The original documents are located in Box 34, folder "Swine Flu (6)" of the James M. Cannon Files at the Gerald R. Ford Presidential Library.

THE WHITE HOUSE

WASHINGTON

July 22, 1976

MEMORANDUM FOR: SECRETARY F. DAVID MATHEWS
MAX FRIEDERSDORF
DAVE GERGEN
SPENCER JOHNSON
JACK MARSH
RON NESSEN
PAUL O'NEILL
ART QUERN

FROM: JIM CAVANAUGH

SUBJECT: Presidential Statement on Flu Vaccine

Attached for your comment and approval is a statement by the President on the flu program which the President would like issued this evening.

We must have your comments by 6 p.m. this evening. Thanks very much.

Attachment

5:00 p.m.
7/22/76

DRAFT STATEMENT BY THE PRESIDENT
ON THE
NATIONAL INFLUENZA IMMUNIZATION PROGRAM

On March 24 I announced the initiation of a National Influenza Immunization Program to inoculate all Americans against a swine-type strain of virus. This extraordinary effort, the first of its kind in the nation's history, was undertaken upon consultation with, and with the unanimous recommendation of, a panel of this country's top public health medical and scientific leaders.

I immediately requested a special appropriation of $135 million from the Congress to ensure the production and distribution of sufficient swine-type influenza vaccine. I was gratified by the rapid response of the Congress in acting on my request which I signed into law on April 15.

Since that time we have made significant progress toward our goal of making this vaccine available to all Americans by the onset of an influenza season. Nearly 90 million doses of vaccine have already been produced; organizational efforts at the state and local levels for delivery of inoculations are well advanced; voluntary groups have been identified, briefed, and organized; and results of the largest pre-certification clinic field

trials ever performed are very positive for the safety and effectiveness of the vaccine.

Despite these tremendous accomplishments, however, we face a real crisis in making this necessary public health program available to the American people. Secretary Mathews reported to me this afternoon that liability insurance for the vaccine manufacturers continues to be unavailable through normal commercial channels because of the inordinate size of this program and the apparent inability of the insurance companies to accurately assess, and thereby reasonably insure, the potential hazards of administering the vaccine to everyone. Although there is normally a very low risk of untoward reactions to influenza vaccine, without essential product liability coverage, the vaccine manufacturers are unwilling to release the vaccine for use in this national program. Secretary Mathews also reported to me this afternoon that unless this liability problem is resolved in the next few days, the manufacturers will terminate their production of swine flu vaccine.

To break this deadlock, on June 16 I directed the Secretary of HEW to submit legislation to the Congress to enable the government to assume all risks for the program except those resulting from negligence of the manufacturer. This measure is still under consideration by the Congress, but further delay, regardless of the reason, could result in the failure of this program to meet this essential public health need for all Americans.

Although I share the concern of the Congress that the vaccine manufacturers and insurers behave responsibly and be held accountable, I am more concerned that a safe and effective vaccine be available to all Americans who want it during the flu season.

I am pleased that the Health Subcommittee of the House Interstate and Foreign Commerce Committee will hold another hearing on this important matter tomorrow morning.

I urge the Congress to act immediately on my legislative proposal. We cannot accept the fact that the health of all Americans can be placed in jeopardy by the failure of the Congress to take action on this important legislation.

While we await Congressional action, I have directed Secretary Mathews to continue to work with the drug manufacturers to ensure that they do not terminate their production of this vital vaccine while negotiations continue.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH
WASHINGTON, D.C. 20201

JUL 22 1976

MEMORANDUM FOR HONORABLE JAMES CAVANAUGH

Attached is the statement from the American Insurance Association which addresses the liability issue.

Theodore Cooper

Theodore Cooper, M.D.

JUL 2 2 1976

American Insurance Association

Many casualty insurers and reinsurers, both foreign and domestic, have excluded coverage for claims related to swine influenza vaccine from vaccine manufacturers' product liability insurance contracts. They believe that the exposure of the manufacturers under the proposed national immunization program is unmeasurable, and, therefore, uninsurable.

The companies' separate decisions in most cases were based not on their evaluation of the medical risks in the program, which appear reasonable, nor on doubts about the wisdom or necessity of the program. Rather, they stemmed from a conviction (1) that the legal climate in which the program will operate is so unsettled that neither the number nor the total cost of claims arising under the program can be predicted with any confidence; and (2) that the manufacturers will be forced to assume legal liabilities and costs that should be borne by the Government.

First, the law of product liability, particularly as it relates to pharmaceuticals, has undergone changes in the past 13 years which have made it easier for plaintiffs to recover. In many jurisdictions, it is no longer necessary to establish negligence to hold a manufacturer liable; in others, under certain circumstances, the manufacturer is absolutely liable if his product causes injury.

Many insurers feel that the unsettled condition of product liability law, combined with the increasing litigiousness of the public and the tendency of juries and courts to make progressively higher awards progressively more frequently, constitutes a poor legal climate into which to launch a highly-publicized crash program that contemplates the administration of a new vaccine to virtually the entire American population. Their uncertainty as to the number and cost of claims that might arise leads them to believe that the program is uninsurable.

Second, the national immunization program is a Government public health initiative in which the vaccine manufacturers will play an extremely limited role. Yet, because of the stringency of the Federal Tort Claims Act, the manufacturers in most cases will be the only reachable targets for claims arising out of the Government's part of the program.

Many insurers feel that the Government should insure most of the risks involved in a program that the Government designed and will in large measure carry out. They believe that the manufacturers should not be exposed to the cost of defending and settling claims that properly should have been brought only against the Government.

Finally, the American property-casualty insurance industry lost more than $7 billion on underwriting operations in 1974 and 1975. Its most severe losses occurred in the product liability line. As a result, product liability coverage in the amounts needed by pharmaceutical manufacturers is expensive and can be obtained today only by exhausting the capacity of the world market.

The sum of the foregoing is that product liability insurance coverage on acceptable terms probably cannot be obtained for the four manufacturers of swine flu vaccine in either the domestic or the foreign market. Insurer participation in the program could be achieved possibly through authorization of federal reinsurance for the manufacturers' primary insurers.

THE WHITE HOUSE

WASHINGTON

July 22, 1976

MEETING WITH SECRETARY MATHEWS ON SWINE FLU

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

From: Jim Cannon

I. PURPOSE

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

II. BACKGROUND, PARTICIPANTS & PRESS PLAN

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

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

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

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

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

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

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

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

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

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

C. Press Plan: To be determined.

III. TALKING POINTS

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

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

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

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

JUL 20 1976

MEMORANDUM FOR THE PRESIDENT

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

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

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

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

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

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

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

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

Secretary

Attachment

National Influenza Immunization Program
Status Report
July 20, 1976

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

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

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

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

MEMORANDUM

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

TO : The Secretary

DATE: July 20, 1976

FROM : Assistant Secretary for Health

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

ISSUE:

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

BACKGROUND

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

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

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

-Influenza remains a serious public health and economic problem.

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

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

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

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

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

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

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

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

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

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

MAJOR PROBLEM

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

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

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

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

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

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

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

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

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

OPTIONS:

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

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

Category I: Modify or Abandon the Program

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

PRO

-Would provide Federal monies to protect some Americans

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

CON

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

-Would force a highly undesirable set of Federal choices:

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

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

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

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

PRO

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

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

CON

-Excludes much of population and raises price of protection

-Could be regarded as a failure of the Administration

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

Category II: Continue Negotiations without Further Legislation

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

PRO

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

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

CON

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

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

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

PRO

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

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

CON

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

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

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

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

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

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

PRO

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

CON

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

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

Category III: Seek New Legislation

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

PRO

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

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

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

CON

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

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

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

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

PRO

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

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

CON

--Manufacturers might not accept limits proposed by Federal government

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

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

PRO

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

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

-Would be applicable to other preventive health programs.

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

CON

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

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

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

Category IV: Other Options

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

PRO

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

CON

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

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

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

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

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

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

1976 JUL 20 PM 7 12

July 20, 1976

MEMORANDUM FOR THE PRESIDENT

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

The insurance companies to be invited should include the following:

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

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

Secretary

THE WHITE HOUSE ACTION

WASHINGTON

July 23, 1976

MEMORANDUM FOR THE PRESIDENT

FROM: JIM CAVANAUGH

SUBJECT: Swine Flu Letter to Paul Rogers

Following our meeting with Secretary Mathews yesterday on swine flu, we have prepared for your signature a letter to Chairman Paul Rogers which indicates your continuing support for this program and urges the Committee to act on your legislative proposal.

The letter has been reviewed and approved by Paul O'Neill, Jack Marsh, Max Friedersdorf, Dick Cheney, and Jim Cannon. We plan to have Secretary Mathews or Dr. Cooper read the letter at this morning's hearing.

After it is delivered, we would plan to release the text of the letter in this morning's press briefing.

RECOMMENDATION

I recommend you sign the attached letter.

Attachment

July 23, 1976

Dear Paul:

I want to convey to you once again the strong commitment of this Administration to a National Influenza Immunization Program.

Almost four months ago to the day, I announced the initiation of this program after a panel of the country's top health, medical and scientific leaders unanimously recommended to me that we move forward. Those leaders convinced me that a strain of virus, popularly known as "swine flu", could threaten the health of our citizenry unless a massive, extraordinary program of national inoculations was immediately undertaken.

I requested a special appropriation of $135 million from the Congress to ensure the production and distribution of sufficient swine-type influenza vaccine. I was gratified by the rapid response of the Congress in acting on my request and I signed it into law on April 15.

Since that time we have made significant progress toward our goal of making this vaccine available to all Americans before the onset of an influenza season this fall. Nearly 90 million doses of vaccine have already been produced; organizational efforts at the state and local levels for delivery of inoculations are well advanced; voluntary groups have been identified, briefed, and organized; and results of the largest pre-certification clinical field trials ever performed are very positive for the safety and effectiveness of the vaccine.

Despite these accomplishments, however, we now face a growing problem in making this public health program available to the American people.

Secretary Mathews reported to me yesterday afternoon that the providers of liability insurance for the vaccine manufacturers continue to resist our efforts to work out an agreement to provide insurance through normal commercial

channels. It is their position that the inordinate size of this program makes it difficult if not impossible to accurately assess, and thereby reasonably insure, the potential hazards of administering the vaccine to everyone.

Although experience indicates that there is a very low risk of untoward reactions to influenza vaccine, we will continue to pursue an agreeable compromise with these companies. Without essential product liability coverage, the vaccine manufacturers are unwilling to release the vaccine for use in this national program. Secretary Mathews reported to me that unless this liability problem is resolved in the next few days, the manufacturers will terminate their production of swine flu vaccine. All of us would be derelict in our responsibilities to the American people if this program comes to a screeching halt.

In anticipation of just this situation, I directed Secretary Mathews on June 16 to submit legislation to the Congress to enable the government to assume a proper share of risks for the program, but not those resulting from negligence of the manufacturer. This measure is still under consideration by the Congress, but further delay, regardless of the reason, could result in the failure of this program to meet this essential public health need for all Americans.

I share the concern of the Congress that the vaccine manufacturers and insurers be held accountable. But my first concern is that a safe and effective vaccine be available to all Americans who want it during the flu season.

I am pleased that the Health and the Environment Subcommittee of the House Interstate and Foreign Commerce Committee will hold another hearing on this important matter. I urge you to act immediately on my legislative proposal. We cannot accept the fact that the health of all Americans can be placed in jeopardy by a failure to take action on this important legislation.

While we await Congressional action -- and I trust that the Congress will act quickly with due regard for the Nation's health and safety -- I have directed Secretary Mathews to ask for the cooperation of the manufacturers again to ensure that they do not terminate their production of this vital vaccine while negotiations continue.

In conclusion, let me reiterate a single point: The threat of swine flu is very genuine. Data from both the scientific and medical communities support the need for an inoculation program. Clinical tests conducted to date show that the vaccine is both safe and effective. There is no excuse now to let this program -- a program that could affect the lives of many, many Americans -- bog down in petty wrangling. Let's work together to get on with the job.

Sincerely,

The Honorable Paul G. Rogers
Chairman
Subcommittee on Health
and the Environment
Interstate and Foreign Commerce
Committee
House of Representatives
Washington, D.C. 20515

THE WHITE HOUSE

WASHINGTON

July 23, 1976

Dear Paul:

I want to convey to you once again the strong commitment of this Administration to a National Influenza Immunization Program.

Almost four months ago to the day, I announced the initiation of this program after a panel of the country's top health, medical and scientific leaders unanimously recommended to me that we move forward. Those leaders convinced me that a strain of virus, popularly known as "swine flu", could threaten the health of our citizenry unless a massive, extraordinary program of national inoculations was immediately undertaken.

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I share the concern of the Congress that the vaccine manufacturers and insurers be held accountable. But my first concern is that a safe and effective vaccine be available to all Americans who want it during the flu season.

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Sincerely,

Gerald R. Ford

The Honorable Paul G. Rogers
Chairman
Subcommittee on Health
and the Environment
Interstate and Foreign Commerce
Committee
House of Representatives
Washington, D.C. 20515

FOR IMMEDIATE RELEASE July 23, 1976

Office of the White House Press Secretary

THE WHITE HOUSE

TEXT OF A LETTER FROM THE
PRESIDENT TO THE CHAIRMAN OF THE
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT,
INTERSTATE AND FOREIGN COMMERCE COMMITTEE,
HOUSE OF REPRESENTATIVES

July 23, 1976

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Sincerely,

GERALD R. FORD

The Honorable Paul G. Rogers
Chairman
Subcommittee on Health
and the Environment
Interstate and Foreign Commerce
Committee
House of Representatives
Washington, D.C. 20515

# # # #

[Aug. 1976]

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R W BYLWYFVYX

‡AM-Ford-Swine Flu; 360

‡By FRANCES LEWINE

‡Associated Press Writer

WASHINGTON (AP) - President Ford; declaring that he was ''frankly dumbfounded'' that Congress has failed to pass a swine flu vaccine insurance plan; called on it Friday to act before its next recess ''so that the health of the American people will be fully protected.''

Making an appearance in the White House briefing room; Ford said he was ''keenly disappointed that the news from the doctors in Pennsylvania has led to another slowdown in Congress'' on the swine flu legislation.

He referred to the report that deaths and illness among American Legion members who attended a convention in Pennsylvania were not the result of swine flu.

Expressing great concern over that ''tragic outbreak'' of the past week and sympathy for the families involved; Ford said that the fact that tests show swine flu was not involved should not slow down efforts on the flu program.

Ford said; ''Clinical tests conducted to date clearly demonstrate that the vaccine is both safe and effective. There is no excuse to let the legislative program that I proposed seven weeks ago - a program that could safeguard the lives of many; many Americans - be delayed any longer.

''I am frankly dumbfounded that Congress; which took the time and effort to enact ill-advised legislation to exempt its own members from certain state income taxes; has failed to act to protect 215 million Americans from the threat of swine flu;'' Ford said.

Congressional leaders; originally alarmed that the Pennsylvania illness might have been related to swine flu; had planned rapid passage of legislation to provide federal insurance for the vaccination program.

The House and Senate will adjourn next week for the Republican National Convention and timing was critical for the flu program.

Ford said legislative delays have put the flu vaccine program at least six weeks away from the time when an effective inoculation program can be launched.

If Congress had acted promptly when he submitted his plan seven weeks ago; Ford said; ''we would have been in a position to dispatch shipments of vaccine today.''

1731pED 08-06

Swine Flu Hearings [Aug. 1976]

12:23 p.m.

BILL GREENER'S COMMENTS ON FLU STATEMENT:

1. I would try and put something in to emphasize that this is not a political matter.

2. I would tone down the first paragraph a little bit. I see no reason to throw up the income tax thing again.

1:40 p.m.

SPENCE JOHNSON'S COMMENTS ON FLU STATEMENT:

He feels that although it's probably too late to do this, he would recommend sending a positive, encouraging message first, perhaps not even expressing disappointment, but saying it's urgent Congress act before recess. Then he would recommend issuing a second harsher statement if Congress fails to act before the recess, to call them back from recess.

THE WHITE HOUSE
WASHINGTON
August 3, 1976

TO: JIM CANNON

FROM: DICK PARSONS

SUBJECT: SWINE FLU BILL

Attached is a copy of our swine flu indemnification bill. The indemnification provisions are drafted as an add-on to Chairman Rogers bill to implement the National Influenza Immunization program. The relavent provisions for your review begin on page 3.

If you have any problem, let me know.

Dick
Looks fine -
Jim

t to authorize the
a national influenza
an exclusive remedy
inoculation with vaccine

House of Representa-
in Congress assembled,
ıtional Influenza

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

"(j)(1) The Secretary is authorized and directed to establish, conduct, and support (by grant or contract)

FOR IMMEDIATE RELEASE AUGUST 4, 1976

Office of the White House Press Secretary

THE WHITE HOUSE

TEXT OF A LETTER FROM THE
PRESIDENT TO THE SPEAKER OF THE
HOUSE OF REPRESENTATIVES
AND THE HONORABLE MIKE MANSFIELD

August 4, 1976

Dear Mr. Speaker: (Senator Mansfield:)

On March 24, 1976, after meeting with a distinguished group of physicians, scientists and public health experts, I asked the Congress to appropriate $135 million dollars for the production of sufficient swine flu vaccine to inoculate every man, woman and child in the United States. I also directed the Secretary of Health, Education, and Welfare to develop plans that would make this vaccine available to all Americans. The Congress moved quickly on my appropriation request, and I was pleased to sign it into law April 15.

Since that time HEW, working with the medical profession, State and local health officials, vaccine manufacturers, and other groups, have developed extensive plans to see to it that our original goal of making this vaccine available to all Americans can be met.

We continue to be faced, however, with a major problem in meeting our goal. Although experience indicates that there is a very low risk of untoward reactions to the vaccine, the drug manufacturers producing this vaccine for HEW need some form of appropriate liability protection.

On June 16, in anticipation of this situation, I directed HEW Secretary Mathews to immediately submit legislation to the Congress to enable the government to assume a proper share of risks so that this important program might move ahead.

This morning I received a report from the Secretary that after seven weeks of discussions and negotiations, the Health and Environment Subcommittee of the House Interstate and Foreign Commerce Committee acted last night to report legislation that would, if enacted by the House and Senate, correct this problem, which has unnecessarily delayed this vital program.

I am writing to you this afternoon to urge that the House of Representatives (Senate) move quickly to enact this legislation so that the vaccine can be made available without further delay.

more

In conclusion, let me reiterate a point that I made in March and again to Chairman Paul Rogers on July 23: The threat of swine flu is genuine. Data from both the scientific and medical communities support the need for an inoculation program. Clinical tests conducted to date show that the vaccine is both safe and effective. There is no excuse now to let this program -- a program that could affect the lives of many, many Americans -- be delayed any longer. Let's work together to get on with the job.

Sincerely,

GERALD R. FORD

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FOR IMMEDIATE RELEASE AUGUST 4, 1976

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GERALD R. FORD

# # #

Health

THE WHITE HOUSE

WASHINGTON

August 4, 1976

MEMORANDUM FOR: JIM CANNON
JIM CAVANAUGH
DICK PARSONS
DAN McGURK

FROM: SPENCE JOHNSON

SUBJECT: Influenza Immunization Program Legislation

Last evening the House Health Subcommittee, chaired by Congressman Rogers, reported the attached bill.

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

Currently, it is the intention of the Chairman to try to pass this measure before the recess. Full committee action could occur any time between now and next Tuesday, and Floor action shortly after.

However, prior to full committee action Chairman Rogers will hopefully clear the measure with the Judiciary Committee so that sequential referral is not necessary. Also, the reaction of the manufacturers and insurance companies will be evaluated to see if further amendments at the full committee are necessary to satisfy any additional concerns.

It is important to note that this legislation was pushed through the subcommittee by the Chairman and two other members by the use of proxies over the objections of four other subcommittee members. This could result in a heated session in the full committee. HEW legislation liaison is preparing to seek support of the full committee members. It might be well for the White House Congressional Relations to do the same.

94th Congress
2d Session

Mr. Rogers

A B I L L

To amend the Public Health Service Act to authorize the establishment and implementation of a national influenza immunization program and to provide an exclusive remedy for persons injured as a result of inoculation with vaccine under such program.

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

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

"(j) (1) The Secretary is authorized and directed to establish, conduct, and support (by grant or contract)

needed activities to carry out, a national influenza immunization program (hereinafter in this section referred to as the 'Program'). The Program shall include the following:

"(A) The development of a safe and effective vaccine against the strain of influenza virus known as influenza A/New Jersey/76 (Hsw 1N1) (commonly referred to as the 'swine flu').

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

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

"(D) The conduct and support of training of personnel for such immunization programs and the conduct and support of research on the nature, cause, and effect of such influenza, the nature and effect of such vaccine, immunization against and treatment of such influenza, and the cost and effectiveness of immunization programs against such influenza.

"(2) The Secretary shall make quarterly reports to the Congress on the administration of the Program. Each such report shall provide information on--

"(A) the current supply of the vaccine to be used in the Program,

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

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

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

"(3) The Secretary shall conduct, or provide for the conduct of, a study of the scope and extent of liability for personal injuries arising out of immunization programs and of alternative approaches to providing protection against such liability and compensation for such injuries. Within one year of the date of the enactment of the National Influenza Program of 1976, the Secretary shall report to the Congress the findings of such study and such recommendations for legislation (including proposed drafts to carry out such recommendations) as the Secretary deems appropriate.

"(k)(1)(A) The Congress finds that--

"(i) in order to assure the participation in the Program of the agencies, organizations, and individuals who will manufacture, distribute, and administer the vaccine purchased and used in the Program and to assure the availability of such vaccine in interstate commerce, it is necessary to protect such agencies, organizations, and individuals against liability for other than their own negligence to persons alleging injury from inoculation with such vaccine; and

"(ii) to provide such protection and to establish an orderly procedure for the prompt and equitable handling of claims by persons alleging injury from inoculation with such vaccine, it is necessary that an exclusive remedy for such claimants be provided against the United States because of the unique role of the United States in the initiation, planning, and administration of the Program.

"(B) To--

"(i) provide liability protection to the vaccine manufacturers and distributors who participate in the Program, to the public and private agencies or organizations that cooperate in administering the Program without charge for such vaccine or its administration, and to the medical and paramedical personnel who, without charge for such vaccine or its administration, administer or assist in administering inoculations under the Program; and

"(ii) assure an orderly procedure for the prompt and equitable handling of any claim for personal injury or death which may result from the administration of such vaccine,

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

"(2)(A) The United States shall be liable with respect to claims for personal injury or death resulting from the administration of vaccine under the Program and based upon the act or omission of an agent of the Government in the same manner and to the same extent as the United States would be liable in any other action brought against it under such section 1346(and chapter 171, except that--

"(i) the liability of the United States arising out of the act or omission of an agent of the Government may be based on any legal principles that would govern an action against a private individual under the law of the place where the act or omission occurred, including negligence, strict liability in tort, and breach of warranty, and

"(ii) the exceptions specified in section 2680 of title 28, United States Code, shall not apply in an action based upon the act or omission of an agent of the Government.

"(B) For purposes of this subsection, the term 'agent of the Government' means the vaccine manufacturers and distributors who participate in the Program, the public and private agencies or organizations that participate in the Program without charge for the vaccine or its administration, and the medical and paramedical personnel who, without charge for the vaccine or its administration, administer or assist in administering inoculations with such vaccine.

"(3) The remedy against the United States prescribed by paragraph (2) for personal injury or death resulting from the administration of vaccine under the Program shall be exclusive of any other civil action or proceeding for such personal injury or death against any employee of the Government (as defined in section 2671 of title 28, United States Code) or agent of the Government whose act or omission gave rise to the claim.

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

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

"(B) Upon a certification by the Attorney General that this subsection applies to a civil action or proceeding commenced in a State court, such action or proceeding shall be removed, without bond at any time before trial, by the Attorney General to the district court of the United States of the district and division embracing the place wherein it is pending and be deemed an action brought against the United States under the provisions of title 28, United States Code, and all references thereto; and the United States shall be substituted as a party defendant. Should a district court of the United States determine on a hearing on a motion to remand held before a trial on the merits that the action or proceeding

is not one to which this subsection applies, the case shall be remanded to the State court, except that where such an action or proceeding is precluded because of the availability of a remedy through proceedings for compensation or other benefits from the United States as provided by any other law, the action or proceeding shall be dismissed, but in that event the running of any limitation of time for commencing, or filing an application or claim in, such proceedings for compensation or other benefits shall be deemed to have been suspended during the pendency of the civil action or proceeding under this subsection.

"(6) An agent of the Government shall cooperate with the United States in the defense of a claim or suit under section 1346(b) and chapter 171 based upon alleged acts or omissions of such agent of the Government. Upon finding that the agent of the Government has failed to cooperate, the district court of the United States shall, upon the motion of the United States, revoke the status as an agent of the Government, substitute such agent as the party defendant in place of the United States, and, upon motion of either party, remove the suit to the court in which it was instituted.

"(7) Should payment be made by the United States to any claimant bringing a claim under this subsection, either by way of administrative settlement or court judgment, the United States shall have the right to indemnity for that portion of the damages so awarded or paid, as well as any costs of litigation, attributable to any negligent act or omission on the part of any agent of the Government in carrying out any obligation or responsibility in connection with the Program. The United States may maintain such action for indemnity against such agent of the Government in the district court of the United States in which such agent of the Government resides or has its pricipal place of business.".

THE WHITE HOUSE

WASHINGTON

August 4, 1976

MEETING WITH HEW SECRETARY DAVID MATHEWS

Wednesday, August 4, 1976
10:45 a.m. (15 minutes)
The Oval Office

From: Jim Cavanaugh

I. PURPOSE

To receive a quick update from the Secretary on:

1. Status on the Swine Flu legislation, and

2. HEW-Communicable Disease Center efforts in Philadelphia.

II. BACKGROUND, PARTICIPANTS AND PRESS PLAN

A. Background: Last week during our meeting with Jim Cannon and Paul O'Neill you directed that we proceed with drafting legislation to bring the operation of the proposed Swine Flu Vaccine program under the Federal Torts Act. Legislation was completed and last night the Health Sub-committee of House Interstate reported the bill. You might be interested to know that on Dr. Carter's motion to take up the legislation, four Democrats (Waxman, Maguire, Scheuer, Florio) voted NAY. On the vote on the legislation two of these same members voted no and the other two voted present.

B. Participants:

Secretary Mathews
Jim Cavanaugh

C. Press Plan: To be announced. Ron Nessen will summarize the Secretary's report to you during his regular morning briefing.

THE WHITE HOUSE

WASHINGTON

August 5, 1976

FACT SHEET

Swine Flu Influenza Immunization Program Legislation

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

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

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

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

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

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

WASHINGTON, D.C. 20201

OFFICE OF THE SECRETARY

AUG 6 1976

The Honorable James Cannon
Executive Director
The Domestic Council
The White House
Washington, D.C. 20500

Dear Mr. Cannon:

Secretary Mathews asked me to get this to you with the following message:

> "Consistent with my conversations with you, I believe we should issue a statement similar in tone to the attached draft. The last three pages of the draft can stand alone."

Sincerely,

Sanford H. Winston

Sanford H. Winston
Executive Assistant
for Administration

Attachment

Cannon

THE WHITE HOUSE

WASHINGTON

August 7, 1976

MEMORANDUM FOR THE HONORABLE F. DAVID MATHEWS
SECRETARY OF HEALTH, EDUCATION AND WELFARE

FROM: JIM CANNON

SUBJECT: Swine Flu Statement

David, this is a good comprehensive statement.

I recommend that you issue it in the form of a statement and send it with a covering note from you to Chairmen Kennedy, Eastland, Staggers and Rogers; Senators Javits and Hruska; Congressman Devine; and Dr. Carter.

I think it would be helpful if the members received this on Monday morning.

In early June of this year, approximately two months ago, it became evident that the manufacturers of the vaccine needed for the federal government's swine flu immunization program were unwilling to sign contracts for the sale of the vaccine to the government. There were two reasons for this. First, it was impossible to guarantee the manufacturers that they would be liable only for those injuries which were caused by their own negligence and not by the government's negligence or another person's. Secondly, the manufacturers were experiencing difficulty in obtaining liability insurance even for their own negligence in connection with the program. This difficulty in obtaining insurance was also being experienced by some other potential participants in the program.

The Administration proposed legislation to the Congress on June 16 to address both these problems. The letter transmitting the legislation stated: "It is essential to conclude agreements for vaccine production as soon as possible to have sufficient vaccine available in the fall." While hearings on the bill were held by the House Health Subcommittee during June, the Congress recessed for two weeks on July 2 without passing legislation. It was hoped that additional efforts at negotiation would be able to resolve the difficulties without legislation. On July 20, the day after the Congress returned, the Administration reported that without legislation the negotiations remained at an impasse, depsite virtually round-the-clock discussions during the two week Congressional recess.

The government could not buy the vaccine, and the immunization program could not go forward.

During the period subsequent to June 16 when discussion was going forward, the manufacturers continued to produce vaccine even though the government had not signed a contract to purchase any of it. More than 100 million doses of vaccine have been produced by the manufacturers to date. Because of the need to have the vaccine available at an early date, both the Administration and Members of Congress urged the manufacturers to continue production while a resolution of the liability and insurance issues was sought.

During the week of July 26, efforts to resolve the impasse continued. At this point, it was recognized on all sides that any conceivable resolution of the problem would require not only concessions on the part of the manufacturers and insurers but also legislation by the Congress. Congressional staff participated in negotiations between the Administration and the manufacturers and insurers.

Legislation was and remains necessary to do two things: To assure that the manufacturers of the vaccine and other program participants are held liable for their own negligence in the program but not for the government's and to provide a prompt and effective remedy for any person who is injured as a result of this government-sponsored program.

On August 3 a legislative approach to this problem was developed through the joint efforts of the Congress, the Administration, and other interested parties which was sponsored by Chairman Rogers of the House Health Subcommittee and had the support of the Administration. The Subcommittee voted to report the bill to resolve this impasse in the evening of August 3.

Senator Kennedy, Chairman of the Senate Health Subcommittee, introduced a similar bill in the Senate on August 5.

It is now more than seven weeks since the Administration initially advised the Congress that legislation was required to resolve this problem and requested it to act. More importantly, it is now less than seven weeks until the typical flu season may begin. The most virulent swine flu epidemic this country has known began on August 27, 1918. The Congress is scheduled to commence another recess at the end of next week, lasting for almost two weeks.

It is imperative that the Congress act to resolve the impasse in the swine flu immunization program before its recess.

While some manufacturers, grown weary and suspicious of government's promises to act, have currently suspended production of the vaccine, if legislation is passed within the week to resolve the impasse, it will be possible to resume production with minimal delays, purchase the vaccine now already manufactured, and begin the distribution of the vaccine to make it available to the public by mid-to-late September. The vaccine produces effective immunity in most cases within two-to-three weeks of injection. It would be possible for the entire population who wished to be vaccinated to develop immunity by mid-December. The peak flu season is typically in January and February.

If legislation is not passed before the Congressional recess to resolve this problem, the situation will be different.

First, the manufacturers will likely cease production. When the Congress returns, we will be where we are today - at least seven weeks away from making any vaccine available to the public, but three weeks closer to the

flu season. The start-up process will be slow after a three or four week hiatus in production; it is unlikely the manufacturers would recommence production until a bill is actually passed and signed. If we were able to keep to our present schedule, which would be difficult in the uncertain circumstances affecting the program, the first vaccine would probably not be available to the public until November; and it would be February before the entire population had access to the vaccine.

Secondly, while our scientific knowledge and health delivery systems in this country will have shown themselves willing and capable of meeting a potential health hazard of significant proportions, the governmental, liability, insurance, and legal systems will have demonstrated not only their inability to prevent possibly serious injuries to the public health, but their capacity to frustrate the efforts of those primarily responsible for the health of the American people.

Thirdly, we may, and I underscore the subjunctive mood, experience a swine flu epidemic which by acting now we could prevent.

Legislation is necessary now to assure a fair allocation of responsibility for negligence amongst all program participants, including the government, and prompt remedies to those few persons who may be injured as a result of negligence in the program. The Administration has suggested four principles that we would hope will guide the Congress in fulfilling its responsibility to legislate in the public interest to protect the public health.

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

Secondly, all program participants, including the government, should

be responsible for their own negligence.

Thirdly, no program participant or other person should make a windfall profit from this public health program.

Fourthly, and finally, 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 and in which the government plays a different and significantly smaller role.

The bills reported from the House Health Subcommittee and sponsored by Senator Kennedy and other Members of the Senate Health Subcommittee reflect these principles. Responsible Members of the Congress in both political parties support those bills. I urge other Members to review them, and also to consider the need for legislative action. Details of the bills are obviously not set in concrete. It is the Congress' responsibility to make choices, and the Administration recognizes that.

What we urge the Congress to do above all is to address this problem and exercise its responsiblity to legislate <u>now</u>, before the recess. Not to do so, not to act at all, would be an unconscionable dereliction of its responsibility to protect the public health.

FOR IMMEDIATE RELEASE August 6, 1976

Office of the White House Press Secretary

THE WHITE HOUSE

STATEMENT BY THE PRESIDENT

I have been following with great concern the investigations into the cause of the tragic outbreak of illness in Pennsylvania this past week. All Americans join me, I am sure, in their sympathy for the families of the more than 20 people who have died and their hope for the speedy recovery of those people currently under treatment.

I am greatly relieved that these tragic deaths were not the result of swine flu. But let us remember one thing: they could have been. The threat of swine flu outbreak this year is still very genuine. Data from the scientific community still clearly supports the need for a full-scale inoculation program. Clinical tests conducted to date clearly demonstrate that the vaccine is both safe and effective. There is no excuse to let the legislative program that I proposed seven weeks ago -- a program that could safeguard the lives of many, many Americans -- be delayed any longer.

Health, Education, and Welfare Secretary Mathews and the leaders of Congress reported to me on Wednesday that after long hours of hearings, discussions, and negotiations, Congress finally would act yesterday to pass legislation to provide swine flu vaccine to all the American people. Needless to say, I was keenly disappointed to learn last evening that the news from the doctors in Pennsylvania has led to another slowdown in the Congress.

I am frankly dumbfounded that Congress, which took the time and effort to enact ill-advised legislation to exempt its own Members from State income taxes, has failed to act to protect 215 million Americans from the threat of swine flu. Drug manufacturers have produced over 100 million doses of swine flu vaccine in bulk form, but the vaccine has not been prepared in suitable dosage form, pending action by the Congress.

Because of these legislative delays, we are, at this moment, at least six weeks away from beginning an effective inoculation program. Had Congress acted promptly after I submitted my proposal, we would have been in a position to dispatch shipments of vaccine today.

As President, I cannot accept any further dilly-dallying by the Congress on this legislation that could be vital to the health and safety of our people.

I call on the Congress to act quickly -- before its next recess -- so that the health of the American people will be fully protected.

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AM-FLU 8-6
BY RICHARD H. GROWALD
WASHINGTON (UPI) -- PRESIDENT FORD CRITICIZED CONGRESS FRIDAY FOR FINDING TIME TO PASS BILLS EXEMPTING MEMBERS FROM STATE INCOME TAXES WHILE FAILING TO PROTECT AMERICANS AGAINST SWINE FLU.
"THERE IS NO EXCUSE TO LET THE (SWINE FLU) LEGISLATIVE PROGRAM THAT I PROPOSED SEVEN WEEKS AGO -- A PROGRAM THAT COULD SAFEGUARD THE LIVES OF MANY, MANY AMERICANS -- BE DELAYED ANY LONGER," FORD TOLD REPORTERS DURING A RARE APPEARANCE IN THE WHITE HOUSE PRESS ROOM.
"I AM FRANKLY DUMBFOUNDED THAT CONGRESS, WHICH TOOK THE TIME AND EFFORT TO ENACT ILL-ADVISED LEGISLATION TO EXEMPT ITS OWN MEMBERS FROM CERTAIN STATE INCOME TAXES, HAS FAILED TO ACT TO PROTECT 215 MILLION AMERICANS FROM THE THREAT OF SWINE FLU."
FORD SAID HE WAS "GREATLY RELIEVED" THAT THE FATAL OUTBREAK OF ILLNESS IN PENNSYLVANIA THE PAST WEEK WAS NOT THE RESULT OF SWINE FLU. "BUT LET US REMEMBER ONE THING: THEY COULD HAVE BEEN," HE SAID.
"THE THREAT OF SWINE FLU OUTBREAK THIS YEAR IS STILL VERY GENUINE."
FORD SAID HE PROPOSED LEGISLATION FOR INOCULATING ALL AMERICANS AGAINST SWINE FLU SEVEN WEEKS AGO.
"NEEDLESS TO SAY, I WAS KEENLY DISAPPOINTED TO LEARN LAST EVENING THAT THE NEWS FROM THE DOCTORS IN PENNSYLVANIA HAS LED TO ANOTHER SLOWDOWN IN THE CONGRESS."
HE SAID THE FLU SHOTS WOULD BE MOVING TOWARD ALL AMERICANS TODAY IF CONGRESS HAD ACTED PROMPTLY.
EVEN IF THE LAWMAKERS ACTED IMMEDIATELY, HE SAID, IT WOULD TAKE AT LEAST SIX MORE WEEKS TO PUT THE INOCULATION PROGRAM INTO EFFECT.
EARLIER THIS WEEK, FORD VETOED A BILL THAT WOULD HAVE EXEMPTED HOUSE MEMBERS LIVING IN MARYLAND FROM PAYING THAT STATE'S INCOME TAX.
THE PRESIDENT ALSO SAID, "ALL AMERICANS JOIN ME, I AM SURE, IN THEIR SYMPATHY FOR THE FAMILIES OF THE MORE THATN 20 PEOPLE WHO HAVE DIED (IN PENNSYLVANIA) AND THEIR HOPE FOR THE SPEEDY RECOVERY OF THOSE PEOPLE CURRENTLY UNDER TREATMENT."
THE PROPOSED SWINE FLU INOCULATION PROGRAM HAS BOGGED DOWN IN CONGRESS OVER THE QUESTION HOW TO PROVIDE FEDERALLY FINANCED INSURANCE AGAINST MEDICAL LAWSUITS THE PROGRAM MIGHT GENERATE. INSURANCE COMPANIES DECLINED TO ASSUME THE RISK ON THEIR OWN.
EFFORTS TO UNTANGLE THE INSURANCE PROBLEM ARE STALLED ON CAPITOL HILL UNTIL NEXT WEEK AND POSSIBLY UNTIL CONGRESS RETURNS TO WORK AFTER THE REPUBLICAN NATIONAL CONVENTION.
UPI 08-06 04:41 PED

THE WHITE HOUSE

WASHINGTON

August 6, 1976

MEMORANDUM FOR: JIM CAVANAUGH

FROM: DAVE GERGEN

SUBJECT: Swine Flu Statement

Here's a revised copy. Once again, I am sorry that it has taken longer than I anticipated.

Attachment

STATEMENT BY THE PRESIDENT ON SWINE FLU

I have been following with great concern the investigations into the cause of the tragic outbreak of illness in Pennsylvania this past week. All Americans join me, -I am sure, in their sympathy for the families of the more than 20 people who have died and their hope for the speedy recovery of those people currently under treatment.

I am greatly relieved that these tragic deaths were not the result of swine flu. But let us remember one thing: they could have been. The threat of swine flu outbreak this year is still very genuine. Data from the scientific community still clearly supports the need for a full-scale inoculation program. Clinical tests conducted to date clearly demonstrate that the vaccine is both safe and effective. There is no excuse to let the legislative program that I proposed seven weeks ago -- a program that could affect the lives of many, many Americans -- be delayed any longer.

HEW Secretary Mathews and the leaders of Congress reported to me on Wednesday that after long hours of hearings, discussions, and negotiations, Congress finally would act yesterday to pass legislation to provide swine

flu vaccine to all the American people. Needless to say, I was keenly disappointed to learn last evening that the news from the doctors in Pennsylvania has led to another slowdown in the Congress.

I am frankly dumbfounded that the Congress has failed to act in the face of such a clear-cut need. Drug manufacturers have produced over 100 million doses of swine flu vaccine in bulk form, but the vaccine ~~has~~ CAN not be prepared in suitable dosage form, pending action by the Congress.

Becuase of these legislative delays, we are, at this moment, at least six weeks away from beginning an effective inoculation program. Had Congress acted promptly after I submitted my proposal, we would have been in a position to dispatch shipments of vaccine today.

As President, I cannot accept any further dilly-dallying by the Congress on this legislation that could be vital to the health and safety of our people.

I call on the Congress to act quickly -- before its next recess -- so that the health of the American people will be fully protected.

Swine flu

THE WHITE HOUSE

WASHINGTON

August 6, 1976

Helen
Move -
Spence
W20
informed.
Jim

MEMORANDUM FOR: JIM CANNON
MAX FRIEDERSDORF
DAVE GERGEN
SPENCE JOHNSON
RON NESSEN
BOB ORBEN

FROM: JIM CAVANAUGH

SUBJECT: Proposed Flu Statement

Attached is a proposed statement for the President to use this afternoon on camera.

I would appreciate receiving your comments and suggestions by 1 p.m.

Thank you very much.

8/6/76 11:30 a.m.

I am deeply disappointed that the Congress that sent me ill-advised legislation to exempt its own members from local income taxes, which I vetoed early this week, has not yet acted on legislation to protect 215 million Americans from the threat of swine flu.

On March 24, 1976, after receiving recommendations from a distinguished group of physicians, scientists and public health experts, I asked the Congress to appropriate $135 million dollars for the production of sufficient swine flu vaccine to inoculate every man, woman and child in the United States against this dread disease. The Congress approved my request, and I signed it into law April 15.

Since that time, the Department of Health, Education and Welfare, working with the medical profession, State and local health officials, vaccine manufacturers, and other groups, have developed extensive plans to see to it that our original goal of making this vaccine available to all Americans will be met.

We continue to be faced, however, with a major problem in meeting our goal. Although experience indicates that

there is a very low risk of untoward reactions to the vaccine, the drug manufacturers producing this vaccine for HEW need some form of appropriate liability protection.

On June 16, in anticipation of this situation, I directed HEW Secretary Mathews to immediately submit legislation to the Congress to enable the government to assume a proper share of risks so that this important program might move ahead.

After seven long weeks of hearings, discussions and negotiations, the Congress has still not acted on this vital legislation. If they had, we would be in the position, if swine flu had been found in Pennsylvania, to dispatch shipments of vaccine today. Even if the Congress acted today, we would be at least six weeks away from being able to make such shipments.

The tragic and unfortunate deaths that occurred in Pennsylvania in recent days were not the result of swine flu. They could have been. The threat of swine flu continues to be genuine. Data from the scientific and medical communities that I received in March continues to support the need for a national inoculation program. Clinical tests conducted to date show that the

vaccine is both safe and effective. There is no excuse now to let this program--a program that could affect the lives of many, many Americans--be delayed any longer.

As President, acting on behalf of the American people, ~~and on the best scientific and medical evidence available,~~ I cannot accept any further delay on this essential legislation. I call on the Congress to act without further delay on this vital legislation to provide this public health protection to the people of this country.

Swine Flu

FOR IMMEDIATE RELEASE AUGUST 6, 1976

OFFICE OF THE WHITE HOUSE PRESS SECRETARY

THE WHITE HOUSE

STATEMENT BY THE PRESIDENT

THE BRIEFING ROOM

3:38 P.M. EDT

I have been following with great concern the investigations into the cause of the tragic outbreak of illness in Pennsylvania this past week. All Americans join me in their sympathy for the families of more than 20 people who have died and their hope for the speedy recovery of those currently under treatment.

I am greatly relieved, of course, that these tragic deaths were not the result of swine flu. But let us remember one thing, they could have been.

The threat of swine flu outbreak this year is still very, very genuine. Data from the scientific community clearly supports the need for a full-scale inoculation program. Clinical tests conducted to date clearly demonstrate that the vaccine is both safe and effective. There is no excuse to let the legislative program that I proposed seven weeks ago -- a program that could safeguard the lives of many, many Americans -- be delayed any longer.

HEW Secretary Mathews and the leaders of Congress reported to me on Wednesday that after long hours of hearings, discussions, negotiations, Congress would finally act yesterday to pass legislation to provide swine flu vaccine to all American people.

Needless to say, I was keenly disappointed to learn last evening that the news from the doctors in Pennsylvania had led to another slowdown in the Congress. I am frankly very dumbfounded to know that the Congress, which took the time and effort to enact ill-advised legislation to exampt its own Members from certain State income taxes, has failed to act to protect 215 million Americans from the threat of swine flu.

Drug manufacturers have produced over 100 million doses of swine flu vaccine in bulk form. But that vaccine has not been prepared in suitable dosage form pending action by the Congress.

MORE

Because of these legislative delays, we are, at this moment, at least, six weeks away from beginning an effective inoculation program.

Had Congress acted promptly after I submitted my proposal, we would have been in a position to dispatch the shipments of vaccine today.

Further delay in this urgently needed legislation is unconscionable. I call on the Congress to act now before its next recess, so that the health of the American people will be fully protected.

Thank you very much.

END (AT 3:41 P.M. EDT)