The original documents are located in Box 34, folder "Swine Flu (7)" of the James M. Cannon Files at the Gerald R. Ford Presidential Library.

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

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

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.

WITHDRAWAL SHEET (PRESIDENTIAL LIBRARIES)

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FORM	Executive Protective Service's form for potential visiters to the White House - contains social security numbers (1 page)	c. 8/1976	C

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James M. Cannon Files, Box 34, Swine Flu, August 11-31, 1976 (1) / TMH / 4/28/2015

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THE WHITE HOUSE

WASHINGTON

SIGNING CEREMONY
NATIONAL SWINE FLU IMMUNIZATION PROGRAM
of 1976
(S. 3735)

Thursday, August 12, 1976
12:00 p.m. (10 minutes)
The Cabinet Room

From: Jim Cannon

I. PURPOSE

To sign into law 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.

II. BACKGROUND, PARTICIPANTS, PRESS PLAN

A. Background: On March 24, 1976, you announced plans for a National Influenza Immunization Program to inoculate Americans against a swine-type influenza virus. You requested the Congress to act on a supplemental appropriation request of $135 million for this program which you signed into law on April 15.

Although significant progress was made toward our goal of making this vaccine available to all Americans, a serious threat developed when it became evident that liability insurance for those involved in the program would not be available through normal channels.

This legislation removes that obstacle by permitting the Federal government to make available necessary liability protection for those manufacturing, distributing, and administering the vaccine. In addition, a claims procedure is established for those few persons who might be injured as a result of receiving inoculations.

B. Participants: Selected Congressional and HEW guests (list attached).

C. Press Plan: Full press opportunity, photo and statement.

III. TALKING POINTS

Talking points to be provided by Bob Orben.

PARTICIPANTS

Secretary David Mathews

Under Secretary Marjorie Lynch

Dr. Delano Meriwether
Program Director for National
Influenza Immunization
Program
Department of Health, Education
and Welfare

Gene Haislip
Director, Office of
Health Legislation
Department of Health, Education
and Welfare

Dr. Theodore Cooper
Assistant Secretary for Health
Department of Health, Education
and Welfare

William H. Taft, IV
General Counsel
Department of Health, Education
and Welfare

Bernard Feiner
Assistant General Counsel
Department of Health, Education
and Welfare

John C. Kruse
Chief, Torts Section
Civil Division
Department of Justice

Dr. James Dickson
Deputy Assistant Secretary
for Health
Department of Health, Education
and Welfare

Eli Bernzweiz
Special Assistant to the Administrator
Federal Insurance Administration
Department of Housing and Urban Development

Howard Clark
Special Assistant to the Administrator
Federal Insurance Administration
Department of Housing and Urban Development

Congressman Tim L. Carter

Jay Cutler
Administrative Assistant
Senator Javits' Office

Wendy Wertheimer
Office of Senator Javits

James Stuber
Legislative Assistant
Congressman Paul Rogers' Office

Francis dePeyster
Office of Congressman Carter

Lee Hyde
Staff Member
Committee on Interstate and
Foreign Commerce

Joseph Bellanti, M.D.
Professor of Pediatrics and Microbiology, Georgetown University; immunologist and virologist; member of the Infectious Disease Advisory Committee.

Gareth Green, M.D.
Member of National Heart and Lung Advisory Council; past president of American Thoracic Society; University of Vermont.

Morton Hilbert, M.D.
President of the American Public Health Association; chairman of the Department of Environmental and Industrial Health, University of Michigan; attended March 24 swine flu meeting.

Raymond T. Holden, M.D.
Chairman of the Board, American Medical Association; attended March 24 swine flu meeting.

Robert Parrott, M.D.
Director of the Children's Hospital, Washington, D.C.

Dr. John Sherman
Vice President, American Association of Medical Colleges.

THE WHITE HOUSE

WASHINGTON

pending Swine Flu

August 28, 1976

MEMORANDUM FOR: DR. TED COOPER

FROM: JIM CANNON

SUBJECT: Swine Flu

Bill Seidman met Dr. Sabin at a recent event in Aspen, and later given this memorandum.

Would you give me a call after you read it.

Many thanks.

TO: Honorable William Seidman, The White House DATE: August 16, 1976

FROM: Albert B. Sabin, M.D.

SUBJECT: NATIONAL SWINE INFLUENZA VACCINATION PROGRAM: NEED FOR A NEW STRATEGY

1. During our encounter at the Aspen Institute picnic on August 7, I promised to prepare a memorandum for a possible meeting with the President on Monday, August 23 when I shall be in Washington on other business.

2. The attached memorandum documents the need for a new strategy for the national swine flu vaccination program to avoid potentially harmful consequences to public health and to public credibility in the reliability and prudence of the health information and recommendations of the government.

3. The main points documented in the enclosed memorandum are:

   (a) Events that were not foreseen on March 24, 1976 have put the present strategy of "piece meal" vaccine administration beginning October 1 in the category of "too little and too late" for prevention or significant modification of a swine influenza epidemic if it should appear during the 1976-77 influenza season (December, January, February, March). The present strategy would be even more ineffective against a potential swine influenza epidemic during the 1977-78 influenza season.

   (b) These events are related not so much to the delays imposed by the legal obstacles, that have now been overcome, as to problems of the different effectiveness of the vaccines produced by the four vaccine manufacturers and the total inadequate organization for vaccine administration that would require 6 months or more after October 1 to reach only a part of the total U.S. population based on the recent DHEW announcement that only one million doses of vaccine would be administered per day.

   The vaccine prepared by only one (Merck) of the four manufacturers is effective in persons, 6 to 24 years of age, and none of the four has acceptable immunizing activity in children under 6 years of age. Moreover the one vaccine that is effective in school-age children has produced a very high rate of high fevers and other signs of illness in 6 to 10 year old children specifically attributable to the killed virus in the vaccine -- a reaction rate that would be acceptable only in the face of a spreading epidemic.

   (c) There is a very high probability that a new influenza strain (A/Victoria/75 that first appeared in Australia in 1975 (and is now causing a very severe epidemic there) and was first detected in the USA in January, 1976, will reappear in the USA during the 1976-1977 influenza season as a cause of a great deal of serious disease and mortality in large numbers of people including those who would have received only the swine flu vaccine. A very unfavorable public reaction to such an event can be expected. This new strain of influenza virus has already produced more influenza disease and mortality in the USA in 1976 than any other strain since the major 1968 epidemic.

(d) The CDC and DHEW "doctrine" that if one waited until a swine influenza epidemic was first detected it would be too late to do anything significant by vaccination is correct only if the present inadequate organization for mass vaccination is used.

(e) A new nation-wide organization for rapid mass vaccination is proposed. It is based on the highly successful procedure used by county medical societies in the national oral polio vaccination campaign of 1962-63 by which 85-95% of the population in large and small communities received the vaccine on a single day. This system can be easily adapted to the rapid mass administration of swine flu vaccine by disposable syringes and needles. The nation-wide establishment of such local volunteer vaccination brigades is needed to meet the challenge not only of a potential swine influenza epidemic but also of another extensive and severe world-wide influenza epidemic that is expected in 1978-80.

(f) It is recommended that the government sponsor the immediate nation-wide organization of such local volunteer vaccination brigades. It is also recommended that swine flu vaccine, especially the one that has been found effective in the 6 to 24 year age group, be stockpiled for mass administration within a few days after evidence of spreading swine influenza virus disease has appeared anywhere in the world. This strategy does not preclude the earliest possible administratio to the so-called high-risk groups of a "trivalent" influenza vaccine, including the currently important A/Victoria/75, the influenza B, and the swine virus strains.

(g) This proposal does not constitute a "scuttling" of the commitment made on March 24 -- it is only a needed change in strategy to use the swine flu vaccine in the most effective way. Two states, Massachusetts and Washington, have already indicated that they will not participate in the currently proposed federal program.

P.S. I shall be in Cincinnati at (513) 731-6430 on Sunday, August 22, and as agreed I will telephone your office on Monday, August 23 immediately after my arrival in Washington at 8:50 A.M. My meeting at the Interamerican Development Bank on 17th Street will last from 10 A.M. to 5 P.M., and I would appreciate it if you could leave word for me at your office whether it would be possible for me to discuss the proposed new strategy with the President sometime after 5 P.M. on August 23 or sometime on August 24.

NATIONAL SWINE INFLUENZA VACCINATION PROGRAM: NEED FOR A NEW STRATEGY

The original March 24, 1976 decision, in which I concurred, to proceed as quickly as possible with the production of the best possible swine influenza vaccine to meet the potential threat of a potentially uniquely virulent (uniquely virulent are the key words) influenza virus was reasonable on the ground that something had to be done even though the probability of such a threat was regarded by many as very low.

The recent legislation directing claims for vaccination — associated damages to the Federal Government instead of to the vaccine manufacturers or persons administering the vaccine is also reasonable, because without it no federally recommended mass vaccination program to protect the public health would be possible now or in the future, although other procedures for dealing with such claims in connection with all annual ongoing and future, federally recommended vaccination programs involving millions of persons also need to be considered for the long range. The provision that the new legislation would become effective until after September 30 is potentially hazardous.

Potentially harmful public health and public credibility consequences emerge from the current administration decision, without adequate debate of the various factors for decision, to vaccinate the entire U.S. population prior to rather than after the appearance of indications that swine influenza virus has reappeared as a cause of serious disease in the USA or elsewhere in the world, on the assumption tha mass vaccination now a) will prevent the reappearance or the subsequent disseminati of swine influenza virus in the USA, and b) that if one waits until the swine influen virus reappears there would not be enough time to administer it.

The validity of the above assumption is being questioned by myself and others, on the basis of the following findings that have emerged from studies subsequent to March, 1976 as well as on preexisting knowledge concerning the dreaded 1918 epidemic and other world-wide influenza epidemics:

a. Extensive serologic tests in the USA and elsewhere in the world have

now provided evidence that swine influenza virus was being extensively disseminated in the USA and some other countries at least until 1929 without the production of the unusually severe illness observed in 1918-1919. The U.S. studies reported at the end of June, 1976 showed that 94% of persons aged 52 and over (i.e. those born in 1924 or earlier) had naturally acquired antibodies for swine influenza virus, with a progressively lower incidence in those younger than 52, down to 6% in the 17 to 23 year age group.

b. There was only circumstantial evidence that the 1918 world-wide influenza epidemic was caused by a swine influenza virus and at least one publication in 1969 (Paul Brown et al, SCIENCE, 66: 117-119) of a study on an isolated Pacific Island population that had not been exposed to influenza A virus infection since 1924, strongly suggested that the influenza virus responsible for the devastating disease in various parts of the world from 1918-1924 was mor closely related to the human influenza viruses of the 1930's. A 1970 report (P.R. Schurrenberger et al, Am. Rev. Resp. Diseases, 102: 356, 1970) of a 1966 study provided evidence of swine influenza virus infection among 16 to 29 year old persons in Illinois occupationally exposed to swine. Four isolated cases of illness (3 of them with prior exposure to swine) have also recently been found to have occurred in 1974 and 1975 in Minnesota, Wisconsin, and Virginia. Moreover, the serologic studies at Fort Dix showed a rather low virulence of the swine influenza virus that appeared there for a brief period in January, 1976 because out of about 500 persons infected with the swine virus only 13 developed influenza that was generally less severe than that caused by t A/Victoria '75 influenza virus that was responsible for most of the influenza at Fort Dix and throughout the USA during the months of January to May, 1976 — a v against which the swine influenza strain could not compete. This A/Victoria '75 was responsible for the most severe influenza epidemic in the USA since the

extensive Hong Kong epidemic of 1968-69. Data that I have just obtained from the National Center for Health Statistics showed that the death certificates of 7,080 persons during the months of January to April, 1976 listed influenza as the primary cause of death. This A/Victoria '75 influenza virus, which first appeared in Australia in 1975, is now causing severe influenza epidemics in Australia and other countries in the Southern Hemisphere. About 50% of adults in the USA currently are still without antibodies for this virus and it is possible that it will be the cause of another influenza epidemic during the 1976-77 season, for which swine influenza vaccine will provide no protection. The adverse affect of such an event on public credibility in the prudence of the Federal Government's current influenza vaccination policy can be expected to be serious.

The A/Victoria '75 influenza virus was first isolated in the USA in January, 1976 and my analysis of recent U.S. influenza epidemics shows that a significantly different new influenza virus causes epidemics in two successive years. This is the basis for expecting another A/Victoria '75 influenza epidemic in January to April, 1977. Moreover, the American people should also be informed that even during a year, such as July 1,1973- June 30, 1974, when there was no special influenza virus activity there were 223 million days of bed disability attributed to clinically indistinquishable serious influenza disease, although the total primary influenza mortality for that year was only 1,887 - compared with the 7,350 deaths for the period of July, 1975 to April, 1976 inclusive.

c. Unfortunately, the four vaccine manufacturers were not requested by the government to use a single procedure for production of the swine influenza vaccine, that on the basis of past experience could have been expected to yield the best results in a population without previous natural infection by related

influenza viruses. As a consequence, the vaccines produced by all four manufacturers proved to be effective in those over 25-30 years of age, although different doses of the four vaccines were required to produce the optimum effect even in this older age group. However, in the age group of 6-23 years, the vaccine of only one manufacturer produced an acceptable antibody response, and in 3-to-6 year old children even this vaccine failed to produce an acceptable immune response. However, the one vaccine that gave an acceptable immune response in 6-10 year old children, produced fevers of 101 degrees to 103.9 degrees in 19% of these children, while no fevers of this magnitude occurred in any of the children of this age group who received a placebo injection. These fevers were accompanied by headache, malaise, muscle pains, and abdominal pains or nausea. In 1974, there were over 38 million children in the 5-14 age group in the USA. Thus, on the basis of the preliminary observations in the small group of 6-10 year old children who received this dose of vaccine, one can anticipate about 150,000 to 190,000 such illnesses per million or about 6 to 7 million such illnesses among 39 million 5 to 14 year old children directly attributable to the (killed virus in the) vaccine. The American people have not yet been fully informed of these findings and they should be. While such a price in illnesses, attributable to the use of the vaccine, might be justified in the face of a spreading swine influenza epidemic, it cannot be justified when the threat of such an epidemic is as low as it now appears to be — much lower than in March, 1976. Despite active national and international surveillance, no swine influenza virus has turned up since January, 1976 at Fort Dix, anywhere in the USA,or during the current winter season in the Southern Hemisphere countries. This is not the behavior exhibited by any previous epidemic strain of influenza virus.

d. Under any circumstances, even total vaccination of those over 24 years of age, and even of all school-age children, cannot be expected to prevent the reappearan

and dissemination of the swine influenza virus late in 1976 or sometime in 1977, however low the probability of its reappearance. Moreover, there is a high probability that the proposed system of vaccine administration, i.e. by state and local health departments, private physicians, and hospitals over a period of many months, will fail to reach a large proportion of the population. The recent announcement that beginning about October first, it is expected that one million persons per day will receive the vaccine is on the face of it almost absurd as a realistic mass vaccination program because this would require 6 to 7 months to reach about 200 million people. This combined with the estimated 70% effectiveness of the vaccine, a priori excludes the possibility of a significant impact on the spread of swine influenza virus if it should reappear late in 1976 or early in 1977. Furthermore there is good reason for expecting that if a swine influenza virus, with an extensive capacity for spread and production of serious disease, does appear in 1976-1977 that it will reappear in 1977-1978, when most of those vaccinated during the forthcoming months will have lost their vaccine-induced immunity.

e. The argument that once a new virulent, epidemic type of influenza virus appears it spreads quickly within a few weeks is correct only for a community in which it appears, but not for a whole nation and particularly not for a large nation. In 1957, the first U.S. outbreaks of influenza occurred in early June and it took 4 months for it to involve the entire USA. In 1968, the first outbreaks in the USA appeared in September and it took about 3 months before the whole country was affected.

f. Accordingly there is time to make a significant impact on such an epidemic, provided a totally different kind of organization for mass vaccination is used. In 1962-63, the local county medical societies surrounded by very large numbers of volunteers (without the financial or other help from the U.S. Public Health service) used a system of mass administration of the oral polio vaccine whereby

85% to 95% of persons in the community received the vaccine on a single day. This applied to large cities like Cleveland, San Francisco and Los Angeles as well as to smaller communities. Although it may be said that it was easier to do it with a vaccine given by mouth than by injection, I believe that the system can be readily adapted to mass administration of influenza vaccine using disposable syringes and needles rather than jet guns. With such a system of vaccine administration, stockpiled vaccine could be administered within a matter of days rather than months (required by the system currently proposed by CDC) provided organization of the communities for a potential massive epidemic, during the forthcoming year as well as in future years is begun now as an official government policy. Such an organization also is based on completely voluntary service by all concerned and the only cost would be for the stockpiled disposable syringes and vaccine that would be supplied by the federal government.

g. Accordingly, I believe that it would be prudent to replace the present commitment to use the swine influenza vaccine prior to any evidence for its need by a program of national preparedness to use it within a matter of days after evidence for its need appears. Under the present commitment the vaccine could very well be used up this year, and if the virus should appear or reappear in 1977-78, there would be none available when it would really do the most good. The prposed neworganization would also be needed if the swine influenza virus never appears as an epidemic threat, because there is good reason to believe that another world-wide influenza epidemic may appear in 1978-1980, and the lessons we have learned in 1976 may prove very useful then.

By Gerald Martineau—The Washington Post

Mr. Ford describes flu shot plans while Assistant HEW secretary Theodore Cooper, center, and Dr. Albert Sabin look on

Ford Asks Nationwide Flu Shots

By Stuart Auerbach
Washington Post Staff Writer

President Ford announced

to cover the cost of the vaccine. State and local govern-

raised up an image of potential seriousness that was not

pay for this vital protection.".

An outbreak of the swine

Some items in this folder were not digitized because it contains copyrighted materials. Please contact the Gerald R. Ford Presidential Library for access to these materials.

DR. ALBERT B. SABIN
DISTINGUISHED RESEARCH PROFESSOR
OF BIOMEDICINE
(803) 792-2165

Medical University of South Carolina
80 BARRE STREET / CHARLESTON, SOUTH CAROLINA 29401

Aug. 17, 1976

Dear Mr. Seidman,

I learned that Asst. Secretary for Health Theodore Cooper will be in Aspen on Aug. 18 and Secretary David Mathews on August 20. Each of them will receive a copy of the memorandum: "National Swine Influenza Program: Need for a New Strategy" that I sent you yesterday.

Kindest personal regards,

Albert B. Sabin

THE WHITE HOUSE

WASHINGTON

August 28, 1976

MEMORANDUM FOR: DR. TED COOPER

FROM: JIM CANNON

SUBJECT: Swine Flu

Bill Seidman met Dr. Sabin at a recent event in Aspen, and later given this memorandum.

Would you give me a call after you read it.

Many thanks.

8/28

Mr. Cannon -

I spoke with Dr. Cooper re: attached. He has a copy of Sabin's memo and will send you on Monday a copy of his response.

Cameron

To Jim Connor

TO: Honorable William Seidman, The White House DATE: August 16, 1976

FROM: Albert B. Sabin, M.D.

SUBJECT: NATIONAL SWINE INFLUENZA VACCINATION PROGRAM: NEED FOR A NEW STRATEGY

1. During our encounter at the Aspen Institute picnic on August 7, I promised to prepare a memorandum for a possible meeting with the President on Monday, August 23 when I shall be in Washington on other business.

2. The attached memorandum documents the need for a new strategy for the national swine flu vaccination program to avoid potentially harmful consequences to public health and to public credibility in the reliability and prudence of the health information and recommendations of the government.

3. The main points documented in the enclosed memorandum are:

   (a) Events that were not foreseen on March 24, 1976 have put the present strategy of "piece meal" vaccine administration beginning October 1 in the category of "too little and too late" for prevention or significant modification of a swine influenza epidemic if it should appear during the 1976-77 influenza season (December, January, February, March). The present strategy would be even more ineffective against a potential swine influenza epidemic during the 1977-78 influenza season.

   (b) These events are related not so much to the delays imposed by the legal obstacles, that have now been overcome, as to problems of the different effectiveness of the vaccines produced by the four vaccine manufacturers and the total inadequate organization for vaccine administration that would require 6 months or more after October 1 to reach only a part of the total U.S. population based on the recent DHEW announcement that only one million doses of vaccine would be administered per day.

   The vaccine prepared by only one (Merck) of the four manufacturers is effective in persons, 6 to 24 years of age, and none of the four has acceptable immunizing activity in children under 6 years of age. Moreover the one vaccine that is effective in school-age children has produced a very high rate of high fevers and other signs of illness in 6 to 10 year old children specifically attributable to the killed virus in the vaccine -- a reaction rate that would be acceptable only in the face of a spreading epidemic.

   (c) There is a very high probability that a new influenza strain (A/Victoria/75), that first appeared in Australia in 1975 (and is now causing a very severe epidemic there) and was first detected in the USA in January, 1976, will reappear in the USA during the 1976-1977 influenza season as a cause of a great deal of serious disease and mortality in large numbers of people including those who would have received only the swine flu vaccine. A very unfavorable public reaction to such an event can be expected. This new strain of influenza virus has already produced more influenza disease and mortality in the USA in 1976 than any other strain since the major 1968 epidemic.

(d) The CDC and DHEW "doctrine" that if one waited until a swine influenza epidemic was first detected it would be too late to do anything significant by vaccination is correct only if the present inadequate organization for mass vaccination is used.

(e) A new nation-wide organization for rapid mass vaccination is proposed. It is based on the highly successful procedure used by county medical societies in the national oral polio vaccination campaign of 1962-63 by which 85-95% of the population in large and small communities received the vaccine on a single day. This system can be easily adapted to the rapid mass administration of swine flu vaccine by disposable syringes and needles. The nation-wide establishment of such local volunteer vaccination brigades is needed to meet the challenge not only of a potential swine influenza epidemic but also of another extensive and severe world-wide influenza epidemic that is expected in 1978-80.

(f) It is recommended that the government sponsor the immediate nation-wide organization of such local volunteer vaccination brigades. It is also recommended that swine flu vaccine, especially the one that has been found effective in the 6 to 24 year age group, be stockpiled for mass administration within a few days after evidence of spreading swine influenza virus disease has appeared anywhere in the world. This strategy does not preclude the earliest possible administration to the so-called high-risk groups of a "trivalent" influenza vaccine, including the currently important A/Victoria/75, the influenza B, and the swine virus strains.

(g) This proposal does not constitute a "scuttling" of the commitment made on March 24 -- it is only a needed change in strategy to use the swine flu vaccine in the most effective way. Two states, Massachusetts and Washington, have already indicated that they will not participate in the currently proposed federal program.

P.S. I shall be in Cincinnati at (513) 731-6430 on Sunday, August 22, and as agreed I will telephone your office on Monday, August 23 immediately after my arrival in Washington at 8:50 A.M. My meeting at the Interamerican Development Bank on 17th Street will last from 10 A.M. to 5 P.M., and I would appreciate it if you could leave word for me at your office whether it would be possible for me to discuss the proposed new strategy with the President sometime after 5 P.M. on August 23 or sometime on August 24.

NATIONAL SWINE INFLUENZA VACCINATION PROGRAM: NEED FOR A NEW STRATEGY

The original March 24, 1976 decision, in which I concurred, to proceed as quickly as possible with the production of the best possible swine influenza vaccine to meet the potential threat of a potentially uniquely virulent (uniquely virulent are the key words) influenza virus was reasonable on the ground that something had to be done even though the probability of such a threat was regarded by many as very low.

The recent legislation directing claims for vaccination — associated damages to the Federal Government instead of to the vaccine manufacturers or persons administering the vaccine is also reasonable, because without it no federally recommended mass vaccination program to protect the public health would be possible now or in the future, although other procedures for dealing with such claims in connection with all annual ongoing and future, federally recommended vaccination programs involving millions of persons also need to be considered for the long range. The provision that the new legislation would become effective until after September 30 is potentially hazardous.

Potentially harmful public health and public credibility consequences emerge from the current administration decision, without adequate debate of the various factors for decision, to vaccinate the entire U.S. population prior to rather than after the appearance of indications that swine influenza virus has reappeared as a cause of serious disease in the USA or elsewhere in the world, on the assumption that mass vaccination now a) will prevent the reappearance or the subsequent dissemination of swine influenza virus in the USA, and b) that if one waits until the swine influenza virus reappears there would not be enough time to administer it.

The validity of the above assumption is being questioned by myself and others, on the basis of the following findings that have emerged from studies subsequent to March, 1976 as well as on preexisting knowledge concerning the dreaded 1918 epidemic and other world-wide influenza epidemics:

a. Extensive serologic tests in the USA and elsewhere in the world have

now provided evidence that swine influenza virus was being extensively disseminated in the USA and some other countries at least until 1929 without the production of the unusually severe illness observed in 1918-1919. The U.S. studies reported at the end of June, 1976 showed that 94% of persons aged 52 and over (i.e. those born in 1924 or earlier) had naturally acquired antibodies for swine influenza virus, with a progressively lower incidence in those younger than 52, down to 6% in the 17 to 23 year age group.

b. There was only circumstantial evidence that the 1918 world-wide influenza epidemic was caused by a swine influenza virus and at least one publication in 1969 (Paul Brown et al, SCIENCE, 66: 117-119) of a study on an isolated Pacific Island population that had not been exposed to influenza A virus infection since 1924, strongly suggested that the influenza virus responsible for the devastating disease in various parts of the world from 1918-1924 was more closely related to the human influenza viruses of the 1930's. A 1970 report (P.R. Schurrenberger et al, Am. Rev. Resp. Diseases, 102: 356, 1970) of a 1966 study provided evidence of swine influenza virus infection among 16 to 29 year old persons in Illinois occupationally exposed to swine. Four isolated cases of illness (3 of them with prior exposure to swine) have also recently been found to have occurred in 1974 and 1975 in Minnesota, Wisconsin, and Virginia. Moreover, the serologic studies at Fort Dix showed a rather low virulence of the swine influenza virus that appeared there for a brief period in January, 1976 because out of about 500 persons infected with the swine virus only 13 developed influenza that was generally less severe than that caused by the A/Victoria '75 influenza virus that was responsible for most of the influenza at Fort Dix and throughout the USA during the months of January to May, 1976 — a virus against which the swine influenza strain could not compete. This A/Victoria '75 viru was responsible for the most severe influenza epidemic in the USA since the

extensive Hong Kong epidemic of 1968-69. Data that I have just obtained from the National Center for Health Statistics showed that the death certificates of 7,080 persons during the months of January to April, 1976 listed influenza as the primary cause of death. This A/Victoria '75 influenza virus, which first appeared in Australia in 1975, is now causing severe influenza epidemics in Australia and other countries in the Southern Hemisphere. About 50% of adults in the USA currently are still without antibodies for this virus and it is possible that it will be the cause of another influenza epidemic during the 1976-77 season, for which swine influenza vaccine will provide no protection. The adverse affect of such an event on public credibility in the prudence of the Federal Government's current influenza vaccination policy can be expected to be serious.

The A/Victoria '75 influenza virus was first isolated in the USA in January, 1976 and my analysis of recent U.S. influenza epidemics shows that a significantly different new influenza virus causes epidemics in two successive years. This is the basis for expecting another A/Victoria '75 influenza epidemic in January to April, 1977. Moreover, the American people should also be informed that even during a year, such as July 1,1973- June 30, 1974, when there was no special influenza virus activity there were 223 million days of bed disability attributed to clinically indistinquishable serious influenza disease, although the total primary influenza mortality for that year was only 1,887 - compared with the 7,350 deaths for the period of July, 1975 to April, 1976 inclusive.

c. Unfortunately, the four vaccine manufacturers were not requested by the government to use a single procedure for production of the swine influenza vaccine, that on the basis of past experience could have been expected to yield the best results in a population without previous natural infection by related

influenza viruses. As a consequence, the vaccines produced by all four manufacturers proved to be effective in those over 25-30 years of age, although different doses of the four vaccines were required to produce the optimum effect even in this older age group. However, in the age group of 6-23 years, the vaccine of only one manufacturer produced an acceptable antibody response, and in 3-to-6 year old children even this vaccine failed to produce an acceptable immune response. However, the one vaccine that gave an acceptable immune response in 6-10 year old children, produced fevers of 101 degrees to 103.9 degrees in 19% of these children, while no fevers of this magnitude occurred in any of the children of this age group who received a placebo injection. These fevers were accompanied by headache, malaise, muscle pains, and abdominal pains or nausea. In 1974, there were over 38 million children in the 5-14 age group in the USA. Thus, on the basis of the preliminary observations in the small group of 6-10 year old children who received this dose of vaccine, one can anticipate about 150,000 to 190,000 such illnesses per million or about 6 to 7 million such illnesses among 39 million 5 to 14 year old children directly attributable to the (killed virus in the) vaccine. The American people have not yet been fully informed of these findings and they should be. While such a price in illnesses, attributable to the use of the vaccine, might be justified in the face of a spreading swine influenza epidemic, it cannot be justified when the threat of such an epidemic is as low as it now appears to be — much lower than in March, 1976. Despite active national and international surveillance, no swine influenza virus has turned up since January, 1976 at Fort Dix, anywhere in the USA,or during the current winter season in the Southern Hemisphere countries. This is not the behavior exhibited by any previous epidemic strain of influenza virus.

d. Under any circumstances, even total vaccination of those over 24 years of age, and even of all school-age children, cannot be expected to prevent the reappearance

and dissemination of the swine influenza virus late in 1976 or sometime in 1977, however low the probability of its reappearance. Moreover, there is a high probability that the proposed system of vaccine administration, i.e. by state and local health departments, private physicians, and hospitals over a period of many months, will fail to reach a large proportion of the population. The recent announcement that beginning about October first, it is expected that one million persons per day will receive the vaccine is on the face of it almost absurd as a realistic mass vaccination program because this would require 6 to 7 months to reach about 200 million people. This combined with the estimated 70% effectiveness of the vaccine, a priori excludes the possibility of a significant impact on the spread of swine influenza virus if it should reappear late in 1976 or early in 1977. Furthermore there is good reason for expecting that if a swine influenza virus, with an extensive capacity for spread and production of serious disease, does appear in 1976-1977 that it will reappear in 1977-1978, when most of those vaccinated during the forthcoming months will have lost their vaccine-induced immunity.

e. The argument that once a new virulent, epidemic type of influenza virus appears it spreads quickly within a few weeks is correct only for a community in which it appears, but not for a whole nation and particularly not for a large nation. In 1957, the first U.S. outbreaks of influenza occurred in early June and it took 4 months for it to involve the entire USA. In 1968, the first outbreaks in the USA appeared in September and it took about 3 months before the whole country was affected.

f. Accordingly there is time to make a significant impact on such an epidemic, provided a totally different kind of organization for mass vaccination is used. In 1962-63, the local county medical societies surrounded by very large numbers of volunteers (without the financial or other help from the U.S. Public Health service) used a system of mass administration of the oral polio vaccine whereby

85% to 95% of persons in the community received the vaccine on a single day. This applied to large cities like Cleveland, San Francisco and Los Angeles as well as to smaller communities. Although it may be said that it was easier to do it with a vaccine given by mouth than by injection, I believe that the system can be readily adapted to mass administration of influenza vaccine using disposable syringes and needles rather than jet guns. With such a system of vaccine administration, stockpiled vaccine could be administered within a matter of days rather than months (required by the system currently proposed by CDC) provided organization of the communities for a potential massive epidemic, during the forthcoming year as well as in future years is begun now as an official government policy. Such an organization also is based on completely voluntary service by all concerned and the only cost would be for the stockpiled disposable syringes and vaccine that would be supplied by the federal government.

g. Accordingly, I believe that it would be prudent to replace the present commitment to use the swine influenza vaccine prior to any evidence for its need, by a program of national preparedness to use it within a matter of days after evidence for its need appears. Under the present commitment the vaccine could very well be used up this year, and if the virus should appear or reappear in 1977-78, there would be none available when it would really do the most good. The prposed new organization would also be needed if the swine influenza virus never appears as an epidemic threat, because there is good reason to believe that another world-wide influenza epidemic may appear in 1978-1980, and the lessons we have learned in 1976 may prove very useful then.

By Gerald Martineau—The Washington Post

Mr. Ford describes flu shot plans, while Assistant HEW secretary Theodore Cooper, center, and Dr. Albert Sabin look on

Ford Asks Nationwide Flu Shots

By Stuart Auerbach
Washington Post Staff Writer

to cover the cost of the vaccine. State and local govern-

raised up an image of potential seriousness that was not

pay for this vital protection."

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Aug. 17, 1976

Dear Mr. Seidman,

I learned that Asst. Secretary for Health Theodore Cooper will be in Aspen on Aug. 18 and Secretary David Mathews on August 20. Each of them will receive a copy of the memorandum: "National Swine Influenza Program: Need for a New Strategy" that I sent you yesterday.

Kindest personal regards,

Albert B. Sabin

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Aspen Institute for Humanistic Studies

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Honorable William Seidman
The White House
Washington, D. C.

PERSONAL: FOR ATTENTION AFTER RETURN TO WASHINGTON