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# Selected Documents

1. Sencer "action-memorandum," written March 13, 1976, dated March 18, from James F. Dickson for Theodore Cooper to HEW Secretary David Mathews.
2. Memorandum for OMB Director James T. Lynn, written and dated March 15, 1976, from HEW Secretary Mathews.
3. Memorandum for President Ford, undated, with talking points for March 22, 1976 meeting, from Budget Director Lynn, with two attachments:
  - Attachment A. "Uncertainties Surrounding Federal Mass Swine Influenza Immunization Program."
  - Attachment B. The Spencer "action-memorandum" (as above).
4. CDC staff study on vaccine stockpiling, prepared in May, 1976 for use at subsequent advisory meetings.
5. Two-page consent form for the swine flu program, as actually used, with two second pages, one for monovalent and the other for bivalent vaccine.

# MEMORANDUM

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

TO : The Secretary  
Through: ES HK <sup>2/18</sup> \_\_\_\_\_

DATE: MAR 18 1976

FROM : Assistant Secretary for Health

SUBJECT: Swine Influenza--ACTION

## ISSUE

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

## FACTS

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

ASSUMPTIONS

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

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

8. Any recommended course of action, other than no action, must assure:

- that a supply of vaccine is produced which is adequate to immunize the whole population.
- that adequate supplies of vaccine are available as needed at health care delivery points.
- that the American people are made aware of the need for immunization against this flu virus.
- that the population systematically reach or be reached by the health system.
- that the Public Health Service maintain epidemiologic, laboratory, and immunization surveillance of the population for complications of vaccination, for influenza morbidity and mortality, and for vaccine effectiveness and efficacy.
- that the unique research opportunities be maximized.
- that evaluation of the effectiveness of the efforts is conducted.

ALTERNATIVE COURSES OF ACTION

1. No Action

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

Pro:

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

Con:

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

2. Minimum Response

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

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

Pro:

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

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

Con:

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

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

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

### 3. Government Program

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

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

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

Pro:

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

Con:

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

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

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

#### 4. Combined Approach

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

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

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

## Pro:

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

## 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.



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

MAR 16 4 03 PM '76 March 15, 1976

OFFICE OF  
MANAGEMENT & BUDGET

MEMORANDUM FOR THE HONORABLE JAMES T. LYNN

There is evidence there will be a major flu epidemic this coming fall. The indication is that we will see a return of the 1918 flu virus that is the most virulent form of flu. In 1918 a half million people died. The projections are that this virus will kill one million Americans in 1976.

To have adequate protection, industry would have to be advised now in order to have time to prepare the some 200 million doses of vaccine required for mass inoculation. The decision will have to be made in the next week or so. We will have a recommendation on this matter since a supplementary appropriation will be required.

Today our two leading epidemiologists are here and are holding a briefing after lunch on this subject. It might be most useful for an appropriate member of your staff to attend. The briefing will be at 2 p. m. in Room 5613 of the HEW North Building.

*David Ballou*  
Secretary



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

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?

Uncertainties Surrounding a Federal  
Mass Swine Influenza Immunization Program

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

## ANALYSIS OF VACCINE STOCKPILE OPTION CENTER FOR DISEASE CONTROL\*

One of the options discussed at the CDC very early after the Fort Dix outbreak was to produce the monovalent A/New Jersey vaccine and stockpile until further evidence of virus spread. This option was again considered at the ACIP meetings on March 10 and May 6. The consensus on all three of these occasions was that stockpiling is not an acceptable alternative to a complete and fully committed vaccination program. In more recent weeks the issue of stockpiling has re-emerged. Reevaluation of this option is the subject of this report. To facilitate analysis we have made the following four basic assumptions:

- (1) Bivalent vaccine (including some monovalent) would be distributed in 1976 for "high risk" groups as planned, presumably in the early fall.
- (2) Monovalent A/New Jersey vaccine would be stockpiled at the state or local level.
- (3) Materials would be accumulated and well-trained key personnel would be placed on a standby basis at the national, state, and local level.
- (4) Evidence of reappearance of swine influenza-like virus in humans would trigger the remobilization of resources and begin the nationwide immunization program.

The concept of stockpiling has been considered on the basis of feasibility and costs in terms of dollars and time for each of the following three major elements of the program:

## A. VACCINE STORAGE

Present FDA regulations list the expiration date of vaccines as 18 months after the date of bottling. This regulation is designed largely to prevent the use of outdated vaccine in the event of an antigenic drift or shift. Considerable evidence suggests that the vaccine may be stored under proper conditions at 4°C without loss of potency for 3 years, and probably longer.

## 1. Dollar cost

A mixture of 10- and 50-dose vials packaged and ready for distribution requires 1 cu. ft. for 5,000 doses, or 32,000 cu. ft. of storage for 160 million doses.

\*As submitted to House of Representatives, Committee on Interstate and Foreign Commerce, Subcommittee on Health and the Environment, 94th Congress, Second Session, June 28, 1976 Supplemental Hearings, Serial No. 94-113, p. 9-11.

The cost in Atlanta for maximum security storage under controlled refrigeration is 60¢ per cu. ft. per month. Assuming this to be an average price throughout the country, storage costs for the vaccine would be \$20,000 per month or approximately \$240,000 per year.

## 2. Time cost

The vaccine could be delivered to the state or local grantees as per present contract with manufacturers, resulting in 62 storage points. An alternative would be for the Federal Government to maintain control and storage of the vaccine at selected sites throughout the country. Distribution from these sites may require more time, however. Distribution of the vaccine from the 62 or more storage points to designated vaccination sites and private physicians would require a minimum of 1 to 2 weeks.

## B. STANDBY PROGRAM ORGANIZATION

Before placing the immunization program on a standby basis, all organizational plans and training sessions will have been completed and all project grantees will have had experience in conducting the bivalent vaccine campaign. Temporary employees would be released and other state or local public health employees detailed to the vaccine program would return to regular jobs. To restart the program would require a well-trained "disaster relief" team consisting of key permanent personnel capable of quickly training newly-hired or assigned personnel to perform essential program functions such as clerical duties, operation of the jet gun, and gun repair.

### 1. Dollar cost

Much of the present \$26 million allocation to grantees would be spent on present organization, training, and delivery of bivalent vaccine. Additional monies would be requested for training new personnel, which may consist of as much as 50% of the total program staff. Additional personnel and training costs may approach \$6 million. The cost for a second publicity campaign at the time of the decision to "go" is unknown. Free publicity from the report of new virus outbreaks may lessen the need for publicly supported publicity campaigns.

### 2. Time cost

Initiating the "disaster plan" publicity, and the hiring and training of new personnel for the vaccination program is estimated to require a minimum of 2 to 4 weeks.

### C. PROGRAM RESPONSIVENESS

As presently planned, most of the vaccine would be administered by jet injector. Additional jet injector guns would be needed since the number of vaccinations given per day would increase under the stockpile option. These guns can be manufactured and delivered.

#### 1. Dollar cost

The major direct cost would be \$1 million for 1,000 more guns. At present, 3,000 guns are to be available on September 1.

#### 2. Time cost

To vaccinate 160 million people with 4,000 guns would require 40 days, or approximately seven 6-day weeks. This does not, of course, account for vaccine given by needle and syringe, which may require a longer period to complete.

### D. CONCLUSION

Obstacles to the stockpiling concept and "disaster relief plan" are not insurmountable. The vaccine could be stored and a qualified team which is capable of responding quickly to an epidemic threat could be maintained if the federal, state and local public health authorities were committed to the program. However, with time, very likely that commitment would become less, key personnel would be lost through reorganization and attrition, and program effectiveness would decrease.

The total cost of stockpiling the vaccine and delaying the program for 1 year would be approximately \$7-8 million. Not included in this figure would be the cost of an "all-out" virus surveillance program. Part of this cost would be diverted from the present \$26 million allocation to project grantees, but many of the 62 grantees are unlikely to agree to the concept of stockpiling without an established mechanism for providing additional funds to cover at least a portion of the above cost. If we can assume for purposes of this report that the Administration and the Congress would agree to additional appropriations, cost also ceases to be an obstacle. The whole issue of stockpiling then becomes a question of time. Can we afford to wait for additional evidence of virus spread before beginning the campaign?

Only 2 years in modern times, 1957 and 1968, can serve as models for predicting the spread of pandemic influenza in the continental U.S.A. The period from the first virus isolation to the first outbreak in the civilian population was 3 weeks in 1957 and 7 weeks in 1968; from virus isolation to documented outbreak in one-third or more of the States was 10 weeks in 1957 and 12 weeks in 1968; from isolation to peak activity was 14 weeks in 1957 and 15 weeks in 1968.

Assuming that an additional 2 weeks are required to produce a protective antibody response after vaccination, the vaccine must be given 1 to 5 weeks after the first virus isolation in order to prevent the first outbreak. This is clearly not possible. The longer the time after 1 to 5 weeks which is required to administer the vaccine, the less effective the program will be. However, if we consider a more modest goal, such as interruption of the pandemic before outbreaks occur in one-third of the States, more time is available. But even to achieve this, vaccination must be completed 8 to 10 weeks after first evidence of virus isolation. According to our estimates above, to complete the vaccination program from the signal "go" would require a minimum of 9-11 weeks. A few smaller, highly urbanized States may require less time. Many may require more. Thus, some States could probably achieve this goal. But in our view, a goal which accepts success in only less populated States cannot be adopted as national policy.

In this report we have consciously attempted to avoid bias by using minimal estimates of dollar and time costs. We have not, for example, considered the additional time which may be required to confirm the next swine influenza-like virus isolation or outbreak, the diminished impact of the initial \$135 million investment of public funds, or the morbidity and mortality from early sporadic outbreaks. On the other hand, by our use of 1957 and 1968 as models we may have overestimated the speed at which the virus might spread. We have no real basis for predicting the epidemic behavior of the swine-like virus. Never before has an antigenic shift been detected so early or associated with such a limited outbreak. Quite likely, the longer the time before the next swine virus isolation, the longer the period of warning before a major epidemic. But we cannot be sure. Therefore, at present there is no acceptable alternative to a complete and fully committed vaccination program.

# Important Information from the U.S. Public Health Service about Swine Flu and Victoria Flu Vaccines

## INTRODUCTION

You probably have heard a good deal about swine flu and swine flu vaccine. You may know, for example, that swine flu caused an outbreak of several hundred cases at Ft. Dix, New Jersey, early in 1976--and that before then swine flu had not caused outbreaks among people since the 1920's.

With the vast majority of Americans being susceptible to swine flu, it is possible that there could be an epidemic this winter. No one can say for sure. However, if an epidemic were to break out, millions of people could get sick. Therefore, a special swine flu vaccine has been prepared and tested which should protect most people who receive it.

Certain people, such as those with chronic medical problems and the elderly, need annual protection against flu. Therefore, besides protection against swine flu, they also need protection against another type of flu (Victoria flu) that was around last winter and could occur again this winter. A separate vaccine has been prepared to give them protection against both types of flu.

These vaccines have been field tested and shown to produce very few side effects. Some people who receive the vaccine had fever and soreness during the first day or two after vaccination. These tests and past experience with other flu vaccines indicate that anything more severe than this would be highly unlikely.

Many people ask questions about flu vaccination during pregnancy. An advisory committee of the Public Health Service examined this question and reported that "there are no data specifically to contraindicate vaccination with the available killed virus vaccine in pregnancy. Women who are pregnant should be considered as having essentially the same balance of benefits and risks regarding influenza vaccination and influenza as the general population."

As indicated, some individuals will develop fever and soreness after vaccination. If you have more severe symptoms or if you have fever which lasts longer than a couple of days after vaccination, please consult your doctor or a health worker wherever you receive medical care.

While there is no reason to expect more serious reactions to this flu vaccination, persons who believe that they have been injured by this vaccination may have a claim. The Congress recently passed a law providing that such claims, with certain exceptions, may be filed only against the United States Government. Information regarding the filing of claims may be obtained by writing to the U.S. Public Health Service Claims Office, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20852.

Attached is more information about flu and flu vaccine. Please take the time to read it carefully. You will be asked to sign a form indicating that you understand this information and that you consent to vaccination.

# IMPORTANT INFORMATION ABOUT SWINE INFLUENZA (FLU) VACCINE (MONOVALENT)

July 15, 1976

### The Disease

Influenza (flu) is caused by viruses. When people get flu they may have fever, chills, headache, dry cough or muscle aches. Illness may last several days or a week or more, and complete recovery is usual. However, complications may lead to pneumonia or death in some people. For the elderly and people with diabetes or heart, lung, or kidney diseases, flu may be especially serious. It is unlikely that you have adequate natural protection against swine flu, since it has not caused widespread human outbreaks in 45 years.

### The Vaccine

The vaccine will not give you flu because it is made from killed viruses. Today's flu vaccines cause fewer side effects than those used in the past. In contrast with some other vaccines, flu vaccine can be taken safely during pregnancy.

One shot will protect most people from swine flu during the next flu season; however, either a second shot or a different dosage may be required for persons under age 25. If you are under 25 and a notice regarding such information is not attached, this information will be provided to you wherever you receive the vaccine.

### Possible Vaccine Side Effects

Most people will have no side effects from the vaccine. However, tenderness at the site of the shot may occur and last for several days. Some people will also have fever, chills, headache, or muscle aches within the first 48 hours.

### Special Precautions

As with any vaccine or drug, the possibility of severe or potentially fatal reactions exists. However, flu vaccine has rarely been associated with severe or fatal reactions. In some instances people receiving vaccine have had allergic reactions. You should note very carefully the following precautions:

- Children under a certain age should not routinely receive flu vaccine. Please ask about age limitations if this information is not attached.
- People with known allergy to eggs should receive the vaccine only under special medical supervision.
- People with fever should delay getting vaccinated until the fever is gone.
- People who have received another type of vaccine in the past 14 days should consult a physician before taking the flu vaccine.

*If you have any questions about flu or flu vaccine, please ask.*

## REGISTRATION FORM

*I have read the above statement about swine flu, the vaccine, and the special precautions. I have had an opportunity to ask questions, including questions regarding vaccination recommendations for persons under age 25, and understand the benefits and risks of flu vaccination. I request that it be given to me or to the person named below of whom I am the parent or guardian.*

INFORMATION ON PERSON TO RECEIVE VACCINE		FOR CLINIC USE	
Name (Please Print) _____	Birthdate _____	Age _____	
Address _____	County of Residence _____		Clinic Ident. _____
			Date Vaccinated _____
			Manufacturer and Lot No. _____
Signature of person to receive vaccine or Parent or Guardian _____		Date _____	

CDC 7.31  
7-76

U.S. Department of Health, Education, and Welfare / Public Health Service / Center for Disease Control / Atlanta, Georgia 30333

# IMPORTANT INFORMATION ABOUT SWINE AND VICTORIA INFLUENZA (FLU) VACCINE (BIVALENT)

July 18, 1976

## The Disease

Influenza (flu) is caused by viruses. When people get flu they may have fever, chills, headache, dry cough or muscle aches. Illness may last several days or a week or more, and complete recovery is usual. However, complications may lead to pneumonia or death in some people. For the elderly and people with diabetes or heart, lung, or kidney diseases, flu may be especially serious.

It is unlikely that you have adequate protection against swine flu, since it has not caused widespread human outbreaks in the past 45 years. You may or may not have adequate protection against Victoria flu, although many Americans had this flu last winter. It was responsible for over 12,000 deaths.

## The Vaccine

The vaccine will not give you flu because it is made from killed viruses. Today's flu vaccines cause fewer side effects than those used in the past. In contrast with some other vaccines, flu vaccine can be taken safely during pregnancy.

One shot will protect most people from swine and Victoria flu during the next flu season; however, either a second shot or a different dosage may be required for persons under age 25. If you are under 25 and a notice regarding such information is not attached, this information will be provided to you wherever you receive the vaccine.

## Possible Vaccine Side Effects

Most people will have no side effects from the vaccine. However, tenderness at the site of the shot may occur and last for several days. Some people will also have fever, chills, headache, or muscle aches within the first 48 hours.

## Special Precautions

As with any vaccine or drug, the possibility of severe or potentially fatal reactions exists. However, flu vaccine has rarely been associated with severe or fatal reactions. In some instances people receiving vaccine have had allergic reactions. You should note very carefully the following precautions:

- Children under a certain age should not routinely receive flu vaccine. Please ask about age limitations if this information is not attached.
- People with known allergy to eggs should receive the vaccine only under special medical supervision.
- People with fever should delay getting vaccinated until the fever is gone.
- People who have received another type of vaccine in the past 14 days should consult a physician before taking the flu vaccine.

*If you have any questions about flu or flu vaccine, please ask.*

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## REGISTRATION FORM

*I have read the above statement about swine and Victoria flu, the vaccine, and the special precautions. I have had an opportunity to ask questions, including questions regarding vaccination recommendations for persons under age 25, and understand the benefits and risks of flu vaccination. I request that it be given to me or to the person named below of whom I am the parent or guardian.*

INFORMATION ON PERSON TO RECEIVE VACCINE			FOR CLINIC USE	
Name (Please Print)	Birthdate	Age		
Address	County of Residence		Clinic Ident.	
Signature of person to receive vaccine or Parent or Guardian			Date Vaccinated	
Date			Manufacturer and Lot No.	

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