures

S. 3735

Swine Flu Bill Dept.

to R. Linder 9/15 (10:20a)

STATEMENT BY THE PRESIDENT

I have today signed S. 3735, the "National Swine Flu Immunization Program of 1976."

I am gratified that the Congress has responded to this potential public health emergency by providing, as I requested, the assurances necessary to make possible the protection of all Americans against this threat.

S. 3735 will permit the Federal Government to assure appropriate liability protection for those manufacturing, distributing and administering the vaccine and provides a claims procedure for persons who might be injured. Extraordinary Federal measures are required to implement a program of this magnitude and I am sure that I speak for all Americans in expressing appreciation for this Congressional action.

Scientific and medical evidence continues to support the need for a national influenza immunization program. We have developed a safe and effective vaccine with a very low risk of adverse reactions. What we must do now is make it available as soon and efficiently as possible.

I strongly reaffirm my commitment to this program and I have directed the Secretary of Health, Education, and Welfare to move as expeditiously as possible to insure that we keep our original commitment of making this vaccine available to all Americans.

I have today signed S. 3735, the "National Swine Flu Immunization Program of 1976."

I am gratified that the Congress has responded to this potential public health emergency by providing, as I requested, the assurances necessary to make possible the protection of all Americans against this threat.

S. 3735 will permit the Federal Government to assure appropriate liability protection for those manufacturing, distributing and administering the vaccine and provides a claims procedure for persons who might be injured. Extraordinary Federal measures are required to implement a program of this magnitude and I am sure that I speak for all Americans in expressing appreciation for this Congressional action.

Scientific and medical evidence continues to support the need for a national influenza immunization program. We have developed a safe and effective vaccine with a very low risk of adverse reactions. What we must do now is make it available as soon and efficiently as possible.

I strongly reaffirm my commitment to this program and I have directed the Secretary of HEW to move as expeditiously as possible to insure that we keep our original commitment of making this vaccine available to all Americans.

STATEMENT BY THE PRESIDENT

I have today signed S. 3735, the "National Swine Flu Immunization Program of 1976."

I am gratified that the Congress has responded to this potential public health emergency by providing, as I requested, the assurances necessary to make possible the protection of all Americans against this threat.

S. 3735 will permit the Federal Government to assure appropriate liability protection for those manufacturing, distributing and administering the vaccine and provides a claims procedure for persons who might be injured. Extraordinary Federal measures are required to implement a program of this magnitude and I am sure that I speak for all Americans in expressing appreciation for this Congressional action.

Scientific and medical evidence continues to support the need for a national influenza immunization program. We have developed a safe and effective vaccine with a very low risk of adverse reactions. What we must do now is make it available as soon and efficiently as possible.

I strongly reaffirm my commitment to this program and I have directed the Secretary of Health, Education, and Welfare to move as expeditiously as possible to insure that we keep our original commitment of making this vaccine available to all Americans.

OFFICE OF MANAGEMENT AND BUDGET

Date: 8-12-76

TO : Bob Linder

FROM: James M. Frey
Assistant Director for
Legislative Reference

Attached is the official HEW views letter on the enrolled bill, S. 3735.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

AUG 11 1976

The Honorable James T. Lynn
Director, Office of Management
and Budget
Washington, D. C. 20503

Dear Mr. Lynn:

This is in response to your request for a report on S. 3735, an enrolled bill "To amend the Public Health Service Act to authorize the establishment and implementation of an emergency national swine flu immunization program and to provide an exclusive remedy for personal injury or death arising out of the manufacture, distribution, or administration of the swine flu vaccine under such program."

In summary, we strongly recommend that the President sign the enrolled bill, as its enactment is necessary to carry out the national program of immunization against swine influenza.

The bill would provide that the United States be substituted as the defendant in suits based on claims for personal injury or death resulting from swine influenza vaccine brought against vaccine manufacturers or other participants in the swine influenza immunization program. The United States, in turn, would have the right to recover for its losses in such a suit from a program participant whose negligence caused the injury or death. The provisions of the bill are summarized in more detail at Tab A.

From the outset of the swine influenza immunization program, the vaccine manufacturers have expressed their concern that they might be held liable for negligence or failures in those aspects of the immunization program over which they had no control. Their concerns stemmed from the trend in court decisions to hold manufacturers of some drugs and vaccines liable to users of the products under principles of strict products liability. Two Federal courts of appeals have held

manufacturers of polio vaccine liable, even in the absence of negligence, for failure to see to it that warnings of the hazards of the vaccine were communicated to the recipients of the vaccine.

In the case of the swine influenza vaccine, the manufacturers were understandably concerned that they would not be able to discharge their obligations to see to it that whatever warning might be appropriate reached the consumer, since the Government would be purchasing the entire output of the vaccine and would be responsible for its distribution to State health agencies, which in turn would arrange for the inoculation of the population. Additionally, in this emergency immunization program, the Government would be assuming functions normally undertaken by the manufacturers, i.e., establishing the specifications for the vaccine, investigating and determining the benefits and risks from its use, developing a statement of such benefits and risks, and seeing to it that the statement was communicated to the persons inoculated with the vaccine.

After carrying out extensive efforts to solve the liability problem of the manufacturers through (1) contract provisions without legislation, (2) proposed legislation indemnifying the manufacturers for losses for other than their own negligence, and (3) attempts to persuade the insurance companies to grant liability coverage to the manufacturers, a new legislative approach was developed through the joint efforts of the Congress, the Administration, and other interested parties.

The enrolled bill, reflecting this approach, embodies three principles:

1. The public's legal remedies for genuine injuries should not be circumscribed and an efficient method of pursuing them should be assured.

2. All program participants, including the Government, should be responsible for their own negligence.

3. No program participant or other person should make a windfall profit from this public health program.

The enrolled bill, by substituting the United States for program participants sued for death or personal injury resulting from swine influenza vaccine, protects not only non-negligent manufacturers, who up to now have been unable to obtain insurance, but also other participants in the program who have been finding difficulties in obtaining insurance. Additionally, except for insurance needed to protect participants against indemnification claims by the Government in those instances in which the participant may be negligent, no other insurance is necessary. This should materially reduce the cost of the vaccine to the Government since its price will reflect the cost of insurance. Windfall profits to insurance companies from excessively high premiums for risks the Government believes to be relatively minor would also be averted.

It is imperative that the President act expeditiously in relation to the enrolled bill. If the enrolled bill is signed, it will be possible to resume production with minimal delays, purchase the vaccine now already manufactured, and begin the distribution of the vaccine to make it available to the public by mid to late September. The vaccine produces effective immunity in most cases within two to three weeks of injection. It would be possible for the entire population who wished to be vaccinated to develop immunity by mid-December. The peak flu season is typically in January and February.

We strongly recommend that the President sign the enrolled bill.

Sincerely,

Secretary

Enclosure

SUMMARY OF THE PROVISIONS OF S. 3735

The bill would provide a redundant authority for carrying out the national swine influenza immunization program, and would require the Secretary to make quarterly reports on the administration of the program.

Each contract for the procurement of the swine influenza vaccine from a manufacturer would be subject to renegotiation to eliminate any profit realized from such procurement, except that with respect to vaccine against the strain of virus, known as influenza A/Victoria/75 (to be mixed with the swine influenza vaccine), a reasonable profit would be permitted. Any insurance premium included in the contract price and which was refunded to the manufacturer under any retrospective experience-rating plan or similar plan would be returned to the United States.

The enrolled bill would establish, as the exclusive remedy for persons alleging injury, a procedure consistent with that now provided for negligence claims against the United States under which all claims in connection with the program would have to be asserted directly against the United States. The enrolled bill would make the United States liable with respect to claims for personal injury or death arising out of the manufacture, distribution or administration of the vaccine in the same manner and to the same extent as the United States is now liable for claims based on the negligence of its own agents, except that the liability would be based on any theory of liability, and not solely negligence, that would govern an action against a program participant under the law of the place where the act or omission occurred, and the normal exceptions to the liability of the United States Government based on the due care or discretionary judgment of a Federal employee would not be available to the United States in defense of a claim against a program participant. Program participants would include the vaccine manufacturers and distributors, public and private agencies or organizations that participated in the program without charge for the vaccine or its administration and in compliance with the

informed consent form and procedures established for the program, and medical personnel who participated without charge for the vaccine or its administration and in compliance with the informed consent form and procedures established for the program.

The Attorney General would be required to defend any civil action or proceeding based on personal injury or death resulting from the administration of swine influenza vaccine brought against any employee of the United States or any program participant. Any person against whom the action or proceeding was brought would be required to deliver all relevant papers to the United States for its use in defending the action. A claim brought in a State court would be removed to the United States district court for that area. Program participants would be required to cooperate with the United States in the defense of claims, and, if they failed to do so, their protection under the enrolled bill would be revoked and suits against them permitted in the usual manner.

If payment were made by the United States to any claimant under the authority of the enrolled bill, the United States would have a right to recover for any portion of the payment attributable to negligent conduct on the part of any program participant in carrying out any obligation or responsibility in connection with the program or to the failure of any program participant to carry out any contract obligation or responsibility.

Within one year of the date of enactment of the enrolled bill and semi-annually thereafter, the Secretary would report to Congress on the conduct of the litigation and settlement activities under the bill.

The Secretary would further be required to conduct a study of the scope and extent of liability for personal injuries arising out of immunization programs and alternative means of providing protection against that liability and compensation for those injuries. The Secretary would have to report on the study within a year after the date of enactment to the Congress with recommendations for legislation as the Secretary deemed appropriate.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET

ROUTE SLIP

DATE 8-11-76

TO: Bob Linder

FROM: Jim Frey

REMARKS:

I should note that the HEW views letter attached is the Advance Copy. We have confirmed with HEW that this is their official recommendation.

OMB FORM 38
REV SEPT 70

To: J. Cavanaugh 8-11-76 6:00 J.M.

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

AUG 11 1976

MEMORANDUM FOR THE PRESIDENT

Subject: Enrolled Bill S. 3735 - National Swine Flu Immunization Program of 1976
Sponsors - Sen. Kennedy (D) Massachusetts and 6 others

Last Day for Action

August 23, 1976.

Purpose

Authorizes the Secretary of Health, Education, and Welfare (HEW) to carry out a national swine flu immunization program until August 1, 1977, and provides legal protection for agencies, organizations, and individuals who manufacture, distribute, and administer swine flu vaccine against liability for other than their own negligence to persons alleging personal injury or death arising out of the administration of the vaccine.

Agency Recommendations

Office of Management and Budget	Approval (Signing statement attached)
Department of Health, Education, and Welfare	Approval
Department of Justice	No objection
Department of Housing and Urban Development	Approval (informally)

Discussion

S. 3735 is the result of extended negotiations between the Administration and the House and Senate Health Committees to obtain legislation that would enable the Government to provide a comprehensive program of swine flu immunization to protect the American public during the next flu season. You previously recommended funding for this program, and the Congress responded to your request by appropriating

$135 million on April 15, 1976 in P.L. 94-266.

The enrolled bill responds to the concern of the vaccine manufacturers that they might be held liable for negligence or failures in those aspects of the immunization program over which they had no control. This concern stemmed from the trend in court decisions to hold manufacturers of some drugs and vaccines liable to users of the products under principles of strict product liability. Moreover, the insurance carriers refused to provide liability insurance because of the magnitude of the program and the uncertainties regarding the risk involved.

S. 3735 has the following three major features.

Program authorization - The enrolled bill would authorize HEW to conduct activities necessary to carry out the national swine flu immunization program until August 1, 1977. These activities include development, preparation, procurement and distribution of safe and effective vaccine, as well as related personnel training and research activities.

The bill would require HEW to develop, in consultation with the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and to implement a written informed consent form and procedures for assuring that the risks and benefits from the swine flu vaccine are fully explained to each person receiving the vaccine -- including information necessary to advise them with respect to their rights and remedies.

The bill would provide that any contract for procurement by the United States of swine flu vaccine shall be subject to renegotiation to eliminate any profit realized from such procurement. A "reasonable" profit -- to be determined by the Secretary of HEW -- would be allowed, however, with respect to influenza A/Victoria/75 vaccine, which would be administered with the swine flu vaccine to high risk groups.

HEW would be required to submit quarterly reports to the Congress on the administration of the swine flu program. The bill states that no funds are authorized to be appropriated for the swine flu activities specifically enumerated in the bill in addition to the funds already appropriated by P.L. 94-266, except for grants to the States to assist in meeting their costs related to the swine flu program.

The authorized activities summarized above are unnecessary, since HEW already has the statutory authority to conduct the program, and the activities have been underway for some time.

Protection against liability - S. 3735 would establish a procedure under which all claims for injury from inoculation with the swine flu vaccine would be asserted directly against the United States. The filing of claims and actions under the Federal Tort Claims Act would be the exclusive remedy for all eligible claimants. Since the United States is responsible only for negligence under that Act, the enrolled bill would make an exception for this program and permit a claimant to recover under any principle of strict liability in tort or breach of warranty which is applicable in the jurisdiction in which the act or ommission is alleged to have occurred.

The bill would not absolve participants in the program -- drug manufacturers, public and private agencies, medical and paramedical personnel, and the government -- from negligence. In those instances in which payment is made by the Government to a claimant, either by court judgment or administrative settlement, the Government could bring an action to recover any damages awarded which are caused by the negligence of any of the other participants in the program.

The protection provided to all participants in the program would be available to public and private agencies and medical and paramedical personnel only if they administer the vaccine without charge and comply with the consent form and procedures requirements. Provisions are included in the bill for the removal to Federal court of suits filed in State court against participants in the program, and for the substitution of the United States as the sole defendant.

Within one year after enactment of the enrolled bill, and semiannually thereafter, the Secretary of HEW would be required to submit a report to the Congress on the conduct of settlement and litigation activities provided for in the bill.

Study of liability - The enrolled bill would require a study to be conducted or provided for by HEW of the scope and extent of liability for personal injuries or death

arising out of immunization programs, and of alternative approaches to providing protection against liability for such injuries in the future. The Secretary would be required to report to the Congress within one year the findings of the study and any appropriate recommendations for legislation.

In a letter to Chairman Rodino of the House Judiciary Committee on an earlier House version of this legislation, Secretary Mathews stated that it reflected the following four principles:

"1. The public's legal remedies for genuine injuries should not be circumscribed and an efficient method of pursuing them should be assured.

2. All program participants, including the Government, should be responsible for their own negligence.

3. No program participant or other person should make a windfall profit from this public health program.

4. No solution to the difficulties which have developed in this Government-sponsored and administered universal immunization program should be established as a precedent for other programs of smaller scope in which the Government plays a different and significantly smaller role."

With respect to the fourth principle, it should be noted that the "findings" section of S. 3735 refers to the "unique role" of the United States in the initiation, planning, and administration of the swine flu program. The bill as enrolled, however, also finds that the procedure instituted for handling claims in this case is necessary "until Congress develops a permanent approach for handling claims arising under programs of the Public Health Service Act." This latter finding, plus the requirement for a study by the Secretary mentioned above, suggests the possibility that S. 3735 may become a precedent for other programs.

The Department of Justice also sent a letter to Chairman Rodino on August 9 favoring enactment of the earlier House version of this legislation. Justice now states in the attached views letter that the additional requirement included in the enrolled bill that program participants comply with the informed consent form and procedure requirements is troublesome and will likely lead to considerable litigation. Justice believes it would

have been preferable if this program could have been accomplished with the normal insurance coverage usually provided to vaccine manufacturers. The Department notes, however, that extensive efforts to obtain such coverage were unavailing and the desirability of conducting the program was such that the legislation was deemed necessary. Justice concludes that the enrolled bill is technically and administratively acceptable, "in consideration of the strong policy reasons requiring the emergency enactment of the legislation."

In view of the general consensus that liability protection legislation is essential to resolve the impasse in the swine flu immunization program, and since the enrolled bill was worked out in lengthy discussions between the various concerned groups, your approval of S. 3735 is recommended. A draft signing statement is attached for your consideration.

James M. Frey
Assistant Director for
Legislative Reference

Enclosures

~~TO THE SENATE:~~

I have today signed S. 3735, the "National Swine Flu Immunization Program of 1976."

I am gratified that the Congress has responded to this potential swine flu emergency by providing necessary protection for all those participants whose cooperation will be essential to assure that every American has the opportunity to obtain the desired protection. This unique threat requires extraordinary Federal measures to assure that we can avoid a catastrophe similar to that which occurred in 1918-1919. I am sure that I speak for all Americans in expressing this appreciation.

Secretary Mathews has recently consulted with the scientific and medical community on the need to continue this national program. The community has reaffirmed the desirability of the program. I urge all Americans to avail themselves of the opportunity to secure protection against swine flu.

THE WHITE HOUSE

ACTION MEMORANDUM WASHINGTON LOG NO.:

Date: August 11 Time: 600pm

FOR ACTION: Spencer Johnson
Max Friedersdorf
Ken Lazarus
Robert Hartmann

cc (for information): Jack Marsh
Jim Cavanaugh
Ed Schmults

FROM THE STAFF SECRETARY

DUE: Date: August 11 Time: asap

SUBJECT:

S. 3735-National Swine Flue Immunization Program of 1976

ACTION REQUESTED:

____ For Necessary Action ____ For Your Recommendations

____ Prepare Agenda and Brief ____ Draft Reply

__X__ For Your Comments ____ Draft Remarks

REMARKS:

please return to judy johnston, ground floor west wing

PLEASE ATTACH THIS COPY TO MATERIAL SUBMITTED.

If you have any questions or if you anticipate a delay in submitting the required material, please telephone the Staff Secretary immediately.

K. R. COLE, JR.
For the President

I have today signed S. 3735, the "National Swine Flu Immunization Program of 1976." O.K. Mart.

I am gratified that the Congress has responded to this potential public health emergency by providing, as I requested, the ~~necessary~~ assurances ~~to those program participants whose~~ necessary to make possible the protection of cooperation is essential to protect all Americans against this threat.

S. 3735 will permit the Federal Government to assure appropriate liability protection for those manufacturing, and distributing ~~and administering~~ the vaccine ~~as well as~~ and provides a claims procedure for persons who might be injured, ~~as a result of receiving the vaccine~~. Extraordinary Federal measures are required to implement a program of this magnitude and I am sure that I speak for all Americans in expressing appreciation for this Congressional action.

Scientific and medical evidence continues to support the need for a national influenza immunization program. We have developed a safe and effective vaccine, ~~with a very low risk of untoward reactions.~~ What we must do now is make it available as soon and efficiently as possible

I strongly reaffirm my commitment to this program and I have directed the Secretary of HEW to move as expeditiously as possible to insure that we keep our original commitment of making this vaccine available to all Americans.

OK as edited
D. Smith
8/11/76

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

ADVANCE COPY

The Honorable James T. Lynn
Director, Office of Management
and Budget
Washington, D. C. 20503

Dear Mr. Lynn:

This is in response to your request for a report on S. 3735, an enrolled bill "To amend the Public Health Service Act to authorize the establishment and implementation of an emergency national swine flu immunization program and to provide an exclusive remedy for personal injury or death arising out of the manufacture, distribution, or administration of the swine flu vaccine under such program."

In summary, we strongly recommend that the President sign the enrolled bill, as its enactment is necessary to carry out the national program of immunization against swine influenza.

The bill would provide that the United States be substituted as the defendant in suits based on claims for personal injury or death resulting from swine influenza vaccine brought against vaccine manufacturers or other participants in the swine influenza immunization program. The United States, in turn, would have the right to recover for its losses in such a suit from a program participant whose negligence caused the injury or death. The provisions of the bill are summarized in more detail at Tab A.

From the outset of the swine influenza immunization program, the vaccine manufacturers have expressed their concern that they might be held liable for negligence or failures in those aspects of the immunization program over which they had no control. Their concerns stemmed from the trend in court decisions to hold manufacturers of some drugs and vaccines liable to users of the products under principles of strict products liability. Two Federal courts of appeals have held

manufacturers of polio vaccine liable, even in the absence of negligence, for failure to see to it that warnings of the hazards of the vaccine were communicated to the recipients of the vaccine.

In the case of the swine influenza vaccine, the manufacturers were understandably concerned that they would not be able to discharge their obligations to see to it that whatever warning might be appropriate reached the consumer, since the Government would be purchasing the entire output of the vaccine and would be responsible for its distribution to State health agencies, which in turn would arrange for the inoculation of the population. Additionally, in this emergency immunization program, the Government would be assuming functions normally undertaken by the manufacturers, i.e., establishing the specifications for the vaccine, investigating and determining the benefits and risks from its use, developing a statement of such benefits and risks, and seeing to it that the statement was communicated to the persons inoculated with the vaccine.

After carrying out extensive efforts to solve the liability problem of the manufacturers through (1) contract provisions without legislation, (2) proposed legislation indemnifying the manufacturers for losses for other than their own negligence, and (3) attempts to persuade the insurance companies to grant liability coverage to the manufacturers, a new legislative approach was developed through the joint efforts of the Congress, the Administration, and other interested parties.

The enrolled bill, reflecting this approach, embodies three principles:

1. The public's legal remedies for genuine injuries should not be circumscribed and an efficient method of pursuing them should be assured.

2. All program participants, including the Government, should be responsible for their own negligence.

3. No program participant or other person should make a windfall profit from this public health program.

The enrolled bill, by substituting the United States for program participants sued for death or personal injury resulting from swine influenza vaccine, protects not only non-negligent manufacturers, who up to now have been unable to obtain insurance, but also other participants in the program who have been finding difficulties in obtaining insurance. Additionally, except for insurance needed to protect participants against indemnification claims by the Government in those instances in which the participant may be negligent, no other insurance is necessary. This should materially reduce the cost of the vaccine to the Government since its price will reflect the cost of insurance. Windfall profits to insurance companies from excessively high premiums for risks the Government believes to be relatively minor would also be averted.

It is imperative that the President act expeditiously in relation to the enrolled bill. If the enrolled bill is signed, it will be possible to resume production with minimal delays, purchase the vaccine now already manufactured, and begin the distribution of the vaccine to make it available to the public by mid to late September. The vaccine produces effective immunity in most cases within two to three weeks of injection. It would be possible for the entire population who wished to be vaccinated to develop immunity by mid-December. The peak flu season is typically in January and February.

We strongly recommend that the President sign the enrolled bill.

Sincerely,

Secretary

Enclosure

SUMMARY OF THE PROVISIONS OF S. 3735

The bill would provide a redundant authority for carrying out the national swine influenza immunization program, and would require the Secretary to make quarterly reports on the administration of the program.

Each contract for the procurement of the swine influenza vaccine from a manufacturer would be subject to renegotiation to eliminate any profit realized from such procurement, except that with respect to vaccine against the strain of virus, known as influenza A/Victoria/75 (to be mixed with the swine influenza vaccine), a reasonable profit would be permitted. Any insurance premium included in the contract price and which was refunded to the manufacturer under any retrospective experience-rating plan or similar plan would be returned to the United States.

The enrolled bill would establish, as the exclusive remedy for persons alleging injury, a procedure consistent with that now provided for negligence claims against the United States under which all claims in connection with the program would have to be asserted directly against the United States. The enrolled bill would make the United States liable with respect to claims for personal injury or death arising out of the manufacture, distribution or administration of the vaccine in the same manner and to the same extent as the United States is now liable for claims based on the negligence of its own agents, except that the liability would be based on any theory of liability, and not solely negligence, that would govern an action against a program participant under the law of the place where the act or omission occurred, and the normal exceptions to the liability of the United States Government based on the due care or discretionary judgment of a Federal employee would not be available to the United States in defense of a claim against a program participant. Program participants would include the vaccine manufacturers and distributors, public and private agencies or organizations that participated in the program without charge for the vaccine or its administration and in compliance with the

informed consent form and procedures established for the program, and medical personnel who participated without charge for the vaccine or its administration and in compliance with the informed consent form and procedures established for the program.

The Attorney General would be required to defend any civil action or proceeding based on personal injury or death resulting from the administration of swine influenza vaccine brought against any employee of the United States or any program participant. Any person against whom the action or proceeding was brought would be required to deliver all relevant papers to the United States for its use in defending the action. A claim brought in a State court would be removed to the United States district court for that area. Program participants would be required to cooperate with the United States in the defense of claims, and, if they failed to do so, their protection under the enrolled bill would be revoked and suits against them permitted in the usual manner.

If payment were made by the United States to any claimant under the authority of the enrolled bill, the United States would have a right to recover for any portion of the payment attributable to negligent conduct on the part of any program participant in carrying out any obligation or responsibility in connection with the program or to the failure of any program participant to carry out any contract obligation or responsibility.

Within one year of the date of enactment of the enrolled bill and semi-annually thereafter, the Secretary would report to Congress on the conduct of the litigation and settlement activities under the bill.

The Secretary would further be required to conduct a study of the scope and extent of liability for personal injuries arising out of immunization programs and alternative means of providing protection against that liability and compensation for those injuries. The Secretary would have to report on the study within a year after the date of enactment to the Congress with recommendations for legislation as the Secretary deemed appropriate.

ASSISTANT ATTORNEY GENERAL
LEGISLATIVE AFFAIRS

Department of Justice
Washington, D.C. 20530

August 11, 1976

Honorable James T. Lynn
Director, Office of Management
and Budget
Washington, D. C. 20503

Dear Mr. Lynn:

In compliance with your request, I have examined S. 3735, a Bill "To amend the Public Health Service Act to authorize the establishment and implementation of an emergency national swine flu immunization program and to provide an exclusive remedy for personal injury or death arising out of the manufacture, distribution, or administration of the swine flu vaccine under such program".

This Bill was passed by both Houses of Congress on August 10, 1976 to make it possible to conduct a national immunization program at the time deemed most advantageous by the physicians. It was recommended by its advocates as necessary emergency legislation.

Prior legislation authorized the Department of Health, Education and Welfare to develop and purchase the vaccine. This emergency legislation was deemed necessary because the vaccine manufacturers were unwilling to contract to sell the vaccine to the government for use in the national program for the reason that they could not obtain insurance coverage. It would have been preferable if this program could have been accomplished with the normal insurance coverage as is usually provided to vaccine manufacturers. However, extensive efforts to obtain such coverage were unavailing and the desirability of conducting the program was such that the legislation was deemed necessary.

As a substitute to the unavailable insurance, the Bill provides that in most contemplated situations the exclusive remedy for personal injury or death resulting from inoculation with the swine flu vaccine shall be against the United States under the Federal Tort Claims Act, 28 U.S.C. §§ 1346(b), 2671-2680. The Bill defines "program participant" to include manufacturers and distributors of the vaccine and agencies, organizations and individuals that provide or administer the inoculations

under the program without charge and in compliance with an informed consent form and procedure to be prescribed. The Bill in effect abolishes any cause of action against any such program participant and substitutes therefor a cause of action against the United States.

The Federal Tort Claims Act is expanded in that a suit based upon the act of a program participant may be based upon theories of strict liability in tort or breach of warranty. Under existing law suits under the Federal Tort Claims Act may only be based upon negligence.

The Bill provides that the Attorney General shall certify that an action is one that arises out of the administration of vaccine under the swine flu program. Upon such certification the suit shall be removed to federal court if it was originally filed in a state court and regardless of where the suit was initially filed the United States shall be substituted as the defendant. The suit shall then proceed in accordance with the provisions governing Federal Tort Claims Act suits.

This Bill is patterned after previous legislation that has abolished suits against different classes of federal employees and provided that the exclusive remedy shall be against the United States under the Federal Tort Claims Act. The first such statute covered suits against government employees based upon their operation of automobiles. 28 U.S.C. § 2679(b)-(e). A statute with almost identical language immunized medical and paramedical employees of the Veterans Administration. 38 U.S.C. § 4116. Later, a very similar statute provided immunity to the medical and paramedical employees of the Public Health Service. 42 U.S.C. § 233(c). Within the last few weeks another similar statute extended this type of immunity to the medical and paramedical employees of the State Department. P.L. 94-350, signed July 12, 1976. This Bill will be interpreted based upon the legislative and court decision precedent developed from those statutes, although this Bill is novel in that it abolishes causes of actions against private individuals and organizations while the prior legislation applied only to federal employees.

The Bill also provides that a program participant shall cooperate with the United States in processing or defending against any claim or lawsuit which is based upon the acts or omissions of such a program participant. Upon a finding by the court that such a program participant has failed to cooperate

the status of a program participant is revoked by the court and such a former participant is then exposed to any and all liability that it would have had without this Bill.

The Bill also creates a right of the United States against any program participant to recover the portion of any damages the United States has paid based upon the failure of a program participant to carry out "any obligation or responsibility assumed by it under a contract with the United States in connection with the program or from any negligent conduct on the part of any program participant in carrying out any obligation in connection with the swine flu program". The effect of the Bill is that program participants will not be subjected to any expense to defend meritless lawsuits, but they will be liable to the United States for amounts paid for personal injuries or deaths caused by the negligence of such program participants.

As originally developed and discussed in the House Interstate and Foreign Commerce Committee the Bill was technically and administratively sound. Because of the need to pass the legislation on an emergency basis prior to the recess some provisions were amended very hurriedly and with minimal consideration. The most troublesome provision is in Section (k)(2)(B) where the definition of a program participant was made subject to the additional requirement that to fit the definition an organization or an individual must have complied "with the informed consent form and procedures requirements prescribed". This additional provision will very likely lead to a considerable amount of litigation and will also leave in doubt the status of many agencies, organizations and individuals until a court ultimately determines any and all questions relating to compliance with the informed consent provisions. However, in consideration of the strong policy reasons requiring the emergency enactment of the legislation, the Bill is technically and administratively acceptable.

The Department of Justice has no objection to Executive approval of this Bill.

Sincerely,

Michael M. Uhlmann

MICHAEL M. UHLMANN
Assistant Attorney General

I have today signed S. 3735, the "National Swine Flu Immunization Program of 1976."

I am gratified that the Congress has responded to this potential public health emergency by providing, as I requested, the necessary assurances to those program participants whose cooperation is essential to protect all Americans against this threat.

S. 3735 will permit the Federal Government to assure appropriate liability protection for those manufacturing, distributing and administering the vaccine as well as a claims procedure for persons who might be injured as a result of receiving the vaccine. Extraordinary Federal measures are required to implement a program of this magnitude and I am sure that I speak for all Americans in expressing appreciation for this Congressional action.

Scientific and medical evidence continues to support the need for a national influenza immunization program. We have developed a safe and effective vaccine with a very low risk of unheard reactions.

I strongly reaffirm my commitment to this program and I have directed the Secretary of HEW to move as expeditiously as possible to insure that we keep our original commitment of making this vaccine available to all Americans.

I have today signed S. 3735, the "National Swine Flu Immunization Program of 1976."

I am gratified that the Congress has responded to this potential public health emergency by providing, as I requested the necessary assurances to those program participants whose cooperation is essential to protect all Americans against this threat.

S. 3735 will permit the Federal Government to assure appropriate liability protection for those manufacturing, distributing and administering the vaccine as well as a claims procedure for persons who might be injured as a result of receiving the vaccine. Extraordinary Federal measures are required to implement a program of this magnitude and I am sure that I speak for all Americans in expressing appreciation for this Congressional action.

Scientific and medical evidence continues to support the need for a national influenza immunization program. We have developed a safe and effective vaccine with a very low risk of untoward reactions.

I strongly reaffirm my commitment to this program and I have directed the Secretary of HEW to move as expeditiously as possible to insure that we keep our original commitment of making this vaccine available to all Americans.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
ROUTE SLIP

DATE 8-11-76

TO: Bob Linder

FROM: Jim Frey

REMARKS:

I should note that the HEW views letter attached is the Advance Copy. We have confirmed with HEW that this is their official recommendation.

OMB FORM 38
REV SEPT 70

S. 3735

Ninety-fourth Congress of the United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Monday, the nineteenth day of January, one thousand nine hundred and seventy-six

An Act

To amend the Public Health Service Act to authorize the establishment and implementation of an emergency national swine flu immunization program and to provide an exclusive remedy for personal injury or death arising out of the manufacture, distribution, or administration of the swine flu vaccine under such program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "National Swine Flu Immunization Program of 1976".

SEC. 2. Section 317 of the Public Health Service Act (42 U.S.C. 247b) is amended by inserting after subsection (i) the following new subsections:

"(j)(1) The Secretary is authorized to establish, conduct, and support (by grant or contract) needed activities to carry out a national swine flu immunization program until August 1, 1977 (hereinafter in this section referred to as the 'swine flu program'). The swine flu program shall be limited to the following:

"(A) The development of a safe and effective swine flu vaccine.

"(B) The preparation and procurement of such vaccine in sufficient quantities for the immunization of the population of the States.

"(C) The making of grants to State health authorities to assist in meeting their costs in conducting or supporting, or both, programs to administer such vaccine to their populations, and the furnishing to State health authorities of sufficient quantities of such swine flu vaccine for such programs.

"(D) The furnishing to Federal health authorities of appropriate quantities of such vaccine.

"(E) The conduct and support of training of personnel for immunization activities described in subparagraphs (C) and (D) of this paragraph and the conduct and support of research on the nature, cause, and effect of the influenza against which the swine flu vaccine is designed to immunize, the nature and effect of such vaccine, immunization against and treatment of such influenza, and the cost and effectiveness of immunization programs against such influenza.

"(F) The development, in consultation with the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and implementation of a written informed consent form and procedures for assuring that the risks and benefits from the swine flu vaccine are fully explained to each individual to whom such vaccine is to be administered. Such consultation shall be completed within two weeks after enactment of this Act, or by September 1, 1976, whichever is sooner. Such procedures shall include the information necessary to advice individuals with respect to their rights and remedies arising out of the administration of such vaccine.

"(G) Such other activities as are necessary to implement the swine flu program.

"(2) The Secretary shall submit quarterly reports to the Congress on the administration of the swine flu program. Each such report shall provide information on—

"(A) the current supply of the swine flu vaccine to be used in the program;

"(B) the number of persons inoculated with such vaccine since the last report was made under this paragraph and the immune status of the population;

"(C) the amount of funds expended for the swine flu program by the United States, each State, and any other entity participating in the program and the costs of each such participant which are associated with the program, during the period with respect to which the report is made; and

"(D) the epidemiology of influenza in the United States during such period.

"(3) Any contract for procurement by the United States of swine flu vaccine from a manufacturer of such vaccine shall (notwithstanding any other provision of law) be subject to renegotiation to eliminate any profit realized from such procurement (except that with respect to vaccine against the strain of influenza virus known as influenza A/Victoria/75 profit shall be allowed but limited to an amount not exceeding a reasonable profit), as determined pursuant to criteria prescribed by the Secretary, and the contract shall expressly so provide. Such criteria shall specify that any insurance premium amount which is included in the price of such procurement contract and which is refunded to the manufacturer under any retrospective, experience-rating plan or similar rating plan shall in turn be refunded to the United States.

"(4) No funds are authorized to be appropriated to carry out the activities of the swine flu program authorized in subparagraphs (A), (B), (D), (E), and (F) of paragraph (1) of this subsection in addition to the funds appropriated by Public Law 94–266.

"(k) (1) (A) The Congress finds that—

"(i) in order to achieve the participation in the program of the agencies, organizations, and individuals who will manufacture, distribute, and administer the swine flu vaccine purchased and used in the swine flu program and to assure the availability of such vaccine in interstate commerce, it is necessary to protect such agencies, organizations, and individuals against liability for other than their own negligence to persons alleging personal injury or death arising out of the administration of such vaccine;

"(ii) to provide such protection and to establish an orderly procedure for the prompt and equitable handling of claims by persons alleging such injury or death, it is necessary that an exclusive remedy for such claimants be provided against the United States because of its unique role in the initiation, planning, and administration of the swine flu program; and

"(iii) in order to be prepared to meet the potential emergency of a swine flu epidemic, it is necessary that a procedure be instituted for the handling of claims by persons alleging such injury or death until Congress develops a permanent approach for handling claims arising under programs of the Public Health Service Act.

"(B) To—

"(i) assure an orderly procedure for the prompt and equitable handling of any claim for personal injury or death arising out of the administration of such vaccine; and

"(ii) achieve the participation in the swine flu program of (I) the manufacturers and distributors of the swine flu vaccine, (II) public and private agencies or organizations that provide inoculations without charge for such vaccine or its administration and in compliance with the informed consent form and procedures requirements prescribed pursuant to subparagraph (F) of paragraph (1) of this subsection, and (III) medical and other health personnel who provide or assist in providing inoculations without charge for such vaccine or its administration and in compliance with such informed consent form and procedures requirements,

it is the purpose of this subsection to establish a procedure under which all such claims will be asserted directly against the United States under section 1346(b) of title 28, United States Code, and chapter 171 of such title (relating to tort claims procedure) except as otherwise specifically provided in this subsection.

"(2)(A) The United States shall be liable with respect to claims submitted after September 30, 1976 for personal injury or death arising out of the administration of swine flu vaccine under the swine flu program and based upon the act or omission of a program participant in the same manner and to the same extent as the United States would be liable in any other action brought against it under such section 1346(b) and chapter 171, except that—

"(i) the liability of the United States arising out of the act or omission of a program participant may be based on any theory of liability that would govern an action against such program participant under the law of the place where the act or omission occurred, including negligence, strict liability in tort, and breach of warranty;

"(ii) the exceptions specified in section 2680(a) of title 28, United States Code, shall not apply in an action based upon the act or omission of a program participant; and

"(iii) notwithstanding section 2401(b) of title 28, United States Code, if a civil action or proceeding for personal injury or death arising out of the administration of swine flu vaccine under the swine flu program is brought within two years of the date of the administration of such vaccine and is dismissed because the plaintiff in such action or proceeding did not file an administrative claim with respect to such injury or death as required by such chapter 171, the plaintiff in such action or proceeding shall have 30 days from the date of such dismissal or two years from the date the claim arose, whichever is later, in which to file such administrative claim.

"(B) For purposes of this subsection, the term 'program participant' as to any particular claim means the manufacturer or distributor of the swine flu vaccine used in an inoculation under the swine flu program, the public or private agency or organization that provided an inoculation under the swine flu program without charge for such vaccine or its administration and in compliance with the

informed consent form and procedures requirements prescribed pursuant to subparagraph (F) of paragraph (1) of this subsection, and the medical and other health personnel who provided or assisted in providing an inoculation under the swine flu program without charge for such vaccine or its administration and in compliance with such informed consent form and procedures requirements.

"(3) The remedy against the United States prescribed by paragraph (2) of this subsection for personal injury or death arising out of the administration of the swine flu vaccine under the swine flu program shall be exclusive of any other civil action or proceeding for such personal injury or death against any employee of the Government (as defined in section 2671 of title 28, United States Code) or program participant whose act or omission gave raise to the claim.

"(4) The Attorney General shall defend any civil action or proceeding brought in any court against any employee of the Government (as defined in such section 2671) or program participant (or any liability insurer thereof) based upon a claim alleging personal injury or death arising out of the administration of vaccine under the swine flu program. Any such person against whom such civil action or proceeding is brought shall deliver all process served upon him (or an attested true copy thereof) to whoever is designated by the Secretary to receive such papers, and such person shall promptly furnish copies of the pleadings and process therein to the United States attorney for the district embracing the place wherein the civil action or proceeding is brought, to the Attorney General, and to the Secretary.

"(5)(A) Upon certification by the Attorney General that a civil action or proceeding brought in any court against any employee of the Government (as defined in such section 2671) or program participant is based upon a claim alleging personal injury or death arising out of the administration of vaccine under the swine flu program, such action or proceeding shall be deemed an action against the United States under the provisions of title 28, United States Code, and all references thereto. If such action or proceeding is brought in a district court of the United States, then upon such certification the United States shall be substituted as the party defendant.

"(B) Upon a certification by the Attorney General under subparagraph (A) of this paragraph with respect to a civil action or proceeding commenced in a State court, such action or proceeding shall be removed, without bond at any time before trial, by the Attorney General to the district court of the United States of the district and division embracing the place wherein it is pending and be deemed an action brought against the United States under the provisions of title 28, United States Code, and all references thereto; and the United States shall be substituted as the party defendant. The certification of the Attorney General with respect to program participant status shall conclusively establish such status for purposes of such initial removal. Should a district court of the United States determine on a hearing on a motion to remand held before a trial on the merits that an action or proceeding is not one to which this subsection applies, the case shall be remanded to the State court.

"(C) Where an action or proceeding under this subsection is precluded because of the availability of a remedy through proceedings for compensation or other benefits from the United States as provided

by any other law, the action or proceeding shall be dismissed, but in that event the running of any limitation of time for commencing, or filing an application or claim in, such proceedings for compensation or other benefits shall be deemed to have been suspended during the pendency of the civil action or proceeding under this subsection.

"(6) A program participant shall cooperate with the United States in the processing or defense of a claim or suit under such section 1346(b) and chapter 171 based upon alleged acts or omissions of the program participant. Upon the motion of the United States or any other party, the status as a program participant shall be revoked by the district court of the United States upon finding that the program participant has failed to so cooperate, and the court shall substitute such former participant as the party defendant in place of the United States and, upon motion, remand any such suit to the court in which it was instituted.

"(7) Should payment be made by the United States to any claimant bringing a claim under this subsection, either by way of administrative settlement or court judgment, the United States shall have, notwithstanding any provision of State law, the right to recover for that portion of the damages so awarded or paid, as well as any costs of litigation, resulting from the failure of any program participant to carry out any obligation or responsibility assumed by it under a contract with the United States in connection with the program or from any negligent conduct on the part of any program participant in carrying out any obligation or responsibility in connection with the swine flu program. The United States may maintain such action against such program participant in the district court of the United States in which such program participant resides or has its principal place of business.

"(8) Within one year of the date of the enactment of the National Swine Flu Immunization Program of 1976, and semiannually thereafter, the Secretary shall submit to the Congress a report on the conduct of settlement and litigation activities under this subsection, specifying the number, value, nature, and status of all claims made thereunder, including the status of claims for recovery made under paragraph (7) of this subsection and a detailed statement of the reasons for not seeking such recovery.

"(l) For the purposes of subsections (j) and (k) of this section—

"(1) the phrase 'arising out of the administration' with reference to a claim for personal injury or death under the swine flu program includes a claim with respect to the manufacture or distribution of such vaccine in connection with the provision of an inoculation using such vaccine under the swine flu program;

"(2) the term 'State' includes the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands; and

"(3) the term 'swine flu vaccine' means the vaccine against the strain of influenza virus known as influenza A/New Jersey/76 (Hsw 1N1), or a combination of such vaccine and the vaccine against the strain of influenza virus known as influenza A/Victoria/75.".

SEC. 3. The Secretary of Health, Education, and Welfare shall conduct, or provide for the conduct of, a study of the scope and extent of liability for personal injuries or death arising out of immunization programs and of alternative approaches to providing protection against such liability (including a compensation system) for such injuries. Within one year of the date of the enactment of this Act, the Secretary shall report to the Congress the findings of such study and such recommendations for legislation (including proposed drafts to carry out such recommendations) as the Secretary deems appropriate.

Speaker of the House of Representatives.

Vice President of the United States and
President of the Senate.

EMBARGOED FOR RELEASE UNTIL 12:00 NOON (EDT),
Thursday, August 12, 1976
Office of the White House Press Secretary

THE WHITE HOUSE

STATEMENT BY THE PRESIDENT

I have today signed S. 3735, the "National Swine Flu Immunization Program of 1976."

I am gratified that the Congress has responded to this potential public health emergency by providing, as I requested, the assurances necessary to make possible the protection of all Americans against this threat.

S. 3735 will permit the Federal Government to assure appropriate liability protection for those manufacturing, distributing and administering the vaccine and provides a claims procedure for persons who might be injured. Extraordinary Federal measures are required to implement a program of this magnitude and I am sure that I speak for all Americans in expressing appreciation for this Congressional action.

Scientific and medical evidence continues to support the need for a national influenza immunization program. We have developed a safe and effective vaccine with a very low risk of adverse reactions. What we must do now is make it available as soon and efficiently as possible.

I strongly reaffirm my commitment to this program and I have directed the Secretary of Health, Education, and Welfare to move as expeditiously as possible to insure that we keep our original commitment of making this vaccine available to all Americans.

######

FOR IMMEDIATE RELEASE AUGUST 12, 1976

OFFICE OF THE WHITE HOUSE PRESS SECRETARY

THE WHITE HOUSE

REMARKS OF THE PRESIDENT
UPON SIGNING S. 3735
THE NATIONAL SWINE FLU
IMMUNIZATION PROGRAM OF 1976

THE CABINET ROOM

12:12 P.M. EDT

Secretary Mathews, Congressman Carter, Dr. Cooper, distinguished members of the medical profession, ladies and gentlemen:

I am deeply appreciative that the Congress, as one of their final actions before the scheduled recess, sent to me for signature the National Swine Flu Immunization Program of 1976. I would like to express my deep appreciation to the bipartisan leadership of both the House and the Senate and responsible leaders in the committees that had jurisdiction for their cooperation in making certain that this legislation got to the White House in time for us to carry forth this program.

This program will permit the Federal Government to assure appropriate liability protection for those who manufacture, distribute and administer this life-saving vaccine. The program also provides a claims procedure for those who might be injured. Scientific and medical evidence continues to support the need for a swine flu inoculation program. A vaccine has been developed that is both safe and effective, with a very low risk of adverse reactions.

I have directed the Secretary of Health, Education and Welfare to move as quickly as possible to make this vaccine available to all Americans. I strongly reaffirm my commitment to this program, which will afford millions of Americans protection against an outbreak of swine flu this winter.

I say again, I am grateful that the Congress did take this action so this program could continue.

END (AT 12:14 P.M. EDT)

White House Photograph

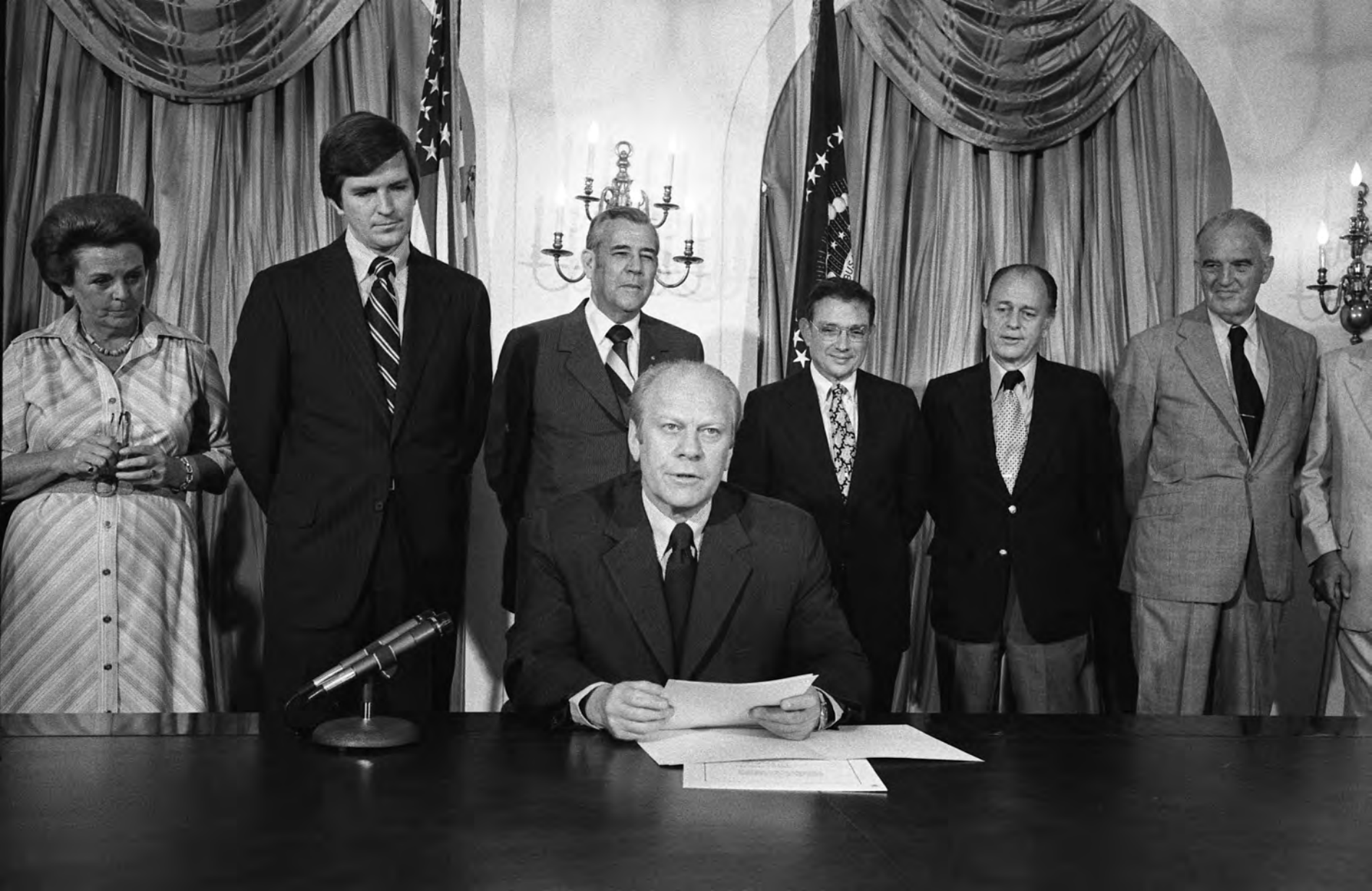
Event: Bill signing ceremony

Location: Cabinet Room

Description: President Ford makes remarks prior to signing S.3735, authorizing the 1976 National Swine Flu Immunization Program. Also shown are [l-r]: HEW Undersecretary Marjorie Lynch, HEW Secretary F. David Mathews, U.S. Rep. Tim Lee Carter (R-KY), Assistant Secretary for Health (HEW) Dr. Theodore Cooper, HEW General Counsel William H. Taft, IV, and HEW Assistant General Counsel Bernard Feiner.

Photographer: Karl Schumacher

Date: August 12, 1976



White House Photograph

Image: B1030-12A

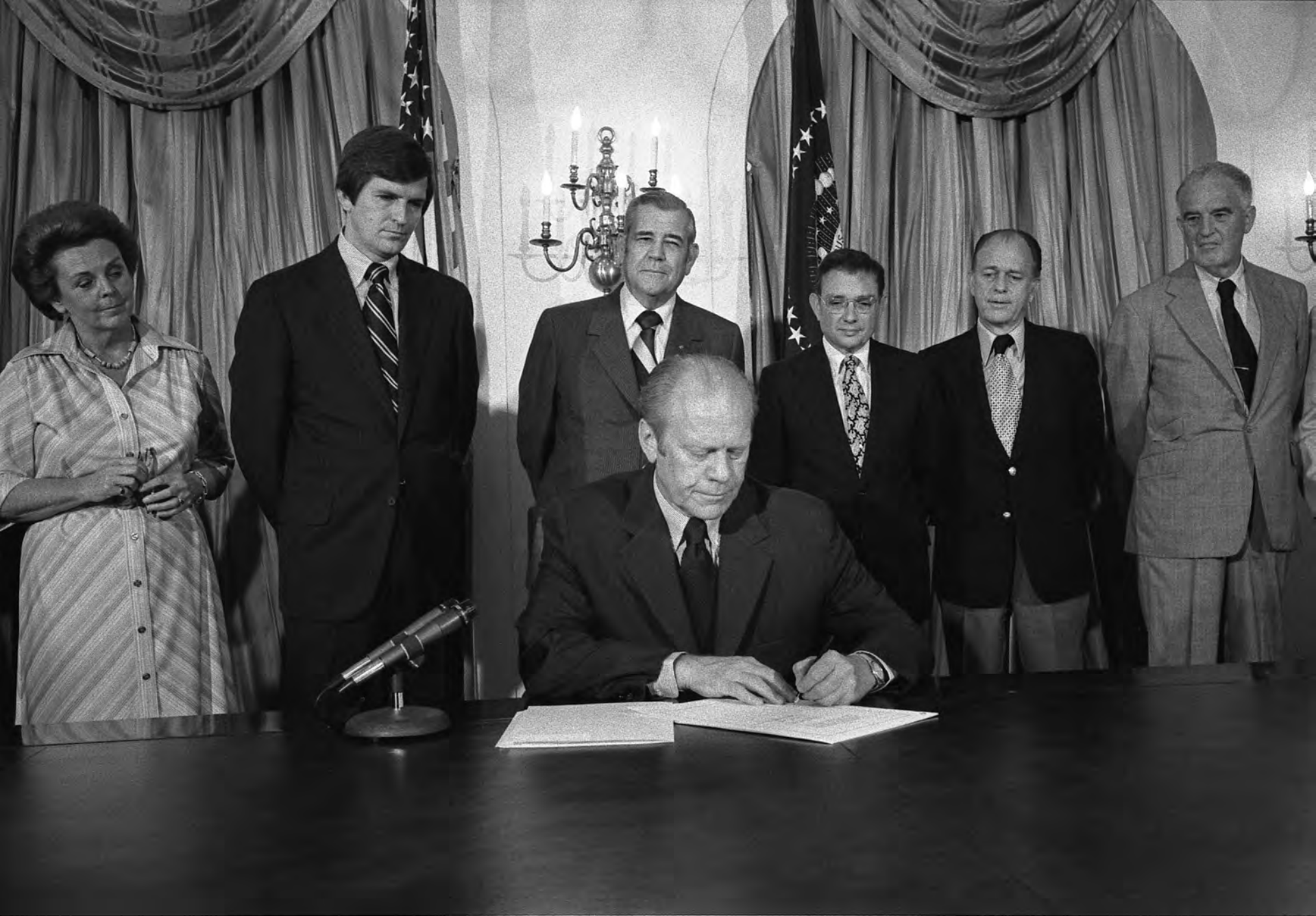
Event: Bill signing ceremony

Location: Cabinet Room

Description: President Ford signs S.3735, authorizing the 1976 National Swine Flu Immunization Program. Also shown are [l-r]: HEW Undersecretary Marjorie Lynch, HEW Secretary F. David Mathews, U.S. Rep. Tim Lee Carter (R-KY), Assistant Secretary for Health (HEW) Dr. Theodore Cooper, HEW General Counsel William H. Taft, IV, and HEW Assistant General Counsel Bernard Feiner.

Photographer: Karl Schumacher

Date: August 12, 1976



White House Photograph

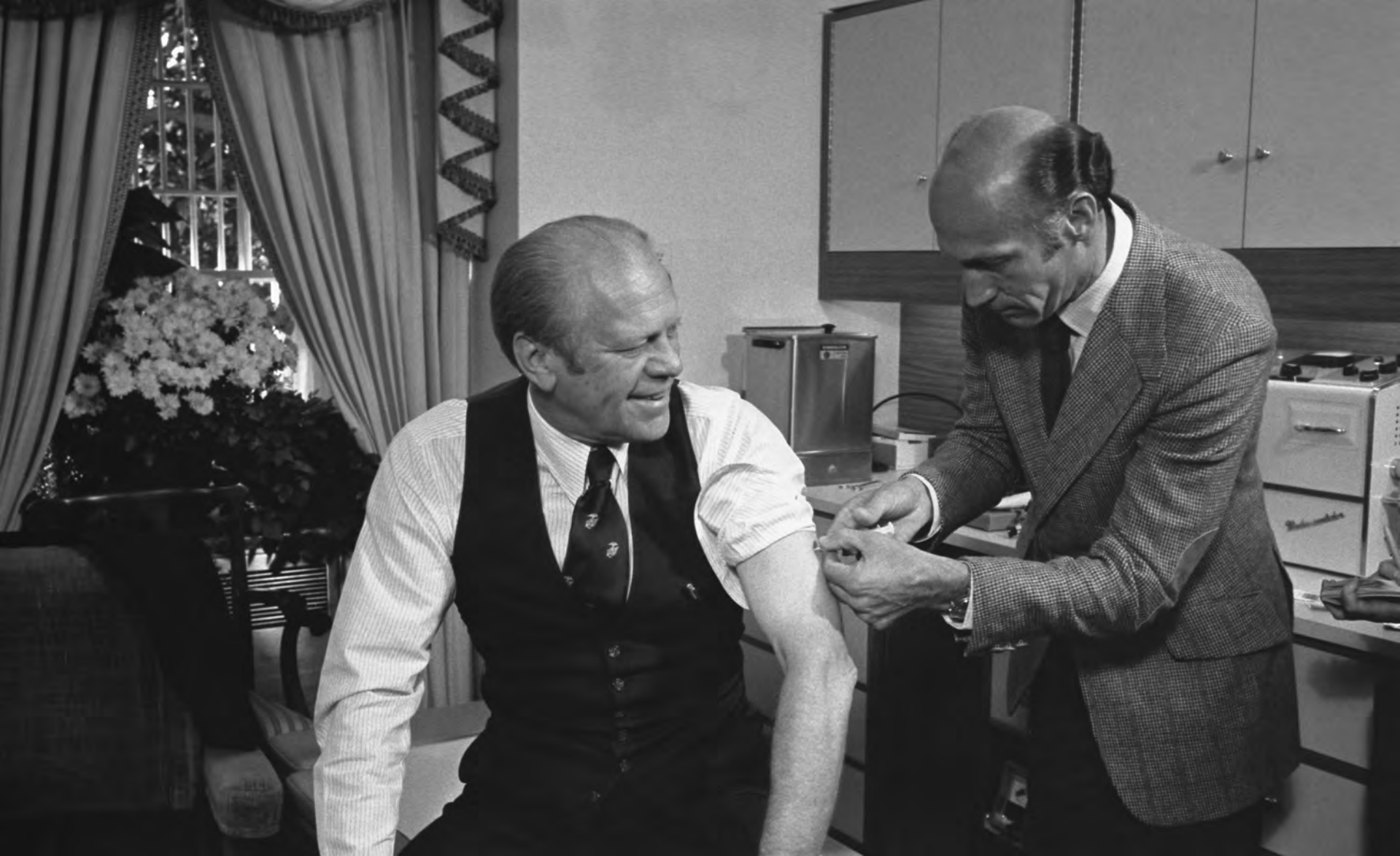
Event: Swine Flu Program

Location: Dr. William Lukash's White House Office

Description: President Ford receives a swine flu inoculation from his White House physician, Dr. William Lukash.

Photographer: David Hume Kennerly

Date: October 14, 1976



Center for Disease Control Journal

Emerging Infectious Diseases Journal

Vol. 12, No. 1, January 2006

Reflections on the 1976 Swine Flu Vaccination Program

by David J. Sencer and J. Donald Millar

Reflections on the 1976 Swine Flu Vaccination Program

David J. Sencer* and J. Donald Millar†

In 1976, 2 recruits at Fort Dix, New Jersey, had an influenzalike illness. Isolates of virus taken from them included A/New Jersey/76 (Hsw1n1), a strain similar to the virus believed at the time to be the cause of the 1918 pandemic, commonly known as swine flu. Serologic studies at Fort Dix suggested that >200 soldiers had been infected and that person-to-person transmission had occurred. We review the process by which these events led to the public health decision to mass-vaccinate the American public against the virus and the subsequent events that led to the program's cancellation. Observations of policy and implementation success and failures are presented that could help guide decisions regarding avian influenza.

"Flu to the Starboard! Man the Harpoons!
Fill with Vaccine! Get the Captain! Hurry!"
Edwin D. Kilbourne, New York Times, February 13, 1976 (*1*)

"Grounding a Pandemic"
Barack Obama and Richard Lugar, New York Times, June 6, 2005 (*2*)

"It has been 37 years since the last influenza pandemic, or widespread global epidemic, so by historic patterns we may be due for another."
New York Times, July 17, 2005 (*3*)

Kilbourne in 1976 (*1*) noted that pandemics of influenza occur every 11 years. Since the latest prediction in the New York Times (*3*) suggests that after 39 years we may be overdue for a pandemic, and since 2 US senators have recently headlined the possibility (2), that observation may become a political fact. Whether it becomes a scientific fact and a policy fact is yet to be seen. Some reflections on 1976 from 2 insiders' viewpoints may identify some of the pitfalls that public health policymakers will face in addressing potential influenza pandemics.

*Atlanta, Georgia, USA; and †Murraysville, Georgia, USA

Swine Flu at Fort Dix

On February 3, 1976, the New Jersey State Health Department sent the Center for Disease Control (CDC) in Atlanta isolates of virus from recruits at Fort Dix, New Jersey, who had influenzalike illnesses. Most of the isolates were identified as A/Victoria/75 (H3N2), the contemporary epidemic strain. Two of the isolates, however, were not typeable in that laboratory. On February 10, additional isolates were sent and identified in CDC laboratories as A/New Jersey/76 (Hsw1N1), similar to the virus of the 1918 pandemic and better known as "swine flu."

A meeting of representatives of the military, the National Institute of Health, the Food and Drug Administration (FDA), and the State of New Jersey Department of Health was quickly convened on Saturday, February 14, 1976. Plans of action included heightened surveillance in and around Fort Dix, investigation of the ill recruits to determine if contact with pigs had occurred, and serologic testing of recruits to determine if spread had occurred at Fort Dix.

Surveillance activities at Fort Dix gave no indication that recruits had contact with pigs. Surveillance in the surrounding communities found influenza caused by the current strain of influenza, A/Victoria, but no additional cases of swine flu. Serologic testing at Fort Dix indicated that person-to-person transmission had occurred in >200 recruits (*4*).

In 1974 and 1975, 2 instances of humans infected with swine influenza viruses had been documented in the United States. Both persons involved had close contact with pigs, and no evidence for spread of the virus beyond family members with pig contact could be found (*5*).

The National Influenza Immunization Program

On March 10, 1976, the Advisory Committee on Immunization Practices of the United States Public Health Service (ACIP) reviewed the findings. The committee concluded that with a new strain (the H1N1 New Jersey strain)

that could be transmitted from person to person, a pandemic was a possibility. Specifically, the following facts were of concern: 1) persons <50 years of age had no antibodies to this new strain; 2) a current interpandemic strain (A/Victoria) of influenza was widely circulating; 3) this early detection of an outbreak caused by A/New Jersey/76/Hsw1N1 (H1N1) provided an opportunity to produce a vaccine since there was sufficient time between the initial isolates and the advent of an expected influenza season to produce vaccine. In the past when a new pandemic strain had been identified, there had not been enough time to manufacture vaccine on any large scale; 4) influenza vaccines had been used for years with demonstrated safety and efficacy when the currently circulating vaccine strain was incorporated; 5) the military vaccine formulation for years had included H1N1, an indication that production was possible, and no documented adverse effects had been described.

ACIP recommended that an immunization program be launched to prevent the effects of a possible pandemic. One ACIP member summarized the consensus by stating "If we believe in prevention, we have no alternative but to offer and urge the immunization of the population." One ACIP member expressed the view that the vaccine should be stockpiled, not given.

Making this decision carried an unusual urgency. The pharmaceutical industry had just finished manufacture of the vaccine to be used in the 1976–1977 influenza season. At that time, influenza vaccine was produced in fertilized hen's eggs from special flocks of hens. Roosters used for fertilizing the hens were still available; if they were slaughtered, as was customary, the industry could not resume production for several months.

On March 13, an action memo was presented to the Secretary of the Department of Health Education and Welfare (DHEW). It outlined the problem and presented 4 alternative courses of action. First was "business as usual," with the marketplace prevailing and the assumption that a pandemic might not occur. The second was a recommendation that the federal government embark on a major program to immunize a highly susceptible population. As a reason to adopt this plan of action, the memo stated that "the Administration can tolerate unnecessary health expenditures better than unnecessary death and illness if a pandemic should occur." The third proposed course of action was a minimal response, in which the federal government would contract for sufficient vaccine to provide for traditional federal beneficiaries—military personnel, Native Americans, and Medicare-eligible persons. The fourth alternative was a program that would represent an exclusively federal response without involvement of the states.

The proposal recommended by the director of CDC was the second course, namely, for the federal government to contract with private pharmaceutical companies to produce sufficient vaccine to permit the entire population to be immunized against H1N1. The federal government would make grants to state health departments to organize and conduct immunization programs. The federal government would provide vaccine to state health departments and private medical practices. Since influenza caused by A/Victoria was active worldwide, industry was asked to incorporate the swine flu into an A/Victoria product to be used for populations at high risk.

Before the discussions with the secretary of DHEW had been completed, a member of his staff sent a memo to a health policy advisor in the White House, raising the specter of the 1918 pandemic, which had been specifically underemphasized in the CDC presentation. CDC's presentation highlighted the pandemic potential, comparing it with the 1968–69 Hong Kong and 1957–58 Asian pandemics. President Gerald Ford's staff recommended that the president convene a large group of well-known and respected scientists (Albert Sabin and Jonas Salk had to be included) and public representatives to hear the government's proposal and make recommendations to the president about it. After the meeting, the president had a press conference, highlighted by the unique simultaneous appearance of Salk and Sabin. President Ford announced that he accepted the recommendations that CDC had originally made to the secretary of DHEW. The National Influenza Immunization Program (NIIP) was initiated.

The proposal was presented to 4 committees of the Congress, House and Senate authorization committees and House and Senate appropriation committees. All 4 committees reported out favorable legislation, and an appropriation bill was passed and signed.

The estimated budgeted cost of the program was $137 million. When Congress passed the appropriation, newspapers mischaracterized the cost as "$1.9 billion" because the $137 million was included as part of a $1.9 billion supplemental appropriation for the Department of Labor. In the minds of the public, this misconception prevailed.

Immediately after the congressional hearing, a meeting of all directors of state health departments and medical societies was held at CDC. The program was presented by CDC, and attendees were asked for comments. A representative from the New Jersey state health department opposed the plan; the Wisconsin state medical society opposed any federal involvement. Otherwise, state and local health departments approved the plan.

Within CDC, a unit charged with implementing the program, which reported to the director, was established. This unit, NIIP, had complete authority to draw upon any resources at CDC needed. NIIP was responsible for relations with state and local health departments (including administration of the grant program for state operations,

technical advice to the procurement staff for vaccine, and warehousing and distribution of the vaccine to state health departments) and established a proactive system of surveillance for possible adverse effects of the influenza vaccines, the NIIP Surveillance Assessment Center (NIIP-SAC). (This innovative surveillance system would prove to be NIIP's Trojan horse.) In spite of the obstacles discussed below, NIIP administered a program that immunized 45 million in 10 weeks, which resulted in doubling the level of immunization for persons deemed to be at high risk, rapidly identifying adverse effects, and developing and administering an informed consent form for use in a community-based program.

Obstacles to the Vaccination Plan

The principal obstacle was the lack of vaccines. As test batches were prepared, the largest ever field trials of influenza vaccines ensued. The vaccines appeared efficacious and safe (although in the initial trials, children did not respond immunologically to a single dose of vaccine, and a second trial with a revised schedule was needed) (*6*). Hopes were heightened for a late summer/early fall kickoff of mass immunization operations.

In January 1976, before the New Jersey outbreak, CDC had proposed legislation that would have compensated persons damaged as a result of immunization when it was licensed by FDA and administered in the manner recommended by ACIP. The rationale given was that immunization protects the community as well as the individual (a societal benefit) and that when a person participating in that societal benefit is damaged, society had a responsibility to that person. The proposal was sent back from a staff member in the Surgeon General's office with a handwritten note, "This is not a problem."

Soon, however, NIIP received the first of 2 crippling blows to hopes to immunize "every man, woman, and child." The first was later in 1976, when instead of boxes of bottled vaccine, the vaccine manufacturers delivered an ultimatum—that the federal government indemnify them against claims of adverse reactions as a requirement for release of the vaccines. The government quickly capitulated to industry's demand for indemnification. While the manufacturers' ultimatum reflected the trend of increased litigiousness in American society, its unintended, unmistakable subliminal message blared "There's something wrong with this vaccine." This public misperception, warranted or not, ensured that every coincidental health event that occurred in the wake of the swine flu shot would be scrutinized and attributed to the vaccine.

On August 2, 1976, deaths apparently due to an influenzalike illness were reported from Pennsylvania in older men who had attended the convention of the American Legion in Philadelphia. A combined team of CDC and state and local health workers immediately investigated. By the next day, epidemiologic evidence indicated that the disease was not influenza (no secondary cases occurred in the households of the patients). By August 4, laboratory evidence conclusively ruled out influenza. However, this series of events was interpreted by the media and others as an attempt by the government to "stimulate" NIIP.

Shortly after the national campaign began, 3 elderly persons died after receiving the vaccine in the same clinic. Although investigations found no evidence that the vaccine and deaths were causally related, press frenzy was so intense it drew a televised rebuke from Walter Cronkite for sensationalizing coincidental happenings.

Guillain-Barré Syndrome

What NIIP did not and could not survive, however, was the second blow, finding cases of Guillain-Barré syndrome (GBS) among persons receiving swine flu immunizations. As of 1976, >50 "antecedent events" had been identified in temporal relationship to GBS, events that were considered as possible factors in its cause. The list included viral infections, injections, and "being struck by lightning." Whether or not any of the antecedents had a causal relationship to GBS was, and remains, unclear. When cases of GBS were identified among recipients of the swine flu vaccines, they were, of course, well covered by the press. Because GBS cases are always present in the population, the necessary public health questions concerning the cases among vaccine recipients were "Is the number of cases of GBS among vaccine recipients higher than would be expected? And if so, are the increased cases the result of increased surveillance or a true increase?" Leading epidemiologists debated these points, but the consensus, based on the intensified surveillance for GBS (and other conditions) in recipients of the vaccines, was that the number of cases of GBS appeared to be an excess.

Had H1N1 influenza been transmitted at that time, the small apparent risk of GBS from immunization would have been eclipsed by the obvious immediate benefit of vaccine-induced protection against swine flu. However, in December 1976, with >40 million persons immunized and no evidence of H1N1 transmission, federal health officials decided that the possibility of an association of GBS with the vaccine, however small, necessitated stopping immunization, at least until the issue could be explored. A moratorium on the use of the influenza vaccines was announced on December 16; it effectively ended NIIP of 1976. Four days later the New York Times published an op-ed article that began by asserting, "Misunderstandings and misconceptions... have marked Government ... during the last eight years," attributing NIIP and its consequences to "political expediency" and "the self interest of government health bureaucracy" (*7*). These simple and sinister

innuendos had traction, as did 2 epithets used in the article to describe the program, “debacle” in the text and “Swine Flu Fiasco” in the title.

On February 7, the new secretary of DHEW, Joseph A. Califano, announced the resumption of immunization of high-risk populations with monovalent A/Victoria vaccine that had been prepared as part of the federal contracts, and he dismissed the director of CDC.

Lessons Learned

NIIP may offer lessons for today’s policymakers, who are faced with a potential pandemic of avian influenza and struggling with decisions about preventing it (Figure). Two of these lessons bear further scrutiny here.

Media and Presidential Attention

While all decisions related to NIIP had been reached in public sessions (publishing of the initial virus findings in CDC’s weekly newsletter, the Morbidity and Mortality Weekly Report (MMWR); New York Times reporter Harold Schmeck’s coverage of the ACIP sessions, the president’s press conference, and 4 congressional hearings), effective communication from scientifically qualified persons was lacking, and the perception prevailed that the program was motivated by politics rather than science. In retrospect (and to some observers at the time), the president’s highly visible convened meeting and subsequent press conference, which included pictures of his being immunized, were mistakes. These instances seemed to underline the suspicion that the program was politically motivated, rather than a public health response to a possible catastrophe.

Annex 11 of the draft DHEW pandemic preparedness plan states, “For policy decisions and in communication, making clear what is not known is as important as stating what is known. When assumptions are made, the basis for the assumptions and the uncertainties surrounding them should be communicated” (*11*). This goal is much better accomplished if the explanations are communicated by those closest to the problem, who can give authoritative scientific information. Scientific information coming from a nonscientific political figure is likely to encourage skepticism, not enthusiasm.

Neither CDC nor the health agencies of the federal government had been in the habit of holding regular press conferences. CDC considered that its appropriate main line of communication was to states and local health departments, believing that they were best placed to communicate with the public. MMWR served both a professional and public audience and accounted for much of CDC’s press coverage. In 1976, no all-news stations existed, only the nightly news. The decision to stop the NIIP on December 16, 1976, was announced by a press release from the office of the assistant secretary for health. The decision to reinstitute the immunization of those at high risk was announced by a press release from the office of the secretary, DHEW.

1. Expect the unexpected: it will always happen.

Some examples:
- Children did not respond to the initial formulation of vaccine.
- Liability for untoward events after immunization became a major issue.
- Deaths occurred in Pittsburgh that were coincidental with but unrelated to the vaccines (*8*).
- Cases of a new and unrelated disease, Legionnaires disease, appeared (*9*).
- "Excess" cases of Guillain-Barré syndrome appeared among recipients of vaccines (*10*).
- Erroneous laboratory reports of viral isolates or serologic conversions occurred in Washington, DC, Boston, Virginia, and Taiwan.
- The pandemic failed to appear.

2. Surveillance for influenza disease worked well. This was plain, "old-fashioned" surveillance without computers. A new strain of influenza was identified within weeks of the first recognized outbreak of illness.

3. Interagency cooperation works without formal agreements. The state health departments, military, National Institutes of Health, US Food and Drug Administration, and Center for Disease Control all worked together in a cooperative and mutually beneficial manner.

4. Surveillance for untoward events demonstrated that only when large numbers of people are exposed to a vaccine or drug are adverse reactions identified (Guillain-Barré syndrome with influenza vaccines; paralysis with the Cutter poliovirus vaccine in 1955).

5. Health legislation can and should be developed on the basis of the epidemiologic picture.

6. Media and public awareness can be a major obstacle to implementing a large, innovative program responding to risks that are difficult, if not impossible, to quantitate.
- Creating a program as a presidential initiative makes modifying or stopping the program more difficult.
- Explanations should be communicated by those who can give authoritative scientific information.
- Periodic press briefings work better than responding to press queries.

7. The advisability of the decision to begin immunization on the strength of the Fort Dix episode is worthy of serious question and debate (see text).

8. The risk of potentially unnecessary costs in a mass vaccination campaign is minimal. (The direct cost of the 1976 program was $137 million. In today's dollars, this is <$500 million.) The potential cost of a pandemic is inestimable but astronomical.

Figure. Lessons learned from the 1976 National Influenza Immunization Program (NIIP).

In retrospect, periodic press briefings would have served better than responding to press queries. The public must understand that decisions are based on public health, not politics. To this end, health communication should be by health personnel through a regular schedule of media briefings.

Decision To Begin Immunization

This decision is worthy of serious question and debate. As Walter Dowdle (*12*) points out in this issue of Emerging Infectious Diseases, the prevailing wisdom was that a pandemic could be expected at any time. Public health officials were concerned that if immunization was delayed until H1N1 was documented to have spread to other groups, the disease would spread faster than any ability to mobilize preventive vaccination efforts. Three cases of swine influenza had recently occurred in persons who had contact with pigs. In 1918, after the initial outbreak of influenza at Fort Riley in April, widespread outbreaks of influenza did not occur until late summer (*13*).

The Delphi exercise of Schoenbaum in early fall of 1976 (*13*) was the most serious scientific undertaking to poll scientists to decide whether or not to continue the program. Its main finding was that the cost benefit would be best if immunization were limited to those >25 years of age (and now young children are believed to be a potent source of spread of influenza virus!). Unfortunately, no biblical Joseph was there to rise from prison and interpret the future.

As Dowdle further states (*12*), risk assessment and risk management are separate functions. But they must come together with policymakers, who must understand both. These discussions should not take place in large groups in the president's cabinet room but in an environment that can establish an educated understanding of the situation. Once the policy decisions are made, implementation should be left to a single designated agency. Advisory groups should be small but representative. CDC had the lead responsibility for operation of the program. Implementation by committee does not work. Within CDC, a unit was established for program execution, including surveillance, outbreak investigation, vaccine procurement and distribution, assignment of personnel to states, and awarding and monitoring grants to the states. Communications up the chain of command to the policymakers and laterally to other directly involved federal agencies were the responsibility of the CDC director, not the director of NIIP, who was responsible for communications to the states and local health departments, those ultimately implementing operations of the program. This organizational mode functioned well, a tribute to the lack of interagency jealousies.

Decision-making Risks

When lives are at stake, it is better to err on the side of overreaction than underreaction. Because of the unpredictability of influenza, responsible public health leaders must be willing to take risks on behalf of the public. This requires personal courage and a reasonable level of understanding by the politicians to whom these public health leaders are accountable. All policy decisions entail risks and benefits: risks or benefits to the decision maker; risks or benefits to those affected by the decision. In 1976, the federal government wisely opted to put protection of the public first.

Dr Sencer was director of CDC from 1966 to 1977.

Dr Millar was director of NIIP in 1976.

References

1. Kilbourne ED. Flu to the starboard! Man the harpoons! Fill with vaccine! Get the captain! Hurry! New York Times. 1976 Feb 13. p. 32, col. 4.
2. Obama B, Lugar R. Grounding a pandemic. Op-ed section. New York Times. 2005 Jun 6. [cited 1 Nov 2005]. Available from http://www.nytimes.com/2005/06/06/opinion/06obama.html?ex=1130994000&en=1b199f715505a19c&ei=5070
3. Unprepared for a flu pandemic [editorial]. New York Times. 2005 Jul 17; Sect. 4:11 (col. 1).
4. Hodder RA, Gaydos JC, Allen RG, Top FH Jr, Nowosiwsky T, Russell PK. Swine influenza A at Fort Dix, New Jersey (January–February 1976). III. Extent of spread and duration of the outbreak. J Infect Dis. 1977;136:S369–75.
5. Dowdle WR, Hattwick MAW. Swine influenza virus infections in humans. J Infect Dis. 1977;136:S386–9.
6. Denny FW, Glezen WP, Karzon DT, Katz SL, Krugman S, McIntosh K, Parrott RH. Commentary. J Pediatr. 1976;88:1057.
7. Schwartz H. Swine flu fiasco. New York Times. 21 Dec 1976:33.
8. Schmeck HM Jr. More deaths reported after shots but no link to flu vaccine is found. New York Times. 1976 Oct 14; Sect. A:1+.
9. Fraser DW, Tsai TR, Orenstein W, Parkin WE, Beecham HJ, Sharrar RG, et al. Legionnaires' disease: description of an epidemic of pneumonia. N Engl J Med. 1977;297:1189–97.
10. Schonberger LB, Hurwitz ES, Katona P, Holman RC, Bregman DJ. Guillain-Barré syndrome: its epidemiology and associations with influenza vaccination. Ann Neurol. 1981;9(Suppl):31–8.
11. Department of Health and Human services. Annex 11: Pandemic influenza response and preparedness plan. Washington: The Department; 2003 Aug 26.
12. Dowdle WR. Influenza pandemic periodicity, virus recycling, and the art of risk assessment. Emerg Infect Dis. 2006;12:34–9.
13. Schoenbaum SC, McNeil BJ, Kavat J. The swine-influenza decision. N Engl J Med. 1976;295:759–65.

Address for correspondence: David J. Sencer, 1097 Mason Woods Dr, Atlanta, GA 30329, USA; email: djud@mindspring.com