

**The original documents are located in Box 34, folder “Swine Flu (3)” of the James M. Cannon Files at the Gerald R. Ford Presidential Library.**

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# MERCK & CO., INC.

RAHWAY, N. J. 07065

April 13, 1976

JOHN J. HORAN  
PRESIDENT

Mr. James H. Cavanaugh  
Deputy Assistant to the President  
for Domestic Affairs  
The White House  
Washington, D. C. 20500



Dear Mr. Cavanaugh:

I want to record with you and others an urgent concern we have about one aspect of the national vaccination program to protect against a possible epidemic of swine influenza.

Merck is one of four vaccine manufacturers licensed and able to produce influenza vaccines this year and thus has a direct interest in the terms and conditions under which swine influenza vaccine is to be made, purchased by the government, and distributed. We are asked to produce as much vaccine as we can, as fast as we can, to government specification. This we will do if our current effort to develop a vaccine is successful.

The government has asked that after the vaccine we produce has demonstrably met government safety, purity, and potency standards, it be made available to the government for national distribution. Under such circumstances, we would have no further role in its distribution and use.

The cause of our concern is that Congressional and HEW actions to date indicate that if there is any failure in the government's programs, through states and municipalities, to use the vaccine properly -- failure to warn responsible adults of any possible adverse reactions to the vaccine, as well as any other failure that might become the basis for litigation -- we would be expected to bear the risk of liability for the government's failures.

HEW proposes to try to help minimize our possible liability by a national program of communication which would plan for appropriate warnings at the same time as it encourages citizen participation. This does not deal with the question of where liability rests if the government fails to inform a patient who is injured and brings suit. Moreover, whatever degree of protection even this HEW proposal may afford will be negated if a recent action in Congress is affirmed.

In Congress, the indemnification question was not dealt with on the House side. On the Senate side, it was dealt with only in language in the report associated with the appropriations measure -- and that language conveyed the intent of the Committee that no arm of the government should assume any liability risk for any part of the swine influenza vaccination program, and that all such risk should be borne by the vaccine manufacturers!

The legal risk is very real, even though the vaccine may prove to be relatively safe. Under similar circumstances involving Sabin polio vaccine, the courts recently held -- and the Supreme Court refused to review the case -- that the vaccine manufacturer was liable for patient injury allegedly related to use of the vaccine on the basis of its failure to provide adequate warning directly to the participant of the risk of such injury, even though the vaccine was properly made and the manufacturer's only involvement was to provide vaccine to government specification and sell it to the state for use in government-sponsored mass immunization programs.

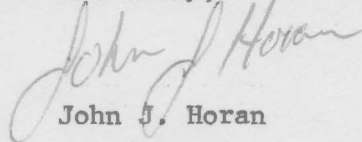
Our own insurance carrier has just told us that it is willing to insure us only against negligence or fault on our part. Moreover, because of the massive number of people involved, the carrier considers it not feasible to place any broader coverage in the existing world insurance markets at virtually any price. Thus, the carrier is willing to provide us with protection only against claims arising from our own negligence or failure to manufacture in accordance with government specifications, i.e., against those risks which are clearly our responsibility.

I do not want to risk being misunderstood. We do not ask to be relieved of our responsibility to produce vaccine which meets government safety and potency standards, or of product liability based on negligence or other fault on our part in manufacturing the vaccine. We do ask to be relieved of liability for matters for which we have no responsibility and over which we have no control. No private company has the resources to assume absolute liability for the actions of others, including Federal, state, and city governments in an immunization program designed to reach the total U. S. population.

We want to participate in this program that has been declared to be in the national interest. But we believe the Administration and the Congress should find a solution to our current dilemma. I urge your participation and that of your staff in the search for a solution. We are of course prepared to cooperate to the fullest in this endeavor.

To assure that our concern, and the sense of urgency we accord it, is known to those who have played active roles in the rapid evolution of this program to meet a national emergency, I am sending identical letters to those listed on the attached sheet.

Sincerely,

  
John J. Horan



Mr. James H. Cavanaugh, The White House  
Mr. Spencer C. Johnson, The White House

Honorable Theodore Cooper, M. D., HEW  
Honorable David Mathews, HEW  
Harry M. Meyer, Jr., M. D., HEW  
Dr. David J. Sencer, HEW

Honorable Edward W. Brooke, United States Senate  
Honorable Clifford P. Case, United States Senate  
Honorable Edward M. Kennedy, United States Senate  
Honorable Warren G. Magnuson, United States Senate  
Honorable Richard S. Schweiker, United States Senate  
Honorable Hugh Scott, United States Senate  
Honorable Harrison A. Williams, Jr., United States Senate

Honorable Tim Lee Carter, House of Representatives  
Honorable Daniel J. Flood, House of Representatives  
Honorable Robert H. Michel, House of Representatives  
Honorable Paul G. Rogers, House of Representatives

cc: C. Joseph Stetler, PMA



Mr. James H. Cavanaugh, The White House  
Mr. Spencer C. Johnson, The White House

Honorable Theodore Cooper, M. D., HEW  
Honorable David Mathews, HEW  
Harry M. Meyer, Jr., M. D., HEW  
Dr. David J. Sencer, HEW

Honorable Edward W. Brooke, United States Senate  
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Honorable Richard S. Schweiker, United States Senate  
Honorable Hugh Scott, United States Senate  
Honorable Harrison A. Williams, Jr., United States Senate

Honorable Tim Lee Carter, House of Representatives  
Honorable Daniel J. Flood, House of Representatives  
Honorable Robert H. Michel, House of Representatives  
Honorable Paul G. Rogers, House of Representatives

cc: C. Joseph Stetler, PMA



THE WHITE HOUSE  
WASHINGTON

INFORMATION

April 14, 1976

MEMORANDUM FOR THE PRESIDENT

FROM:

JIM CANNON

SUBJECT:

Secretary Mathews' First Biweekly Report  
on Immunization Campaign

Last week you asked Secretary Mathews for a biweekly report on the status of implementation of the national influenza immunization program. Attached is his first report.

We have sent a copy of the report to our staff and to Jim Lynn for necessary follow-up and action.



THE WHITE HOUSE  
WASHINGTON

4/12/76

TO: JAMES CAVANAUGH

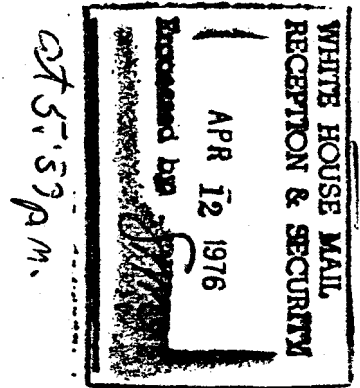
Per our conversation.

  
Robert D. Linder



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

APR 9 1976



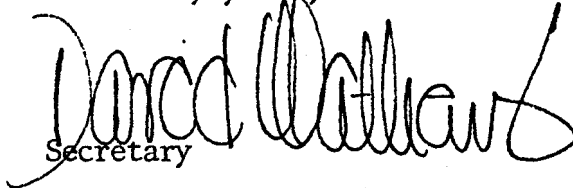
The President  
The White House  
Washington, D.C. 20500

Dear Mr. President:

I have your memorandum of April 6th concerning the influenza immunization campaign.

I will most certainly keep you informed as you requested, and am attaching the first of the reports that you asked for with this reply.

Faithfully yours,

  
Secretary

Attachment

cc: The Honorable James Lynn  
The Honorable James Cavanaugh  
Theodore Cooper, M.D., Assistant  
Secretary for Health





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

APR 9 1976

MEMORANDUM FOR THE PRESIDENT

Since you announced the National Influenza Immunization Program, hearings have been held before both Houses of Congress. The House has passed authorization legislation that it felt was necessary to carry out this program and the House and Senate have passed appropriation bills designed to implement it.

I have established an Intradepartmental Task Force, chaired by the Assistant Secretary for Health, Dr. Theodore Cooper, that will report directly to me. It will serve as a device for exchanging information rapidly, expediting needed decisions assuring rapid clearance for action items, and, in general, facilitating the successful completion of the program.

In addition, Dr. Cooper has established a management focus in his office to implement the operational objectives cited by you in your memorandum of March 31. This management focus will develop policy, set priorities, and provide guidance for the implementation of the program. An Operational Planning System Objective with targeted milestones to monitor the progress of the program has been developed. The three agencies of the Public Health Service (PHS) that will carry out these objectives are the Center for Disease Control (CDC), the Bureau of Biologics (BoB) of the Food and Drug Administration (FDA), and the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health.

To date (1) initial steps have been taken that will lead to field testing and subsequent production of the vaccine, (2) an effort is under way to ensure that the nation's health professionals will be encouraged to fully support this effort, and that the public will be fully aware of the necessity to receive the vaccine, (3) a plan is being developed for the distribution and administration of the vaccine, and (4) steps are under way to ensure adequate epidemiologic and laboratory surveillance of this effort.

On March 25, a workshop was held at the BoB, FDA to discuss developments relevant to influenza immunization for the 1976-77 influenza season. This workshop was attended by scientists from BoB, NIAID, and CDC, representatives from the Department of Defense and Veterans Administration, university investigators working on influenza research, members of BoB, NIAID, and CDC advisory committees, pharmaceutical manufacturers engaged in producing influenza vaccines, biologics control authorities from other countries (in this instance Canada), the general public, and the press. Despite the rapid pace of events, it appears that the various groups involved in this effort are working together reasonably well and that a rather remarkable amount of progress has been made in the short time since the A/swine-like virus was recovered in early February.

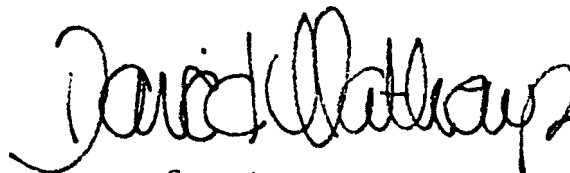
On April 2, CDC, the lead PHS agency for the program, discussed it with members of the State and Territorial Health Officers Association representatives from the State medical societies, officials of the major drug companies, and personnel from other PHS agencies. During the meeting, the attendees were briefed on the scientific basis for the program and the general strategy for its implementation. While some health officers questioned the adequacy of the funds available to the States, and some health officers and private practitioners questioned the ability to carry out such a massive immunization effort in such a short period of time, the overwhelming majority thought it could be done. They indicated they would make every effort to see to it that the program was successfully carried out.

On April 12, a meeting was held by Dr. James H. Cavanaugh, Deputy Director of the Domestic Council, with some 20 principals concerned in this effort. Its purpose was to review the current status of the program vis-a-vis your charge to it and to consider emerging policy, priority, and implementation problems.

At present:

- (1) the lack of an appropriation for the program is the major impediment to its forward progress;
- (2) the question of liability indemnification for the manufacturers of the vaccine requires further resolution.

Close attention is being given to both of these matters.



Secretary

THE WHITE HOUSE  
WASHINGTON

April 14, 1976

MEMORANDUM FOR: JIM CANNON *sq*  
FROM: SPENCE JOHNSON  
SUBJECT: Presidential Decision Memorandum on  
Canadian Vaccine Purchase

Secretary Mathews' memorandum to the President on this subject was returned to HEW Assistant Secretary Ted Cooper yesterday to be redrafted to reflect new information.

A new Presidential decision memorandum will be prepared as soon as a new memorandum is received from the Secretary.

THE WHITE HOUSE

ACTION

WASHINGTON

Last Day: April 24

April 15, 1976

MEMORANDUM FOR

THE PRESIDENT

FROM:

JIM CANNON

SUBJECT:

H.J. Res. 890 - Emergency  
Supplemental Appropriations, 1976

Attached for your consideration is H.J. Res. 890, sponsored by Representative Mahon, which provides a total of \$1,942,384 for the following activities:

- HEW: Nationwide swine influenza immunization program;
- Labor: Temporary employment assistance; summer youth employment program and community service employment for older Americans;
- Community Services Administration: Summer youth recreation and sports program.

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

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

RECOMMENDATION

That you sign H.J. Res. 890 at Tab B.

That you approve the signing statement at Tab C.

Approve \_\_\_\_\_ Disapprove \_\_\_\_\_




THE WHITE HOUSE

WASHINGTON

SIGNING CEREMONY  
EMERGENCY SUPPLEMENTAL APPROPRIATIONS BILL  
(H.J. Res. 890)

Thursday, April 15, 1976  
1:45 p.m. (10 minutes)  
The Oval Office

From: Jim Cannon 

I. PURPOSE

To sign into law H.J. Res. 890, Joint Resolution making emergency supplemental appropriations for public employment programs, summer youth programs, and preventive health services (the flu program) for the fiscal year ending June 30, 1976, and for other purposes.

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 your supplemental appropriation request of \$135 million for this program before the Easter recess.

This appropriation will be used to manufacture the necessary vaccine, assist the states in distribution and inoculation efforts, test the efficacy and effectiveness of the vaccine, continue ongoing surveillance of disease trends in outbreaks, and conduct professional and public awareness programs.

In addition, the measure included the following program appropriations: \$300 million, EPA construction grants; \$528,420,000, summer youth jobs; \$1,200,000,000, public services jobs; \$55,900,000, older americans jobs; \$17 million, summer recreation program; \$6 million, summer sports program.

- B. Participants: HEW Secretary David Mathews and Congressman Paul Rogers (D-Florida), chairman of the Health and Environment Subcommittee of the House Interstate and Foreign Commerce Committee. Also Congressman Dan Flood (D-Penn.), chairman of the Labor-HEW Appropriations Subcommittee.

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

III. TALKING POINTS

Talking points to be provided by Bob Orben.

5  
Spencer Johnson

Mr. & Mrs. Harry W. Lewis  
10 Oak Street  
North Billerica, MA 01862

April 19, 1976

Dear Mr. President,


Since February fourth, we have been acutely aware of the news surrounding the swine influenza, since our son David was the one who died from it at Fort Dix.

For a time it seemed nothing would be done, so many were saying one death didn't warrant concern. We were very relieved when you came on TV and showed real concern, and let us know that indeed something was being done. Now that the serum is a fact, we know the possibility of his illness causing an epidemic has lessened greatly.

Although this concern, and the actions taken, can't bring us back our son, we have an assurance it will help protect other sons and daughters. We thank you so much for this.

Sincerely,

(Mrs) Harry W. Lewis



THE WHITE HOUSE  
WASHINGTON

April 27, 1976

MEMORANDUM FOR: JIM CANNON *sel*  
FROM: SPENCE JOHNSON  
SUBJECT: Correspondence for Presidential  
Signature

Attached is a draft letter for Presidential signature in response to an incoming letter from the parents of the swine-flu victim who died at Fort Dix in February.

I recommend that you sign the attached memorandum and forward the package to Roland Elliott for appropriate action.

*[Handwritten signature]*





THE WHITE HOUSE

WASHINGTON

April 27, 1976

MEMORANDUM FOR:      ROLAND ELLIOTT  
FROM:                 JIM CANNON  
SUBJECT:              Correspondence for Presidential  
                         Signature

Attached is a draft letter for Presidential signature in response to an incoming letter from the parents of the swine-flu victim who died at Fort Dix in February.

I recommend that you prepare the letter for transmittal over the President's signature.

Dear Mr. and Mrs. Lewis:

Your recent letter in support of my national influenza immunization effort is very much appreciated.

I truly regret that your son was fatally stricken by this swine-type influenza virus. As you have pointed out, however, this specific incident has served as a crucial warning so that we can protect every man, woman and child against this potential danger.

I also specially commend you for your selfless outlook in your concern for the well-being of the entire nation.

Warm personal regards,

Gerald R. Ford

Spencer Johnson

April 19, 1976

Dear Mr. President,

Since February fourth, we have been acutely aware of the news surrounding the swine influenza, since our son David was the one who died from it at Dart Dix.

For a time it seemed nothing would be done, so many were saying one death didn't warrant concern. We were very relieved when you came on TV and showed real concern, and let us know that indeed something was being done. Now that the serum is a fact, we know the possibility of his illness causing an epidemic has lessened greatly.

Although this concern, and the actions taken, can't bring us back our son, we have an assurance it will help protect other sons and daughters. We thank you so much for this.

Sincerely,  
(Mrs) Harry W. Lewis

Mr. & Mrs. Harry W. Lewis  
10 Oak Street  
North Billerica, MA 01862



President Gerald Ford  
White House  
Washington, D.C. 2000



*Personal*



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

MAY 5 1976



MEMORANDUM FOR THE PRESIDENT

I am submitting here the second in a series of Biweekly Reports on the National Influenza Immunization Program. It indicates our progress and problems in achieving essential program goals and timetable targets as requested in your memorandum on April 6.

Four major goals have been achieved since our last Biweekly Report of April 12, 1976.

First, on April 15, you signed H.R. Res. 890, Emergency Supplemental Appropriations for Preventive Services, which contained a \$135 million appropriation for the National Influenza Immunization Program.

Subsequently, during the same week, 24,000 doses of A/New Jersey/76 (the technical and preferred name for swine influenza-type vaccine) were provided to the Bureau of Biologics of the Food and Drug Administration for laboratory testing and verification of purity and quality.

On April 21, clinical trials began involving the participation of 3,000 volunteers in an effort to document reactivity, efficacy, and potency and to determine the dosage of vaccine which is adequate for immunization against the A/New Jersey/76 virus.

Recently, Immunization Program Guidelines for Grant Applications were sent to State and Regional Offices and contacts with State and other health officers have been firmly established by the Center for Disease Control to insure rapid exchange of technical and administrative information.

The problems of the moment are confined to three areas.

First, legal concerns consisting of potential tort liability and possible antitrust violations have not been formally resolved between vaccine manufacturers and the Department. The General Counsel of DHEW, however, along with members of the Antitrust Division of the Department of Justice have met with legal representatives of the four vaccine manufacturers and have taken steps that promise to resolve these issues effectively.

A major unresolved question still exists. That is, whether the United States should consider sharing, in view of uncertain and possibly limited vaccine, our A/New Jersey/76 (swine influenza-type) vaccine with other countries, and on what basis should we determine our position vis-a-vis Canada, Mexico, and the rest of the world. We have reached a preliminary decision as to how to proceed in this matter and it is the subject of an accompanying memorandum. Presently, the Assistant Secretary for Health is in regular contact with Dr. Alex Morrison, Deputy Minister of Health for Canada, regarding our status on the question of vaccine availability and our ability to assist them in meeting their needs.

A final potential problem relates to the coordination of offers of assistance by volunteer organizations and the management of plans for this activity by well-meaning groups. To address this problem, a series of meetings is planned between members of the Center for Disease Control, the Office of the Secretary and volunteer groups to determine how to generate, coordinate, and maximize participation by volunteer agencies. The first Departmental meeting to formally address this matter is scheduled for Thursday, May 6, 1976.

/s/David Mathews

Secretary

Enclosure



Cannon FYI

THE WHITE HOUSE  
WASHINGTON

INFORMATION

May 6, 1976

MEMORANDUM FOR THE PRESIDENT

FROM: JIM CANNON

SUBJECT: Influenza Immunization Program Report

Attached is the second in a series of Biweekly Reports on the National Influenza Immunization Program by HEW Secretary David Mathews.



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

MAY 5 1976

MEMORANDUM FOR THE PRESIDENT

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Secretary

Enclosure

THE WHITE HOUSE

WASHINGTON

May 12, 1976

MEMORANDUM FOR

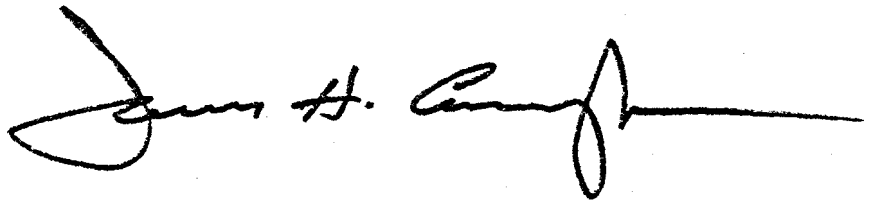
THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE

The purpose of this memorandum is to clarify the requirements for the President's bi-weekly status report on the National Influenza Immunization Program.

In order to reduce confusion over the due date of the report, the report will be due on the 1st and 15th of every month. In addition, certain format requirements are necessary in order to coordinate the informational needs and activities of the Domestic Council and OMB, as indicated in the President's original communication.

The report should include a brief outline summary of accomplishments, as well as identification of problems and actions taken to resolve problems. Also, the charts developed that express quantifiable targets for the Federal effort, State and local efforts, and industrial efforts, should be included.

Thank you very much.

A handwritten signature in black ink, appearing to read "James H. Camp". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

THE WHITE HOUSE

WASHINGTON

May 5, 1976

MEMORANDUM TO: JIM CAVANAUGH *sel*  
FROM: SPENCER JOHNSON  
SUBJECT: DHEW Secretary Bi-weekly Influenza  
Program Status Report.

Attached is a draft memorandum for your signature to the Secretary defining the contents of the bi-weekly report to the President.

First, in order to avoid due date confusion and slippage, I suggest that we require the report on the 1st and 15th of every month. Also, in order to solve the format dispute and fulfill the necessary informational requirements I propose that the report be in three parts:

- A. A summary memorandum by the Secretary to the President,
- B. An outline of accomplishments, problems and actions, and;
- C. The inclusion charts that OMB developed for the program.

Samples are attached.

Tab A Draft memorandum to the Secretary.  
Tab B Sample summary of accomplishments, problems and actions.  
Tab C Sample OMB target charts.

A

B

# MEMORANDUM

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

DRAFT

TO : The President

FROM : The Secretary

SUBJECT: Biweekly Status Report on the National Influenza Immunization Program (NIIP), for the Period Ending April 30, 1976

## ACCOMPLISHMENTS

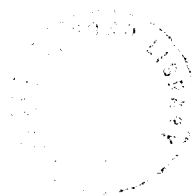
1. The President signed H.J. Res. 890, Emergency Supplemental Appropriations for Preventive Services, which contained the \$135 million appropriation for NIIP, April 15, 1976.
2. 24,000 doses of vaccine were provided to the Bureau of Biologics of FDA for laboratory testing for purity and quality.
3. Clinical trials were launched on April 21, 1976, involving 3,000 volunteers to document reactivity, efficacy, potency and dosage of vaccine adequate for immunization against A/New Jersey/76 (swine influenza-type) virus.
4. Immunization Program Guidelines for grant applications have been sent to state and regional offices, April 14, 1976.
5. Contacts with state and other health officers were established for continuing information and technical exchange.

## PROBLEMS

1. Legal problems of vaccine manufacturers.
2. International aspects of NIIP.
3. Coordination of offers of assistance and plans of activity by volunteer organizations.

## ACTIONS TAKEN TO RESOLVE PROBLEMS

1. General Counsel of HEW along with members of Anti-trust Division of the Department of Justice have met with legal representatives of the four vaccine manufacturers and have taken steps to resolve the issues that relate to potential tort liability and possible antitrust violations.
2. The Assistant Secretary for Health has been in regular communication with Dr. Alex Morrison, Deputy Minister of Health of Canada, regarding vaccine availability.
3. A series of meetings is planned between the Center for Disease Control, the Office of the Secretary, and volunteer groups to determine how to generate, coordinate, and maximize participation by volunteer agencies.





# MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
CENTER FOR DISEASE CONTROL

TO : Special Assistant to  
The Assistant Secretary for Health

DATE: April 30, 1976

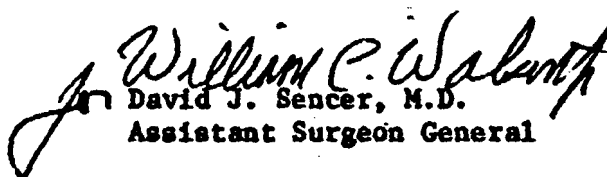
FROM : Director  
Center for Disease Control

SUBJECT: Biweekly Status Report on Nationwide Influenza Immunization Program

Enclosed is the biweekly status report on the National Influenza Immunization Program and three copies of the Program Guidelines for influenza immunization project grants.

The biweekly status report provides projected target information for CDC, Bureau of Biologics (FDA), NIAID, and industry. Dr. George Galazzo, Chief, Infectious Disease Branch, and Mr. Lawrence Stern, Executive Officer, will provide the information necessary for completion of the report from NIAID and BOB, respectively. Dr. Galazzo has requested the "number of contractual actions" be reduced from 20 to 16 to reflect what currently appears to be a more accurate and realistic figure.

Accomplishments noted since our preliminary status report of April 26 are: (1) Initiation of clinical testing of pilot lots at George Washington University Medical School; (2) verbal approval from OMB regarding waiver of A-95 review and comment procedures relative to influenza immunization projects grants (A-95 Clearinghouses will be notified of grant awards, but pre-award reviews will be waived); and (3) bids to supply jet injector guns have been received and are currently being evaluated. We anticipate that contracts will be awarded next week.

  
David J. Sencer, M.D.  
Assistant Surgeon General

Enclosures

NO MEMO FILE

5 pages

4/30/76

Please hardcopy to Dr. Meriwether

Hardcopy No. 447-5436



# FEDERAL EFFORT

FDA							NIH					
BIWEEKLY DATES	NO. OF EMPLOYEES			NO. OF LOTS OF VACCINE CERTIFIED			NO. OF EMPLOYEES			NO. OF CONTRACTUAL ACTIONS		
	TARGET	ON TARGET		TARGET	ON TARGET		TARGET	ON TARGET		TARGET	ON TARGET	
		YES	NO		YES	NO		YES	NO		YES	NO
APRIL 30	1	X										
MAY 14	3						1					
MAY 28	4						1					
JUNE 11	5						1			7		
JUNE 25	2						2			3		
JULY 9	2			32			3			3		
JULY 23	2			80						1		
AUG. 6	1			80						1		
AUG. 20				80								
SEPT. 3				80			1			1		
SEPT. 17				64								
OCT. 1				48								
OCT. 15				48								
OCT. 29				48								
NOV. 12				48								
NOV. 26				22								
TOTAL	20			630			9			16		

# FEDERAL EFFORT

CDC

BIWEEKLY DATES	VACCINE CONTRACT AWARDS			NO. OF DOSES OF VACCINE PURCHASED AND DISTRIBUTED			APPROVAL OF STATE PLANS AND AWARD OF GRANTS TO STATES			NO. OF EMPLOYEES		
	TARGET	ON TARGET		TARGET	ON TARGET		TARGET	ON TARGET		TARGET	ON TARGET	
		YES	NO		YES	NO		YES	NO		YES	NO
APRIL 30												
MAY 14												
MAY 28	4						32			8		
JUNE 11							30			5		
JUNE 25										10		
JULY 9				8,000,000						16		
JULY 23										5		
AUG. 6												
AUG. 20												
SEPT. 3				120,000,000								
SEPT. 17												
OCT. 1												
OCT. 15												
OCT. 29				200,000,000								
NOV. 12												
NOV. 26												
TOTAL	4			200,000,000			62			44		

# STATE AND LOCAL EFFORTS

BIWEEKLY DATES	NO. OF STATE PLANS SUBMITTED			NO. OF DOSES OF VACCINE DISTRIBUTED			NO. OF PEOPLE IMMUNIZED		
	TARGET	ON TARGET		TARGET	ON TARGET		TARGET	ON TARGET	
		YES	NO		YES	NO		YES	NO
APRIL 30									
MAY 14	32								
MAY 28	30								
JUNE 11									
JUNE 25									
JULY 9				8,000,000			4,000,000		
JULY 23									
AUG. 6									
AUG. 20									
SEPT. 3									
SEPT. 17				120,000,000			75,000,000		
OCT. 1									
OCT. 15									
OCT. 29									
NOV. 12				200,000,000					
NOV. 28							200,000,000		
TOTAL	62			200,000,000			200,000,000		

# INDUSTRY REPORT

BIWEEKLY DATES	VACCINE PRODUCTION			JET INJECTOR GUNS DELIVERED		
	TARGET	ON TARGET		TARGET	ON TARGET	
		YES	NO		YES	NO
APRIL 30						
MAY 14						
MAY 28						
JUNE 11				600		
JUNE 25						
JULY 9	8,000,000			600		
JULY 23						
AUG. 6				800		
AUG. 20						
SEPT. 3	120,000,000					
SEPT. 17						
OCT. 1						
OCT. 15						
OCT. 29	200,000,000					
NOV. 12						
NOV. 26						
TOTAL	200,000,000			2,000		

THE WHITE HOUSE

WASHINGTON

May 25, 1976

MEMORANDUM FOR: JIM CAVANAUGH  
FROM: SPENCE JOHNSON *SPJ*  
SUBJECT: The National Influenza Immunization  
Program update.

The purpose of this memorandum is to outline several issues that have arisen in the implementation of the President's National Influenza Immunization Program.

1. Reporting Procedures and Management Practices

A problem still exists with the timeliness and format of the bi-weekly reports. The May 15th report was not received until May 20th. In addition, it did not comply with the format described to the Secretary in your recent memorandum. Also, in terms of management practices, there appears to be an undue delay in programmatic decisions to be made by the Secretary. For example, the delegation of authority to award state program grants was delayed for one week pending the Secretary's approval; and a recommendation from the Secretary to the President on the question of assistance to Canada and Mexico has been pending since late March. No serious complications have arisen yet, however, unless a mechanism is established to rapidly respond to such decisions, a problem could arise later in the program when there is shorter turn-around time.

2. Seed Virus Error

It has been discovered that a lot of vaccine manufactured by the Parke-Davis Company was at variance with the production protocol. A team from CDC and FDA are at the Parke-Davis facility to determine the extent of the problem. Apparently the cause of this error is that the wrong seed virus for the manufacture of the vaccine was supplied to Parke-Davis. One unconfirmed estimate is that 15 million doses may be involved. The doses produced would not represent any danger to those being inoculated, however, they do not contain the appropriate antibodies for the A/New Jersey/1976 strain, but rather



a strain isolated in the 1930's identified as Swine Flu/1976.

3. Liability and Indemnity

Arrangements have been made by the General Counsel of HEW, with concurrence of the legal representatives of the four vaccine manufacturers, to relieve the producers from liability for those parts of the immunization program under government control. This was achieved by inclusion of specific language in the purchase contracts. Merrill National, the smallest of the producers, has retained former Secretary of State William Rogers to reopen this question with HEW. Mr. Rogers has indicated that Merrill National wishes the government to assume all risks connected with the manufacture of the vaccine and further that they deem the assurances in the contract language as insufficient. Unless their liability is limited specifically by legislative action by the Congress, they will withdraw from the program. The HEW General Counsel and the Assistant Secretary for Health are meeting with Secretary Mathews today to discuss alternative approaches to this issue.

4. Liability of Health Professionals

Several questions have been raised by various health professional organizations about the liability of practitioners and allied health personnel in delivering the vaccine. Because of the unusual nature of the program these organizations feel that health professionals engaging in the mass delivery of the vaccine should be held harmless from any liability. A meeting has been set for June 3rd with various provider organizations to discuss this issue. Also on June 4th, there will be meetings to discuss inter-agency organization and volunteer efforts.

5. International Assistance

We are still waiting for a decision from Secretary Mathews as to the best possible solution to the question of whether or not we commit ourselves to share vaccine production with Canada and Mexico. Our Ambassador in Canada has been contacted several times by the Canadian Health Minister and the State Department is anxious to formulate a response as soon as possible, and they have circulated a draft telegram

for White House approval. (Copy attached). It is my understanding that this telegram was sent to Secretary Mathews about two weeks ago for his concurrence and was rejected.

I believe it is essential to convene a meeting of principals to reassess our efforts in the program. I would suggest that the meeting include and be limited to Secretary Mathews, Assistant Secretary Cooper, and Paul O'Neill.

cc: Jim Cannon ✓  
Art Quern

THE WHITE HOUSE  
WASHINGTON

DATE: May 18, 1976  
TO: Spencer Johnson

FROM: JIM CAVANAUGH / *fw*

SUBJ:

FYI \_\_\_\_\_

ACTION \_\_\_\_\_





File To MR Conaway, WH.  
HAND DELIVER

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EUR/CAN: JHROUSE, JR: OES/APT/BMP: WJWALSH, III  
22170 5/17/76  
OES/APT: OHGANLEY

ARA: HARYAN  
WHITE HOUSE:  
OES: FIRVING(SUBST)

NSC:  
S/S:

PRIORITY

OTTAWA

E.O. 11652: N/A

TAGS: TPHY, TBIO, OSCI, CA

SUBJECT: SWINE FLU VACCINE

FOR THE AMBASSADOR

OSC  
JEB/  
HAR

1. IN RESPONSE TO REQUEST OF CANADIAN MINISTER OF HEALTH FOR U.S. ASSISTANCE IN MEETING CANADIAN NEEDS FOR SWINE FLU VACCINE, YOU SHOULD RESPOND DRAWING FROM FOLLOWING TALKING POINTS:

--PRESIDENT FORD HAS MADE A PUBLIC COMMITMENT TO VACCINATE ALL AMERICANS THIS SEASON AGAINST SWINE FLU. U.S. MUST BE SURE WE HAVE ADEQUATE SUPPLIES TO MEET THAT COMMITMENT BEFORE WE CAN DETERMINE EXTENT TO WHICH WE WILL BE ABLE TO ASSIST IN MEETING CANADA'S VACCINE NEEDS AND REQUESTS FROM OTHER COUNTRIES.

--WE WILL NOT KNOW HOW MANY DOSES VACCINE PRODUCTION WILL YIELD UNTIL CLINICAL TESTS TO DETERMINE DOSAGE OF VACCINE NECESSARY FOR EFFECTIVE IMMUNIZATION, ARE COMPLETED. THESE TESTS ARE NOW UNDERWAY. WIDE POSSIBLE VARIATION IN STRENGTH OF DOSE NECESSARY FOR IMMUNIZATION MAKES EVEN ROUGH PREDICTION OF TOTAL NEEDS IMPOSSIBLE AT THIS TIME. WE EXPECT TEST RESULTS TO BE AVAILABLE AROUND MID-JUNE, AND AT THAT POINT WE WILL BE ABLE TO DETERMINE AVAILABILITY QUESTIONS.

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QUESTIONS.

--THE UNITED STATES WILL DO EVERYTHING POSSIBLE WITHIN ITS MANUFACTURING CAPABILITY TO MAKE THE A/NEW JERSEY/76 STRAIN VACCINE AVAILABLE FOR PURCHASE FOR HIGH RISK POPULATIONS IN THE NORTH AMERICAN EPIDEMIOLOGIC REGION.

--ONCE SUFFICIENT SUPPLIES ARE ASSURED TO MEET THE U.S. DEMAND FOR VACCINE, THE HIGH RISK POPULATIONS IN CANADA AND MEXICO WILL RECEIVE FIRST PRIORITY IN HAVING THE VACCINE MADE AVAILABLE TO THEM. FYI: MEXICO HAS NOT YET REQUESTED VACCINE SUPPORT BUT SHOULD IT DO SO WE WILL TREAT SUCH A REQUEST PARALLEL TO THAT OF CANADA, AS THE MEDICAL CONSIDERATIONS WITHIN THE WHOLE NORTH AMERICAN EPIDEMIOLOGICAL REGION ARE NOT DISTINGUISHABLE AS TO RISK OR SEVERITY. END FYI.

--SHOULD U.S. DETERMINE THAT VACCINE IS AVAILABLE, WE WILL WORK CLOSELY WITH GOC TO MAKE SUPPLIES AVAILABLE TO CANADIAN HIGH-RISK POPULATION AS EARLY AS POSSIBLE. WE WOULD EXPECT TO BE ABLE TO BEGIN TO SUPPLY VACCINE TO CANADA ONCE U.S. NEEDS ARE ASSURED AND WHILE OUR OWN INOCULATION PROGRAM IS UNDERWAY.

--WE SUGGEST THAT CONCERNED OFFICIALS ON BOTH SIDES GET TOGETHER SOON TO DISCUSS DETAILS OF CANADIAN AND U.S. ~~PROGRAMS~~ IN ORDER TO PREPARE AS FULLY AS PSS PROGRAMS IN ORDER TO PREPARE AS FULLY AS POSSIBLE TO PUT COOPERATIVE EFFORT INTO PLACE WITHOUT DELAY SHOULD FAVORABLE SUPPLY DETERMINATION BE MADE. YY



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