The original documents are located in Box 34, folder "Swine Flu (8)" of the James M. Cannon Files at the Gerald R. Ford Presidential Library.

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THE WHITE HOUSE

WASHINGTON

September 9, 1976

MEMORANDUM TO:

JIM CANNON

FROM:

SPENCER JOHNSON

SUBJECT:

Secretary Mathews' Biweekly Influenza Immunization Program Report to the

President

I have prepared a cover memorandum as you requested, however, this information has not changed since Secretary Mathews and Dr. Cooper briefed the President and the press last Thursday.

I would advise against forwarding the report to the President.

Olymin Line

30800



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

MEMORANDUM FOR THE PRESIDENT

SUBJECT: Biweekly Status Report on the National Influenza Immunization Program (NIIP), for the Period Ending September 1, 1976

ACCOMPLISHENTS

- 1. An introductory statement entitled "Important Information from the U.S. Public Health Service About Swine Flu and Victoria Flu Vaccines" has been developed in consultation with the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This information and the original information/registration form will be made available to insure that informed consent is obtained from all persons participating in the National Influenza Immunization Program.
- The initial Implementation Flan for the "National Swine Flu Immunization Act of 1976" (Public Law 94-380) is being developed.

PROBLEMS

- 1. A comparison of June and August proposals submitted by manufacturers shows a decrease in availability of monovalent and bivalent influenza vaccines through December 1. An insufficient quantity of vaccine will be available for initiation of the influenza immunization program in October. Compared to earlier projections by industry, a decrease of 74.3% in vaccine availability will exist at the time the inoculation phase of the program is scheduled to begin on October 1.
- 2. Vaccine manufacturers have not received notification as to the availability, or cost, of normal product liability (negligence) insurance. The anticipated \$50 million insurance coverage for each of the four manufacturers has not been fully subscribed by members of the insurance industry. The \$45 million excess coverage aspect of this policy is only 75% subscribed. Lloyd's of London is a major hold-out.

ACTIONS TAKEN TO RESOLVE PROBLEMS

- 1. Vaccine contract negotiations continue with manufacturers to resolve delivery schedule delays and to increase the quantity of influenza vaccine available for early programming.
- Discussions are continuing within the insurance sector, and between the insurance sector and manufacturers in an effort to get negligence insurance, at a reasonable price.

Secretary

THE WHITE HOUSE WASHINGTON

Sept. 8

TO: SPENCER JOHNSON

FROM: JIM CANNON

Please prepare for the President a summary of the attached memo to him from Secretary Mathews on Swine Flu ASAP.

thanks

THE WHITE HOUSE WASHINGTON

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Robert D. Linder

Swine Alu

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THE WHITE HOUSE

WASHINGTON

September 3, 1976

MEMORANDUM FOR:

JIM CANNON

FROM:

SPENCE JOHNSON

SUBJECT:

Congressional hearings on

swine flu

Congressman Rogers' Subcommittee will hold hearings on swine flu September 10, 1976 -- both HEW and the drug companies will be star witnesses.

Thought you would want to have this information.

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Meanings?

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THE WHITE HOUSE

WASHINGTON

September 7, 1976

MEMORANDUM FOR:

JIM CANNON

FROM:

SPENCE JOHNSON

SUBJECT:

Congressional hearings on swine fla

un Commangh -

Attached is a notice from the House Subcommittee on Health and the Environment for oversight hearings on the implementation of the swine flu immunization program this Friday.

This hearing is in response to a <u>Washington Post</u> article last week indicating delays in the immunization program. The only witnesses planned are the Administration and the drug companies. Having passed the indemnity legislation, Congress does not want to take the rap for any further programatic problems.

090705

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

PAUL G. ROGERS, FLA., CHAIRMAN

PAUL G. ROGERS, F.L., CHAIRMAN
DAVID E. SATTERFIELD III, VA.
RICHARDSON PREYER, N.C.
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JAMES H. SCHEUER, N.Y.
HENRY A. WAXMAN, CALIF.
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CHARLES J. CARNEY, OHIO
ANDREW MAGUIRE, N.J.
HARLEY O. STAGGERS, W. VA.
(EX OFFICIO)

JAMES T. BROYHILL, N.C. H. JOHN HEINZ III, PA. EDWARD R. MADIGAN, ILL. SAMUEL L. DEVINE, OHIO (EX OFFICIO)

Congress of the United States

House of Representatives

Subcommittee on Bealth and the Environment of the

Committee on Interstate and Foreign Commerce Washington, D.C. 20515

September 3, 1976

ROGERS,

NOTICE OF PUBLIC HEARINGS

The Subcommittee on Health and the Environment will hold public hearings promptly at 10:00 A.M. on Friday, September 10, 1976, in Room 2123 Rayburn Building, on the following:

Oversight on the Implementation of the Swine Flu Immunization Program

Witnesses by invitation only.

If the Interstate and Foreign Commerce Committee subsequently schedules a meeting at 10:00 A.M. the Subcommittee hearing will begin at 1:30 P.M.

Chairman

Spena Jehnsm

THE WHITE HOUSE

September 3, 1976

MEMORANDUM FOR:

JIM CANNON

FROM:

SPENCE JOHNSON

SUBJECT:

Congressional hearings on

swine flu

Congressman Rogers' Subcommittee will hold hearings on swine flu September 10, 1976 -- both HEW and the drug companies will be star witnesses.

Thought you would want to have this information.

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Meaning?

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Thursday, September 2, 197

Flu Vaccine Production Lags Badly

By Stuart Auerbach Washington Post Staff Writer



THE NEW YORK TIMES, THURSDAY, SEPTEMBER 2, 1976

PRODUCTION LAGS ON FLU. VACCINES

Types Needed for Federal Program Are Affected

By HAROLD M. SCHMECK Special to The New York Times

The new actimates of vaccine alou against the int vitus talicu

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Some items in this folder were not digitized because it contains copyrighted

these materials.

THE WHITE HOUSE

WASHINGTON

September 24, 1976

MEMORANDUM FOR THE PRESIDENT

FROM:

JIM CANNO

SUBJECT:

Influenta Immunization Program Report

The attached biweekly status report on the swine flu immunization program from Secretary Mathews indicates:

- -- State and community innoculation plans have been adjusted to meet the new vaccine delivery schedules which began this week.
- -- High risk persons will begin receiving injections October 1st, with mass community clinics slated for later in the month.
- -- Recommendations are being developed for the immunization of high risk children, under age 18, for protection against the swinetype virus with a two-dose series of booster shots.

NFORMATION



THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE WASHINGTON, D.C. 20201 SEP 2 3 1976

MEMORANDUM FOR THE PRESIDENT

SUBJECT: Biwackly Status Report on the National Influenza Immunisation Program (NIIP), for the Pariod Ending September 15, 1976

ACCOMPLISHMENTS

1. On September 13, HEW presented data on vaccine availability (starting October 1) to the House Subcommittee on Health during Oversight hearings. HEW also discussed the status of negotiations with vaccine manufacturers, and new resommendations for High Risk Children. These hearings were considered to have been helpful in identifying and resolving issues which were causing program delays.

2. Letters of contract have been signed by three of the four manufacturers of influenza vaccine. Negotiations are continuing with Parke Davis, Inc. Additional vaccine will be produced in excess of recent August estimates (113 million doses), although most of the additional vaccine will be delivered in December and early January. A total of 147 million doses

are now expected to be delivered by January 15.

3. A committee of the American Academy of Padiatrics met on September 8 to develop influence vaccination recommendations for High Rick Children under the age of 18 who are at rick of suffering from serious complications of influence. This group includes children with heart disease, cystic fibrosis, asthma, and other lung disorders. A two-dose ("beceter-shot") program using bivalent vaccine is anticipated for High Rick Children. An official report is expected this week.

4. Forty-eight bulk lots of monovalent and bivalent vaccine totalling 33,272,007 doses have been submitted to BoB by the manufacturers for concurrent testing and approval. Seven lots (4,831,900 doses) of monovalent vaccine and 10 lots (5,985,011 doses) of bivalent vaccine have been approved. Fifteen lots (11,209,130 doses) of monovalent vaccine and 16 lots (11,245,966 doses) of bivalent vaccine are pending approval, contingent upon completion of the standard series of tests.

PROBLEMS

1. The recent vaccine availability estimates (including the December-January deliveries) have invalidated most State timetables for vaccination programs.

ACTIONS TAKEN TO RESOLVE PROBLEMS

1. State plans are being adjusted to coincide with anticipated vaccine deliveries. In general, mass community clinics have been delayed until the latter part of October, with delivery of bivalent vaccine to established health care providers serving high risk persons beginning in early October. Bivalent and monovalent vaccine will generally be available in mass clinics.

/s/David Mathews

Secretary

THE WHITE HOUSE WASHINGTON

		9/23/76
TO:	JIM CANNO	N
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	Md	
	6 SEP 23	Robert D. Linder

THE WHITE HOUSE

WASHINGTON

SCHEDULE PROPOSAL

DATE: September 27

FROM: Jim Cannon

MEETING:

President receiving an influenza

inoculation.

DATE:

Any time after October 1, 1976.

PURPOSE:

For the President to receive his swine-type influenza immunization and to express his support of this nationwide health protection program.

FORMAT:

The shot could be given in the Oval Office, the Cabinet Room, or at some

other appropriate place.

CABINET

PARTICIPATION:

Secretary Mathews, Dr. Cooper.

SPEECH

MATERIAL:

Talking Points.

PRESS COVERAGE:

Full press and photo opportunity.

STAFF:

Spencer Johnson.

RECOMMEND:

Secretary Mathews, Jim Cannon.

OPPOSED:

None.

PREVIOUS

PARTICIPATION:

The last time the President made a public statement on this program was on August 12, when he signed the "National Swine Flu Immunization

Program of 1976".

	ACTION
DOMESTIC COUNCIL FROM: SPENCER JOHNSON	sorpres,
SUBJECT:	
Memo to the President summa Secretary Mathew's biweekly report on the swine flu pro (attached)	status
	<u>Date:</u>
COMMENTS	
I recommend you sign the attac	hed memo.
	A.M.
American muser	J. COROLIANAS

ACTION:

Date:

THE WHITE HOUSE WASHINGTON

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TO: _	ЛМ	CANNO	N					
								
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THE WHITE HOUSE

WASHINGTON

INFORMATION

October 11, 1976

MEMORANDUM FOR THE PRESIDENT

FROM:

JIM CANNO

SUBJECT:

Influenza Immunization Program Report

The attached biweekly status report on the swine flu immunization program from Secretary Mathews indicates:

- -- About 25.1 million doses of swine flu vaccine had been shipped to the states and territories by the time the inoculation program began on October 1.
- -- A system has been initiated by which occurrences of swine flu can be immediately reported and confirmed.
- -- HEW and the Justice Department are implementing procedures to handle any claims that may arise under the Federal Tort Claims Act.
- -- A scientific conference has been scheduled for October 22 to formulate recommendations for the administration of the influenza vaccine to normal (not medically high risk) persons under 18 years of age.



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

OCT 7 1976

MEMORANDUM FOR THE PRESIDENT

SUBJECT: Biweekly Status Report on the National Influenza Immunization Program (NIIP), for the Period Ending October 1, 1976

ACCOMPLISHMENTS

 As of the end of the day, September 30, 12,280,000 doses of monovalent vaccine and 12,851,650 doses of bivalent vaccine have been shipped by manufacturers (total 25,131,650). This exceeds the total contractual commitments of the manufacturers for October 1 shipments by approximately 4,000,000 doses. Shipments were made to every State in the Union and U.S. Territory.

A total of 29 lots of monovalent and 22 lots of bivalent vaccine have been released by the Bureau of Biologics, representing approximately 21,000,000 and 14,000,000 doses respectively (total 35,000,000). Those supplies which have not been shipped are in various stages of bottling,

final testing, and preparation for shipment.

2. Virus surveillance comprises, or soon will comprise, 40 Norld Health Organization Collaborating Laboratories, 10 National Institute of Allergy and Infectious Diseases-sponsored laboratories, 35 sentinel physicians, 48 hospitals and clinics throughout the country, and 25 other laboratories which will report results to the Center for Diease Control. Current computer data consist of records from 284 industries, 727 schools, 380 hospitals and 1,408 counties. Reports, some of which are obtained by telephone, include influenza morbidity data such as absenteeism, and visits for influenza-like illness. Pneumonia and influenza mortality data are received weekly from 121 cities.

Since May 22, 1976, when this year's influenza surveillance system was implemented, virus isolations have been performed on more than 6,500 specimens. No A/New Jersey/76 isolates have been identified.

3. The Department of Justice in collaboration with the Office of the General Counsel of the Deartment of Health, Education, and Welfare, is in the process of organizing and preparing for any claims that may arise under provisions of the P.L. 94-380 which utilizes the Federal Tort Claims Act.

PROBLEMS

1. There is growing public concern about the current lack of recommendations as to the use of influenza vaccine in normal children.

Page 2 - The President

ACTIONS TAKEN TO RESOLVE PROBLEMS

 A major public, open scientific meeting is scheduled for October 22 at the National Institutes of Health to review all data involving hundreds of normal children. On the basis of scientific information presented at this conference, recommendations will be made with respect to vaccine use, dosage, and administration schedule in persons less than 18 years of age.

/s/David Mathews





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

OCT 7 1978

MEMORANDUM FOR THE PRESIDENT

SUBJECT: Biweekly Status Report on the National Influence Immunization Program (NIIP), for the Period Ending October 1, 1976

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Page 2 - The President

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/s/David Mathews

Secretary

THE WHITE HOUSE

WASHINGTON

October 12, 1976

MEMORANDUM FOR:

JIM CANNON

THROUGH:

ART QUERN H

FROM:

SPENCER JOHNSON

SUBJECT:

Deaths Reported in Conjunction with the National Influenza Immunization Program

HEW reports that it has received notification of three deaths within the last 24 hours associated with the National Influenza Immunization Program.

The three deaths occurred in Pittsburgh, Pennsylvania after three aged persons (two women, one man; ages 71, 74 and 75) received their shots at the South Side Clinic in the Allegheny County city. One individual died within four minutes of receiving the shot and the other two individuals died within 24 hours. About 23,000 shots of bi-valent vaccine administered by syringe and needles had been given in this clinic before Allegheny County health officials stopped the program until a determination of the causes of death can be made. The vaccine being used was from a lot manufactured by Parke-Davis. Parke-Davis indicates that they do not believe that the deaths are vaccine-related.

One autopsy has been completed and the cause of death given was heart attack, not associated with the vaccination. Another autopsy is on-going and in the last case, relatives have refused permission for an autopsy.

Officials from the Center for Disease Control (CDC) are in Pittsburgh to evaluate the relationships of these deaths with the swine-type influenza vaccine. They plan to issue a press release as soon as something is determined.

Also, HEW officials have been in contact with Jonas Salk and he is prepared to make a statement supporting the program once final determinations are made that indicate the cause of death.



Health

1976 OCT 13 AM 9 16

October 12, 1976

Dear Dr. Woodward:

I am writing on behalf of Mr. James Cannon, Director of the Domestic Council, to acknowledge receipt of your letter of October 5, 1976.

We very much appreciate your forwarding the "Resolution on IMfluenza Vaccine Procurement for the Armed Forces." adopted by the Armed Forces Epidemiological Board.

Sincerely,

SPENCER C. JOHNSON
Associate Director of the
Domestic Council

Theodore E. Woodward, M.D.
President
Armed Forces Epidemiological Board
University of Maryland
School of Medicine
Baltimore, Maryland 21201



THE WHITE HOUSE WASHINGTON

FROM:

DATE: 10/8
TO: Spense

SUBJECT:

ACTION

Plr. acknowledge on JMC's behalf

UNIVERSITY OF MARYLAND

SCHOOL OF MEDICINE
BALTIMORE, MARYLAND 21201

THEODORE E. WOODWARD, M. D. PROFESSOR OF MEDICINE

October 5, 1976

Mr. James M. Cannon Director The Domestic Council 1600 Pennsylvania Avenue, N. W. Washington, D. C. 20500

Dear Mr. Cannon:

1 Incl

In view of your interest in the National Swine Influenza Immunization Program, I am bringing the attached resolution to your attention.

Sincerely,

THEODORE E. WOODWARD, M. D.

President

Armed Forces Epidemiological Board

ESALD TORON OF

Spencer Johnson



DEPARTMENT OF DEFENSE ARMED FORCES EPIDEMIOLOGICAL BOARD

ADDRESS REPLY TO

AFEB

4 October 1976

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

THE SURGEON GENERAL, DEPARTMENT OF THE ARMY THE SURGEON GENERAL, DEPARTMENT OF THE NAVY

THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Resolution on Influenza Vaccine Procurement for the Armed Forces

The Armed Forces Epidemiological Board, after reviewing the report and recommendations of the ad hoc Study Team on Influenza as concluded in its 30 August 1976 telephone conference, concurs in the findings of this group and hereby resolves that:

"WHEREAS: Throughout the decades of existence of the Armed Forces Epidemiological Board, the special immunization requirements of our Armed Forces have always been recognized by the Board. Historical and epidemiologic evidence substantiate that the military population cannot be characterized as representing a cross-section of the civilian population by age group, physiological stress or disease-exposure. Further, considering the perceived threat to our National survival and world peace, the potential cost of failure to protect our military personnel against epidemic diseases such as influenza is unacceptable. Therefore, influenza vaccines used by the Armed Forces in the past have been specifically formulated and have often differed from those recommended for use in civilian groups.

WHEREAS: The Armed Forces Epidemiological Board voices apprehension and concern at the outcome of management decisions regarding procurement of influenza vaccine for use by the Armed Forces during 1976-77. The failure of the National Swine Influenza Immunization Program management to take cognizance of the special immunization requirements of the military and specific recommendations made by this advisory group has caused a potentially disastrous delay in protection of Armed Forces personnel and a greatly increased cost of administration.

AFEB

SUBJECT: Resolution on Influenza Vaccine Procurement for the Armed Forces

THEREFORE, BE IT HEREBY RESOLVED:

- 1. The Armed Forces Epidemiological Board views the attitude with alarm and decries the decision which resulted in separation of military influenza vaccine procurement from the control of the Surgeons General of the Armed Forces.
- 2. Future military procurement of vaccines of all types should be under the direct control of the Surgeons General of the Armed Forces in order to assure timely and effective protection of this unique population group.

THEODORE E. WOODWARD, M.D.

President

THE WHITE HOUSE

WASHINGTON

October 14, 1976

MEMORANDUM FOR:

DAVE GERGEN

FROM:

ART QUERN L

SUBJECT:

Carter Statement on Swine Flu Shot

There is a report that Carter this afternoon said he was not going to get a Swine flu shot because Doctors Sabin and Salk said it was not necessary.

Dr. James Salk called the Assistant Secretary for Health at HEW this afternoon and stated that he had never said anything like that, and, that, indeed he was urging people to get their Swine flu vaccine shot.

Dr. Sabin, while originally supportive of the program, has in the past indicated that he believed we should be stockpiling the vaccine until more specific evidence of the risk of Swine flu became available.

Salk says it is class if Salk says it is class if the breadent mants to say the Tonight

Jim Cannon cc: Jim Cavanaugh Spence Johnson

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DOMESTIC COUNCIL

FROM:

Secretary Mathews

SUBJECT:

Bi-weekly status report on swine flu immunization

Date: 10/26/76

COMMENTS:

Spence has drafted a brief cover memo.



ACTION:

Date:

THE WHITE HOUSE WASHINGTON

FROM:

DATE: 10/25 TO: Spene

ALLEN MOORE

SUBJECT:

ACTION:

for cour note.

THE WHITE HOUSE WASHINGTON

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Robert D. Linder

THE WHITE HOUSE

INFORMATION

WASHINGTON

October 28, 1976

MEMORANDUM FOR THE PRESIDENT

FROM:

JIM CANNON

SUBJECT:

Influenza Immunization Program Report

The attached biweekly status report on the swine flu immunization program from Secretary Mathews indicates:

- --As of Wednesday, October 13, more than 2.5 million doses of flu vaccine had been administered, 1 million to persons over age 65 and the rest to high risk persons with chronic illness.
- --As of Friday, October 15, 44 million doses had been shipped to all 50 states and trust territories.
- --Although the program had been briefly disrupted by the coincidental deaths of many persons, there is no evidence that those deaths were connected to inoculation with the swine-type influenza vaccine. All programs have been resumed throughout the country.



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

OCT 2 2 1976

MEMORANDUM FOR THE PRESIDENT

SUBJECT: Biweekly Status Report on the National Influenza Immunization Program (NIIP), for the Period Ending October 15, 1976

ACCOMPLISHMENTS

- 1. The inoculation phase of the National Influenza Immunization Program began on October 1, 1976. The first shots were given in Indianapolis, Indiana. As of Wednesday, October 13, more than 2.5 million doses of flu vaccine had been administered to citizens around the country. More than 1 million shots have been given to individuals over age 65; the remainder was given primarily to other high-risk individuals with chronic illness to protect them against both the A/New Jersey/76 ("swine flu") strain and the A/Victoria strain of influenza virus.
- 2. As of Friday, October 15, 1976, a total of 44 million doses had been shipped to all 50 States and Trust Territories.

PROBLEMS

1. As of Friday, October 15, there had been news reports that dozens of elderly individuals had died in connection with NIIP.

ACTIONS TAKEN TO RESOLVE PROBLEMS

1. An intensive surveillance program provided us with data on 35 individuals who became ill within 48 hours of vaccination and subsequently died. Based on extensive epidemiological, laboratory, and post-mortem data, there is no evidence to link these deaths -- which occurred in elderly persons (average age 71 years) -- with the vaccine or vaccination program. A major press conference was held on October 14 to present current information on this matter. It was called by Dr. Theodore Cooper who was complemented by representatives from the Center for Disease Control, Bureau of Biologics of FDA, National Institute of Allergy and Infectious Diseases, National Center for Health Statistics, and the National Heart and Lung Institute. It was attended by dozens of reporters as well as all three major television networks. We feel that this news conference has helped allay fears. The few State and local vaccination programs that had suspended their programs have, or are in the process of restarting their vaccination efforts. Allegheny County and other local programs in Pennsylvania have restarted their programs.

1976 OCT 22 PM 5 13

RECEP. AND SECURITY UNIT

Page 2 - The President

FUTURE EVENTS

1. A major public, open scientific meeting is scheduled for October 22 at the National Institutes of Health to review all data involving hundreds of normal children. On the basis of scientific information presented at this conference, recommendations will be made with respect to vaccine use, dosage, and administration schedule in persons less than 18 years of age.

goretary success

DOMESTIC COUNCIL

FROM:

SPENCE JOHNSON

SUBJECT:

Summary of bi-weekly swine flu report from HEW

Date: 11/18/76_

COMMENTS:

Spence has prepared his regular summary cover memo from you to the President.

Please sign.



ACTION:

Date:

THE WHITE HOUSE WASHINGTON

11.17.76
TO. Jun Cannon
For Your Information:
For Appropriate Handling:
NR

THE WHITE HOUSE

WASHINGTON

INFORMATION

Alm

November 19, 1976

MEMORANDUM FOR THE PRESIDENT

FROM:

JIM CANNON

SUBJECT:

Influenza Immunization Program Report

The attached biweekly status report on the swine flu immunization program from Secretary Mathews indicates:

- --As of November 6, about 14.2 million doses of swine flu vaccine have been administered to persons over the age of 17.
- --As of November 13, 84 million doses of the vaccine have been shipped to the states and territories.
- --No community-wide immunization programs for persons between 3 and 17 will be undertaken, but vaccine will be available beginning in December through the normal health delivery system channels.
- --Public response to the immunization program has fallen below expectations; intensive public awareness programs are being carried out to combat the lack of receptivity.
- --The Secretaries of HEW, Defense and State are currently developing a policy regarding the immunization of Americans overseas.



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

NOV 1 7 1976

MEMORANDUM FOR THE PRESIDENT

SUBJECT: Biweekly Status Report on the National Influence Immunisation Program (NIIP), for the Period Ending November 15, 1976

ACCOMPLISHMENTS

1. Since the inoculation phase of the National Influensa Immunisation Program began on October 1, until November 6, approximately 14,200,000 doses of the flu vaccine have been given to people around the country, representing 10.9% of the U.S. population above the age of seventeen.

Eighteen of the 63 project areas had reached or surpassed vaccinating 20% of the population above the age of 17. Wyoming (68%), Trust Territories (58.3%), Puerto Rico (41.3%) and Alaska (47%) continue to lead the way. (The 63 project areas include the 50 States, the District of Columbia, American Samoa, Trust Territories of the Pacific Islands, Guam, Puerto Rico, Virgin Islands and seven cities which receive direct grants).

2. As of November 13, manufacturers had shipped 84 million doses of vaccine.

3. On November 15, the Assistant Secretary for Health announced the PHS policy on the vaccination of normal, healthy children between 3 and 17 years. The position is that no community-wide programs should be undertaken; however, vaccine for immunizing approximately 4 million children with 2 doses will be made available in December for individuals wishing to obtain it through the normal channels of the health delivery system. A safe and effective regimen exists, but this fact is overshadowed by the reality that manufacturers cannot supply sufficient quantities of the required vaccine type ("split virus monovalent" - see below).

PROBLEMS

1. While the 10 million doses of influenza vaccine administered during October represents the most influenza vaccinations ever administered in one month in the United States, public response is generally felling below the goals set for the program. There is a continuing concern, therefore, about the public reticence to seek flu vaccinations. This concern has focused on minority groups, particularly the black communities



of the large urban centers where response has been particularly poor. This group's lack of response has been anecdotally, but strongly and consistently, linked to the temporally associated deaths of early October which were widely reported in the media. The negative impact of the reports of deaths was not countered effectively in the media, primarily because strong public awareness programs in local areas were generally not planned for early October because of uncertainties in the availability of vaccine.

- 2. Three of the four vaccine manufacturers have formally indicated that they do not believe that additional supplies of vaccine can be produced this year.
- 3. As yet, there is no approved policy or plan for the immunisation of overseas Americans. A proposal was forwarded through channels in early October for consideration. In early November it was referred back to the Secretaries of HEW, Defense, and State for action. Meanwhile, various multi-national corporations earlier informed that a policy decision would be made by November 10, have had to suspend plans to proceed with distribution and vaccination.

ACTIONS TAKEN TO RESOLVE PROBLEMS

- 1. State and local health departments have begun carrying out intensive public awareness programs, and are attempting to develop new approaches to counter the fear of the vaccine which resulted from the deaths in early October. Primary amphasis is being placed on public affirmation of influenza vaccination by respected community leaders. Similar statements by national leaders are being sought.
- 2. The Department is exploring the legal and technical feasibility of submitting the viruses grown by the largest manufacturer of whole-virus vaccine to the virus-splitting process of another, smaller manufacturer. While this would not increase the overall supply of vaccine, it would make the availability of split-virus vaccine and whole-virus vaccine more nearly equal.
- 3. A policy decision on vaccination of overseas Americans is expected as an outcome of joint discussions by the Secretaries of HEW, Defense, and State on the vaccination of overseas Americans.

7s/David Mathews

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THE WHITE HOUSE

WASHINGTON

MEMORANDUM FOR THE PRESIDENT

FROM:

JIM CANNON

SUBJECT:

Influenza Immunization Program Repor

Attached is the latest biweekly status report on the swine flu immunization program from Secretary Nathews. (The report was submitted prior to Thursday's announcement of the program's suspension due to a report of several cases of a rare paralytic disease called Guillain-Barre syndrome. Both Dr. Theodore Cooper and the CDC in Atlanta indicate that no link between the disease and the shots has been proven at this time and the halt is seen as a precautionary measure.)

Secretary Mathews' report indicates:

- --As of November 27, approximately 30 million doses of swine flu vaccine have been administered.
- --As of November 30, manufacturers had shipped 109.9 million doses to the states and territories.
- --On November 22, health officials announced that a case of A/New Jersey/76 influenza had been diagnosed in Concordia, Missouri. The patient is fully recovered and no other cases have been identified to date.



THE WHITE HOUSE WASHINGTON

DATE: (2 /16 5

FROM: ALLEN MOORE

SUBJECT:

ACTION:

FYI:

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THE WHITE HOUSE WASHINGTON

976 DEC 12.15.76
TO: Jim Connon
For Your Information:
For Appropriate Handling:
Robert D. Linder

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

DEC 8 1976

MEMORANDUM FOR THE PRESIDENT

SUBJECT: Biweekly Status Report on the National Influenza Immunization Program (NIIP), for the Period Ending December 1, 1976



ACCOMPLISHMENTS

- 1. The National Influenza Immunization Program began inoculations on October 1. Since that time through November 27, at least 30,154,895 people have received flu vaccine. A total of 4,763,546 doses of vaccine were given during the week November 21-27, which included a period of reduced vaccination activity due to the Thanksgiving Holidays.
- 2. By the close of business on November 30, manufacturers had shipped 68.2 million doses of monovalent and 41.7 million doses of bivalent vaccine (109.9 million doses total). Included in this total were 2.5 million doses of split-virus monovalent vaccine available for vaccinating normal, healthy children 3 to 17 years of age. We expect a total of 8 8.5 million doses of split-virus monovalent vaccine to be available by January 15, 1977.
- On November 22, health officials in Missouri announced that a case of A/New Jersey/76 influenza had been diagnosed in Concordia, a rural area in the west central part of the State. The 32 year old patient became ill on October 10 and returned to the physician on October 20 with classic flu-like symptoms necessitating 4 days of bed rest. An acute serum sample was obtained on October 20 and a convalescent serum sample was drawn on November 13. The physician attending the patient was voluntarily participating in the Missouri influenza morbidity surveillance network. The Missouri State laboratory found no diagnostic rise in titers for A/Victoria/75 and B/Hong Kong/72. The diagnostic rise, however, was observed for A/New Jersey/76 from 1:10 to 1:80. The Center for Disease Control (CDC) has confirmed these findings. A serologic survey of the community continues as does the epidemiologic investigation surrounding this sero-confirmed infection. date, no other cases of A/New Jersey/76 influenza have been identified, and there is no evidence of unusual influenza trends in the area. This episode demonstrates the overall effectiveness and sensitivity of the influenza surveillance network established for the Swine Flu Program.



PROBLEMS

We have received the results of the National Survey of Public Attitudes for the period November 1-12. While 97% of those sampled are aware of swine flu and 93% are aware of the immunization program, only 14% said they had been vaccinated and just 33% said they intended to get a shot while 19% expressed uncertainty. The 31% of respondents who said they would not seek a vaccination represented a significant increase from the 19% so responding in the October survey. The greatest decline in vaccine acceptance has been noted among young people (18-20), persons in rural areas, those living in the East and South, and Blacks. The most frequent reasons given for not accepting the vaccine were a sensed lack of need and the fear of side effects. (It should be noted that this survey was conducted after the widely publicized deaths in Pittsburgh and before the announced case of swine influenza in Missouri in mid-November). Finally, a disturbing 5% of respondents reported their reluctance was due directly to advice from a personal physician against getting the immunization. This finding supports mounting anecdotal evidence gathered by the NIIP staff through contacts with grantees.

ACTIONS TAKEN TO RESOLVE PROBLEMS

1. Dr. Cooper has written to all Station Managers of Black radio stations reiterating the rationale for the program and asking for supportive actions. A number of public figures identified with both minority groups and the general population have made video as well as audio taped endorsements of the program. These individuals include Reverend Jesse Jackson, Angelo Dundee, James Snyder ("Jimmy the Greek"), Lydell Mitchell, Jackie Wallace, and Dr. Delano Meriwether. These spot announcement tapes are now being distributed to media outlets with special emphasis going to radio stations popular among inner city residents. Video tapes developed by the New York State Department of Health featuring Larry Czonka have also been distributed nationwide.

Additional radio and television spot announcements developed by the Advertising Council have also been distributed. Supportive letters or other informational statements have been distributed to affiliate chapters or memberships of the National Association of Black Disc Jockeys, Black Social Workers, Urban League, Neighborhood Health Centers, National Black Health Executives, National Heart Associations, and National Lung Associations, among others. Several articles supportive of the influenza programs have been published in American Medical News.

CDC officials have met with the Directors of several projects where public response has been poor to coordinate a revitalization of public awareness activities. Dr. Meriwether has visited numerous project areas augmenting their efforts to encourage inner city, Blacks and other ethnic groups to get vaccinated.



THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE WASHINGTON, D.C. 20201 DEC 8 1976

MEMORANDUM FOR THE PRESIDENT

SUBJECT: Biweekly Status Report on the National Influence Immunisation Program (HIIP), for the Period Ending December 1, 1976

ACCOMPLISIONATS

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January 15, 1977.

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/s/David Mathews



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

DEC 8 1976

MEMORANDUM FOR THE PRESIDENT

SUBJECT: Biweekly Status Report on the National Influence Immunication Program (NIIP), for the Period Ending December 1, 1976

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/s/David Mathews

Secretary

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

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The President
The White House
Washington, D. C.



THE WHITE HOUSE WASHINGTON 1977 JAN 4 PM 3 38 Date To: Jim Cannon From: Spencer C. Johnson FYI For Appropriate Action Comments: The Prisident is mo up-to-date than this sent to She President. We have normely done this with outdated reports Sperie

THE WHITE HOUSE WASHINGTON

DATE:

TO:

FROM:

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ACTION:

FYI:

THE WHITE HOUSE WASHINGTON

12.29.76
1976 DLC 29 TM 12 40
TO. Jam Cannon
For Your Information:
For Appropriate Handling:
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Robert D. Linder

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

DEC 27 1976

MEMORANDUM FOR THE PRESIDENT

SUBJECT: Biweekly Status Report on the National Influenza Immunization

Program (NIIP), for the Period Ending December 15, 1976

TORD TORNAL

ACCOMPLISHMENTS

- 1. The National Influenza Immunization Program began inoculations on October 1. Since that time through December 11, at least 39,269,496 people have received flu vaccine. During the two week period following the last submission of the Biweekly Status Report a total of 8,985,203 doses of influenza vaccine have been administered.
- 2. By the close of business on December 14, manufacturers had shipped 112.2 million doses of vaccine.
- 3. The Center for Disease Control has completed work on specimens obtained during the investigation of two cases of A/New Jersey influenza (see Biweekly Status Report of December 1, 1976). The results do not suggest that any close contacts of the patients or others with recent influenza-like illness experienced A/New Jersey infection.

PROBLEMS

1. On December 16, the Assistant Secretary for Health announced a temporary suspension of the National Influenza Immunization Program. The suspension will be in effect until the Center for Disease Control completes an investigation into reports that some vaccinated individuals have developed a neurological condition known as Guillian-Barre syndrome.

The Guillian-Barre syndrome is an infrequent, poorly understood, and usually non-fatal condition. It is characterized by symmetric weakness in the limbs loss of sensation, diminished reflexes, and sometimes more severe paralysis. Occassionally, the disease progresses to respiratory difficulty which can lead to death.

The disease usually begins as a rapidly developing weakness in the legs, with loss of sensation and diminished reflexes. Then the hands and arms become involved, and then the trunk, neck, and face. This is referred to as "ascending paralysis". In a third of the cases reviewed in the literature, there is no pre-existing illness or event before the onset of weakness. In two-thirds of cases, there is a pre-existing illness one or two weeks before the onset of paralysis. A great variety of different types of illness have been observed to precede the onset of the Guillian-Barre syndrome. The most frequent preceding illness is some acute respiratory illness with fever. Influenza vaccination, however, was rarely reported to precede the illness.

Page 2 - The President

The Guillian-Barre syndrome may persist for weeks before complete recovery. However, most patients do recover fully. There is no specific treatment for the condition other than general support of the patient and the use of a respirator if respiration becomes impaired.

As of December, a total of 94 cases of Guillian-Barre syndrome have been reported to CDC from 14 States. Of this number, 51 have been vaccinated, in most cases within 1-3 weeks before the onset of illness. Thirty-one have not been vaccinated and the vaccination status of 12 is unknown as of this writing. Most cases reported to date, both in vaccinated and unvaccinated individuals are in people in the 20-60 year age group.

Guillian-Barre syndrome is not a reportable disease. Hence, its true prevalence in the general population is unknown. However, instances of Guillian-Barre syndrome among vaccinated individuals is quite precisely known due to the efforts of the NIIP intensive surveillance program designed to monitor and follow any type of postvaccination adverse reaction. Since the attack rate is still quite low, this apparent relationship may be diminished by the discovery of additional episodes among persons not vaccinated. An intensive search for all cases is continuing.

The degree of uncertainty involved, coupled with the apparent high relative attack rate among vaccinated persons was viewed as sufficient to suspend vaccination operations until the extent of vaccine culpability could be assessed fully. The time required to complete this assessment is estimated at between 2 and 4 weeks.

ACTIONS TAKEN TO RESOLVE PROBLEMS

1. Grantee resources as well as those of the NIIP intensive surveillance systems are being mobilized to attempt to define fully the prevalence of Gullian-Barre syndrome in the country. Efforts will be made to contact hospitals and other health care providers, both to assess the occurrence of the condition and conduct, where feasible, epidemiologic investigations to obtain any medical and immunization histories that could shed light on the current phenomenon.

Assistant Secretary for Health

From: Dr. William H. Foege

Assistant Director for Operations

Summary of Reports on Guillian-Barre 20 December, 1976

State	Total	Vac.	Unvac.	Unk.
AL	7	5(1)	2	0
AZ	1	1(1)	0	0
CO	8	3	5	0
CI	12	8(1)	4	0
ID ·	1	0	0	1
HD	4	3	1	0
HI	11	8	2	1
HZ	15	11(1)	4	0
HÐ	1	1	. 0	0
NE	<u> </u>	ō	Ö	1
NH	ĩ	ĭ	Ŏ	0
NJ .	23	5	18	0
OH	23	16(1)	6	1
OK	4	1	3	Ō
PA	Å	3	Ŏ	ì
RI	93	2	i	ō
UI	2	2(1)	ō ·	0
VA	4	3	<u>i</u>	_0
Total	125	73	47	5

() = Deaths

DEC 27 1976

MEMORANDUM FOR THE PRESIDENT

SUBJECT: Biweekly Status Report on the National Influenza Immunization Program (NIIP), for the Period Ending December 15, 1976



ACCOMPLISHMENTS

- The National Influenza Immunisation Program began inoculations on Getober 1. Since that time through Pecember 11, at least 39,269,496 people have received flu vaccine. During the two week period following the last submission of the Siveskly Status Report a total of 5,985,203 doses of influenza vaccine have been administered.
- 2. By the close of business on December 14, manufacturers had shipped 112.2 million doses of vaccine.
- 3. The Center for Disease Control has completed work on specimens obtained during the investigation of two cases of A/New Jersey influenza (see Diweckly Status Report of December 1, 1976). The results do not suggest that any close contacts of the patients or others with recent influenza-like illness experienced A/New Jersey infection.

PROBLEMS

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The Guillian-Barra syndrome is an infrequent, poorly understood, and usually non-fatal condition. It is characterized by symmetric weakness in the limbs less of sensation, diminished reflexes, and sometimes more severe paralysis. Occassionally, the disease progresses to respiratory difficulty which can lead to death.

The disease usually begins as a rapidly developing weakness in the legs, with loss of sensation and diminished reflexes. Then the hands and ares become involved, and then the trunk, neck, and face. This is referred to as "ascending paralysis". In a third of the cases reviewed in the literature, there is no pre-existing illness or event before the onset of weakness. In two-thirds of cases, there is a pre-existing illness one or two weeks before the onset of paralysis. A great variety of different types of illness have been observed to precede the onset of the Guillian-Earre syndroms. The most frequent preceding illness is some scute respiratory illness with fever. Influenza vaccination, however, was rarely reported to precede the illness.

The Guillian-Barre syndrome may persist for weeks before complete recovery. However, most patients do recover fully. There is no specific treatment for the condition other than general support of the patient and the use of a respirator if respiration becomes impaired.

As of December, a total of 94 cases of Guillian-Barre syndrome have been reported to CDC from 14 States. Of this number, 51 have been vaccinated, in most cases within 1-3 weeks before the onset of illness. Thirty-one have not been vaccinated and the vaccination status of 12 is unknown as of this writing. Most cases reported to date, both in vaccinated and unvaccinated individuals are in people in the 20-60 year age group.

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ACTIONS TAKEN TO RESOLVE PROBLEMS

1. Grantee resources as well as those of the NIIP intensive surveillance systems are being mobilized to attempt to define fully the prevalence of Gullian-Barre syndrome in the country. Efforts will be made to contact hospitals and other health care providers, both to assess the occurrence of the condition and conduct, where feasible, epidemiologic investigations to obtain any medical and immunization histories that could shed light on the current phenomenon.

Us/David Mathews



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

DEC 27 1976

MEMORANDUM FOR THE PRESIDENT

SUBJECT: Biweekly Status Report on the National Influence Immunication Program (WIIP), for the Period Ending December 15, 1976

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Zs/David Mathews

Secretary

From: Dr. William H. Foege Assistant Director for Operations

Summary of Reports on Guillian-Barre 20 December, 1976

State	Total	Vac.	Unvac.	Unk.
AL .	7	5(1)	2	0
AZ	1	1(1)	0	0
CO	- 8	3	5	0
CI	12	8(1)	4	0
ID	1	0	0	1
M	4	3	1	0
HI	11	8	2	1
HO	15	11(1)	4	0
HP	1	1	. 0	0
NE	1	0	. 0	1
NH	1	1	0	0
NJ.	23	5	18	0
OH	23	16(1)	6	1
OK	4	1	3	0
PA	&	3	0	1
RI	23	2	1	0
UI	2	2(1)	0	0
VA	4	3	1	0
Total	125	73	47 .	5

^{() =} Deaths