The original documents are located in Box 34, folder "Swine Flu (2)" of the James M. Cannon Files at the Gerald R. Ford Presidential Library.

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Digitized from Box 31 of the James M. Cannon Files

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET

Congressional Relations

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Jim -

FYI - This is what we've put out on Swine Flu today

Ken

at the Gerald R. Ford Presidential Library

[April 1976]

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HR 13012 NATIONAL INFLUENZA IMMUNIZATION PROGRAM

The Administration opposes any additional authorization language on this issue since existing authority under the Public Health Service Act is all that is needed. A separate authorization bill risks the possibility of a disagreement between Congress and the President which could delay this vital effort.

THE WHITE HOUSE
WASHINGTON

DATE: April 5, 1976

TO: NANCY KENNEDY

FROM: JIM CAVANAUGH

SUBJ:

FYI_____

ACTION_____

GERALD R. FORD LIBRARY

[April 1976]

GERALD R. FORD LIBRARY

COLLOQUY CONCERNING INDEMNIFICATION OF DRUG COMPANIES PRODUCING SWINE FLU VACCINE

Q: I would like to ask a question concerning the liability of drug companies for possible injuries to those administered the flu vaccine. The Senate Report recites that "the various governmental units shall be free from liability in terms of the vaccine," but that "[t]he drug producers shall remain responsible for the vaccine, its quality, and any adverse reactions directly attributable to the vaccine." I would like to know of the effect, if any, the report recital will have on the tort liability of the producers and of the government and what the managers of this bill perceive that liability to be.

A: The recital in the Senate Report cannot, of course, amend either State or Federal law concerning tort liability, and I do not understand the language of the supplemental appropriation to effect an amendment of the Federal Tort Claims Act. I, therefore, understand the language of the Senate Report as merely attempting to insure that the drug companies retain responsibility for the manufacture of the vaccine with due care, and that the government not assume responsibility for indemnifying the industry for any negligence in the manufacture of that vaccine.

I should add that I think the drug producers have a legitimate concern regarding whether they might be held vicariously liable for the claimed adverse effect of an innoculation where the result is unrelated to their care in producing the vaccine. This concern, however, can be adquately dealt with in the arrangements by which the Secretary of HEW procures the vaccine from the producers. Indeed, I am advised that the Secretary, in requesting contract proposals for the vaccine, intends to include a commitment along the following lines:

> The Government hereby assumes the responsibility (1) for developing the content of a notice of the hazards, if any, of innoculation with the swine influenza vaccine, and (2) of notifying the public or of taking reasonable steps to assure that it is notified of such hazards. Although this responsibility might ordinarily devolve upon the contractor as the manufacturer or seller of the vaccine, the Government is assuming this responsibility because the distribution of the vaccine purchased under this contract will be arranged by the Government.

I believe that this type of commitment, in whatever form of words it finally takes, will adequately meet the producers concerns and will also be consistent with the underlying concern expressed in the Senate Report.

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TALKING POINTS ON INFLUENZA IMMUNIZATION PROGRAM

1. On March 24 I announced plans for a national immunization program to inoculate every American against a swine-type influenza virus. This flu strain, discovered during a recent outbreak among Army recruits at Fort Dix, New Jersey, was the cause of a pendemic in 1918-19 that killed an estimated 548,000 Americans--200 million people around the world.

2. I have asked the Congress for a supplemental appropriation of $135 million for the program. This effort can be carried out under current health authorities, and I do not favor separate authorizing legislation which would impede the swift initiatives that are required for an endeavor of this magnitude.

3. The Secretary of Health, Education, and Welfare, David Mathews, is taking the lead in this effort, with the Public Health Service, under the direction of HEW Assistant Secretary for Health, Dr. Theodore Cooper, proceeding with the planning and implementation efforts to make the vaccine available to the public at the critical time. State and local health agencies will be utilized to conduct immunization programs and as distribution centers for the vaccine. But it will be essential to have the full cooperation and participation of private sector health professionals and facilities, as well as government, to ensure the immunization of the total population in the brief time available.

4. Since there are no precedents for such a massive undertaking, I intend to give this matter my direct and continuous attention. I have asked for weekly reports from the Secretary of HEW, so that I can gauge our progress toward our goal of ensuring that the flu vaccine is widely available and that a maximum of Americans avail themselves of it.

Note for the President: We have asked Dr. Theodore Cooper, Assistant Secretary for Health at HEW, to be in attendance at the meeting to take any questions.

THE WHITE HOUSE

WASHINGTON

April 5, 1976

MEMORANDUM FOR: JIM CAVANAUGH

FROM: SPENCE JOHNSON

SUBJECT: Influenza Immunization Program Talking Points for Bipartisan Briefing, April 6th.

TALKING POINTS

1. On March 24th, I announced plans for a national immunization program to inoculate every American against a swine-type influenza virus. This flu strain, discovered during a recent outbreak among Army recuits at Fort Dix, New Jersey, was the cause of a pandemic in 1918-19 that killed an estimated 548,000 Americans -- 20 million people around the world.

2. I have asked the Congress for a supplemental appropriation of $135 million for the program. This effort can be carried out under current health authorities and I do not favor separate authorizing legislation which would impede the swift initiatives that are required for an endeavor of this magnitude.

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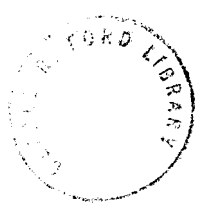
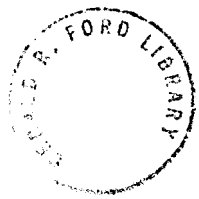
Note for the President: We have asked Dr. Theodore Cooper, Assistant Secretary for Health at HEW, to be in attendance at the meeting to take any questions.



THE WHITE HOUSE

WASHINGTON

April 6, 1976



MEMORANDUM FOR: JIM CAVANAUGH
ART QUERN

FROM: SPENCE JOHNSON

SUBJECT: Senate appropriation subcommittee action on swine flu program.

The Subcommittee on Labor, Health, Education and Welfare of the Senate Appropriations Committee today attached a $1.8 billion Second Supplemental Appropriation to the President's $135 million request for the nationwide influenza immunization program.

The program breakdown: $1.2 billion for the public service jobs extension program; $525 million for summer youth jobs; $56 million for Older Americans; $6 million for youth sports; and $17 million for summer youth recreation programs.

THE WHITE HOUSE

WASHINGTON

April 6, 1976

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MEMORANDUM FOR: JIM CANNON

FROM: JIM CAVANAUGH

SUBJECT: Conversation with David Mathews this Morning on the NY Times Editorial on Flu Vaccine.

I noticed you are meeting with Secretary Mathews this afternoon, and I wanted you to know that I called him this morning and pointed out the negative New York Times editorial on the flu vaccine. I suggested that he respond to it, which he said he would do.

You might want to suggest to him having someone like Dr. Jonas Salk also respond to the Times.

Jim
good

THE WHITE HOUSE
WASHINGTON

April 6, 1976

Jim Cavanaugh

I have not shown the attached to Brent and would like not to bother him with this.

I believe our guy, Hal Horan, wants to be helpful in solving such international problems as may arise in the course of carrying out the President's concept of immunizing the US and other populations against the flu. His reaction (like most good bureaucrats) is to set up a committee. That may be the answer, but before getting everyone all exercised, I wanted to check with you to see if there weren't a way to informally crank our guy and State into the HEW operation on this program? Perhaps something formally and in writing is necessary, but I hope not.

Please let me know what you think? (and please protect me on the attachments)

Many thanks

Bud

MEMORANDUM

1937

NATIONAL SECURITY COUNCIL

~~CONFIDENTIAL~~ (GDS)

ACTION
April 1, 1976

MEMORANDUM FOR: BRENT SCOWCROFT

FROM: Hal Horan

SUBJECT: The Federal Program to Immunize all Americans Against Swine Influenza

Last week you asked me to look into the international implications of the program the President announced March 24 to begin a crash program to immunize all Americans against swine influenza. Today I attended a briefing session in the Department of State given by HEW officials to explain the program, the reasons behind it, and the international implications. My impression is that the decision to immunize Americans was strictly a domestic one and that State has not made any input. There are a number of issues which I believe should be examined and resolved in an inter-agency context.

For example, Secretary Mathews has written to the President (Tab A) suggesting that we provide Canada with enough vaccine to immunize their population. Once again, I do not believe there was a State input which I think is essential before the President makes a decision. Secondly, State has already begun to receive inquiries from embassies in town seeking information as to how they might procure vaccines for their own citizens. There is as well the question of what we do about providing immunization for the millions of official and private Americans abroad. In this connection I understand DOD will have its own worldwide immunization program. State, of course, will be faced with the responsibility for other American citizens abroad. A final example -- we must prepare public statements and a public posture with regard to the needs and demands of the rest of the world should these arise. This is not considered by HEW as a panic situation since relatively few developing countries ever engage in flu immunizations anyway. What we seem to have, rather, is a damage-limiting problem.

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~~CONFIDENTIAL~~ (GDS)

DAP
11/17/83

Central to the problems we face is that U.S. capacity to manufacture vaccine does not, under the best of circumstances, exceed the number of doses that will be required to carry out the President's program (approximately 200 million doses) and provide Canada with its need (approximately fifteen million doses). Another complicating factor is that under the President's program the Federal Government will purchase the entire U.S. production, and therefore any third country requests will be government-to-government.

RECOMMENDATION:

In view of the international implications, I believe it is urgent that an informal interagency group be organized under the chairmanship of HEW but to include State, Defense and possibly others. Since Jim Cannon's office has had action on the program within the White House, I recommend that you seek his agreement that you issue instructions that such a group be formed and report back to the White House in writing on the foreign policy implications and proposals for dealing with them.

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

MAR 31 1976

MEMORANDUM FOR THE PRESIDENT

SUBJECT: Cooperation with Canada on Swine Influenza

Attached is a memorandum to me from the Public Health Service recommending cooperation with the Canadian government on immunizing their population. I believe the recommendation is a sound one. Both our relationships with the Canadians and the special circumstances surrounding immunizing of their population warrant the cooperation without setting any other international precedents or jeopardizing our ability to meet our own needs. Unless you feel differently, I would intend to proceed with a cooperative arrangement with the Canadian authorities.

David Mathews
Secretary

Attachment

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: The Secretary
Through: U
ES

DATE: March 31, 1976

OM : Assistant Secretary for Health

BJECT: Swine Influenza Vaccine for Canada

As you know, vaccine production in Canada and the U. S. is closely coordinated at all times. In the case of swine influenza vaccine, the Canadians are entirely dependent upon the U. S. for a supply. On March 30, 1976, they announced that they too would undertake a national immunization effort. Privately, they have indicated that they would like to purchase approximately 15 million doses this year so that they may vaccinate that segment of their population which they have designated as their priority.

At the moment, we estimate U. S. production capability at approximately 200 million doses. The Canadian request is a small fraction - 7% of this amount. Considering our vaccine manufacturing capabilities and the ability of the public and private sector of American medicine to deliver it, I believe that we can accommodate Canada's needs.

From an international policy point of view, it would be unthinkable to deny the Canadians any vaccine at all. The preferred solution, assuming all goes as planned, is to provide them with an appropriate proportion of our production as it becomes available and after sufficient supplies are assured for our high risk population so that their needs can be met.

I might note that we have not received formal requests from other countries on the matter of our providing them with a supply of swine influenza vaccine. We have discussed the Mexican situation and conclude that, due to their population density and climate, they are unlikely to be affected in the way that Canada might be and that the consideration of swine influenza is not a high priority item with them at this time. Our positive position as regards providing vaccine to Canada stems from our humanitarian interest in their situation, their being a contiguous

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neighbor who is receptive to launching an immunization effort, their winter climate, their delivery system capabilities, their socio-cultural practices and a past history of cooperative relationships with respect to drug production and health.

Theodore Cooper, M. D.

Prepared by: OASH, JFDickson, 3/31/76, x56811

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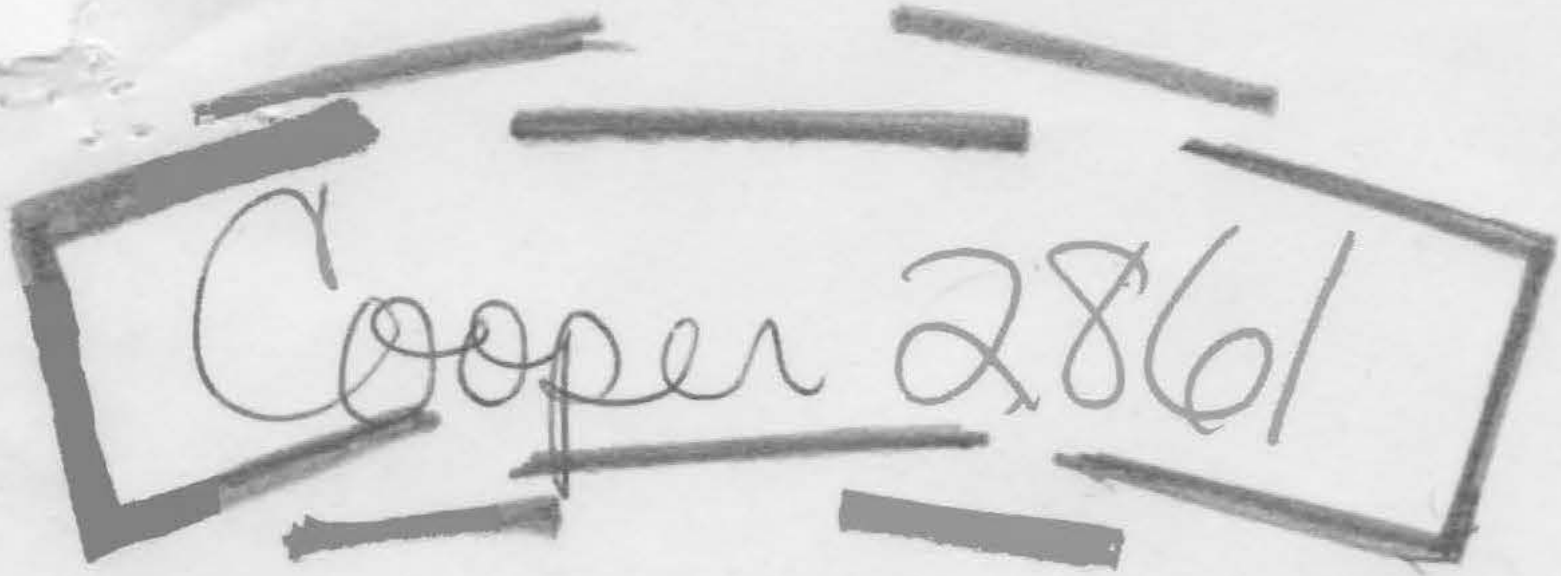
Cooper 2861

THE WHITE HOUSE

WASHINGTON

April 6, 1976

MEMORANDUM FOR: JIM CAVANAUGH

FROM: SPENCE JOHNSON SJ

SUBJECT: Presidential memorandum requesting flu immunization reports from Secretary Mathews

Attached is a memorandum for the President's signature requesting a biweekly status report from Secretary Mathews. Also, attached is a copy of the agreed-upon format between Paul O'Neill and Ted Cooper.

MEMORANDUM

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

TO : Director, Office of Management and Budget DATE:

FROM : Assistant Secretary for Health

SUBJECT: Biweekly Status Report on Nationwide Influenza Immunization Program

Accomplishments

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Problems

Actions Taken to Resolve Problems

INFLUENZA TIMETABLE

	VACCINE PRODUCTION	STATE AND COMMUNITY PROGRAMS	NATIONAL ACTIONS
March	Vaccine Formulations Prepared		Policy Decisions on National Program
April	Vaccine Evaluation Trials Initiated	Program Planning	Program Guidelines Professional Education Appropriations Enacted
May		Professional Education Community Organization	Vaccine Contracts Awarded Award Grants
June	First Lots of Vaccine Approved		
July		Immunization of High Risk Groups	First Distribution of Vaccine Implementation of Surveillance System
August		Public Awareness Community Mobilization	Public Awareness
September		Immunization of General Population	

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FEDERAL EFFORT

Biweekly Dates	CDC											
	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												
June 11												
June 25												
July 9												
July 23												
Aug. 6												
Aug. 20												
Sept. 3												
Sept. 17												
Oct. 1												
Oct. 15												
Oct. 29												
Nov. 12												
Nov. 26												
Total	4			200,000,000			62			44		

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FEDERAL EFFORT

Biweekly Dates	FDA						NIH					
	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												
May 14												
May 28												
June 11												
June 25												
July 9												
July 23												
Aug. 6												
Aug. 20												
Sept. 3												
Sept. 17												
Oct. 1												
Oct. 15												
Oct. 29												
Nov. 12												
Nov. 26												
Total	20			630			9			20		

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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						
June 25						
July 9						
July 23						
Aug. 6						
Aug. 20						
Sept. 3						
Sept. 17						
Oct. 1						
Oct. 15						
Oct. 29						
Nov. 12						
Nov. 26						
Total	200,000,000			2,000		

THE WHITE HOUSE

WASHINGTON

SIGNATURE

April 6, 1976

MEMORANDUM FOR THE PRESIDENT

FROM: JIM CANNON

SUBJECT: Memorandum to Secretary Mathews

Attached for your signature is a memorandum requesting Secretary Mathews to submit a biweekly progress report to you on the influenza immunization program. We will see that the reports are staffed to Jim Lynn and that you are kept informed of the program's progress.

The memorandum has been approved by OMB (O'Neill). The text has been approved by Doug Smith.

RECOMMENDATION

I recommend that you sign the attached memorandum.

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THE WHITE HOUSE

WASHINGTON

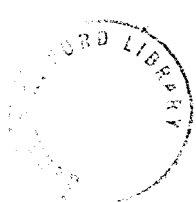
April 6, 1976

MEMORANDUM FOR

THE SECRETARY OF HEALTH, EDUCATION AND WELFARE

Last week, in my memorandum to department and agency heads, I indicated the steps necessary to ensure our goal of having the influenza vaccine available to every American this fall. I directed that the Department of Health, Education and Welfare, under your supervision, assume the responsibility for this effort. Due to the importance that I place on this effort, I plan to give it my direct and continuous attention. I expect to be kept informed, and where necessary, personally involved as the program proceeds.

Therefore, I am requesting a biweekly report from you indicating our progress toward the essential program goals and timetable targets. This is the single most important public health undertaking by the Federal Government, and we must assure completion of the task in a proper and timely manner.



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,

/s/David Mathews

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

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April 12, 1976

MEMORANDUM FOR: JIM CAVANAUGH
PAUL O'NEILL

FROM: SPENCER JOHNSON sej

SUBJECT: National Influenza Immunization Program Meeting

Monday, April 12, 1976
11:00 a.m., Roosevelt Room

Today's meeting will provide an opportunity for the Domestic Council and OMB to be brought up to date on HEW's implementation of the President's National Influenza Immunization Program. It will also be an opportunity to discuss policy and management questions.

Dr. Theodore Cooper, Assistant Secretary for Health, will be called upon to open the meeting by presenting a status report. The meeting will be attended by HEW, DOD, State, VA, CSC, and NSC.

Possible areas of discussion:

1. The question of any conflict with antitrust laws on the part of pharmaceutical manufacturers in carrying out the program. (See Tab C).

2. The question of relief of liability for manufacturers for injuries caused by properly manufactured vaccines. (See Tab D).

3. When will firm production estimates be available? This information is required as soon as possible for distribution, organization and supply planning. (Also, the Canadian memorandum; see Tab E).

4. What steps are being taken to determine the method of delivery and the types of supplies necessary? (See Tab F).

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5. How are the vaccine distribution priorities being determined? (i.e., by class of people, high risk, old, young; by states where flu outbreaks are present; by states whose delivery programs are developed; by concentration of population; or through the public system before the private because of less cost and higher rate of inoculation?)

6. How were the funding requirements of $26 million for state project grants determined? What is the significance of the States' request for an additional $30 million? Does HEW anticipate the need for additional appropriations in this area?

7. What are the cost implications for Medicare, Medicaid, and other public programs as a result of inoculation fees?

8. Will the State and local health departments be permitted to charge nominal fees for inoculation and administrative costs?

9. What are the implications for similar programs in coming years?

This is by no means an exhaustive list of questions, but rather those that have been asked most since the President's announcement.

One major topic of discussion should be the program management. At this time no one individual is totally responsible, nor spending 100 percent of their effort on the program implementation. There is, however, an HEW Intra-agency Task Force. The question is one of management accountability. Since this is a highly visible Presidential initiative it would seem that there should be a specific fulltime management team and one individual accountable 100 percent of the time.

Under the current arrangement, either HEW programs will suffer in deference to the immunization program, or the immunization program will suffer in deference to HEW priorities.

Finally, there may be some time for discussion of interagency cooperation.

Attachments

Tab A. Participants
Tab B. OPS Plan
Tab C. Antitrust Letters
Tab D. Liability Memorandum
Tab E. Vaccine Production Memorandum
Tab F. Equipment Questions: HIMA Letter
Tab G. Sample HEW Status Report

A

PARTICIPANTS

Dr. Theodore Cooper	(HEW)
Mr. St. John Barrett	(HEW)
Mr. John Blamphin	(HEW)
Dr. James F. Dickson III	(HEW)
Ms. Vivian Dobson	(HEW)
Dr. Donald S. Fredrickson	(HEW)
Dr. James C. King	(HEW)
Dr. Richard M. Krause	(HEW)
Mr. Michael J. Licata	(HEW)
Dr. Harry M. Meyer, Jr.	(HEW)
Dr. J. Donald Millar	(HEW)
Mr. Rupert Moure	(HEW)
Dr. Alexander M. Schmidt	(HEW)
Dr. John R. Seal	(HEW)
Mr. John D. Young	(HEW)
Mr. James C. Wilder	(HEW)
Dr. Paul A. Haber	(VA)
Dr. Oswald Ganley	(Dept. of State)
Mr. Vernon McKenzie	(Dept. of Defense)
Mr. Thomas Campagna	(CSC)

B

B

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
ROCKVILLE, MARYLAND 20852

APR 07 1976

NOTE TO DR. COOPER:

re: National Influenza Immunization Plan

Attached are the operating plans of the Center for Disease Control, Bureau of Biologics, and the National Institutes of Health. We have discussed these plans with other operating elements of PHS and have found no disagreement with the approach and scheduling described in the plans.

It should be noted that the public information activities related to this campaign should be further developed if other elements of PHS as well as DHEW are to play a role in this area. Attention will have to be given to the use of Secretarial and Presidential involvement vis-a-vis major public appearances and/or national television programming. The timing of such events anticipated difficulty or success in selling the campaign to the public, and the availability of key participants is critical. Accordingly, you should direct the development by CDC of a public information discussion paper.

Of additional concern is Bureau of Biologics activities related to evaluation of vaccines used by other agencies in clinical trials. Although this is treated in the operating plan, the potential difficulty of coordinating DHEW, VA, and DOD clinical trial activities to ensure that a fully representative sample is used would justify the development by BOB of a discussion paper on this matter.

William R. Berry

Attachment

FORD LIBRARY

MEMORANDUM

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

TO : The Assistant Secretary for Health
Through: ES/PHS _____ _____

DATE: MAR 25 1976

FROM : Director
Center for Disease Control

SUBJECT: National Influenza Immunization Plan - INFORMATION

The enclosed documents (TAB A) outline the national influenza immunization plan we have developed at CDC, using the Operational Planning System (OPS) approach. The objective and operating plan delineate the key steps which must be undertaken, and the points in time at which these steps must be completed. We are continuing to develop plans in greater detail for managing this program; however, the OPS influenza objective presents all the essential elements required to implement the program.

for William C. Watson, Jr.
David J. Sencer, M.D.
Assistant Surgeon General

Enclosure

Prepared by: CDC, SENCER, 3/25/76, 283-3291

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OPERATIONAL PLANNING SYSTEM

CENTER FOR DISEASE CONTROL

Objective No. 1: NATIONAL INFLUENZA IMMUNIZATION PLAN - Establish an integrated, comprehensive immunization delivery system utilizing official health agencies and private medicine, capable of making swine influenza immunization available to every person in the U.S. for whom it is not contraindicated.

Resources Required: CDC Direct Operations: $101,851,000
Project Grants to States: $ 26,000,000

JUSTIFICATION AND APPROACH

Influenza viruses are in a constant state of change with new strains frequently emerging. Hence, influenza epidemics recur periodically. The severity of these epidemics depends on a number of factors, but chief among them is the absence of immunologic familiarity of the population with the emerging strain. Thus, if major changes occur in the virus producing a strain to which most people are susceptible, vast epidemics or "pandemics" are expected. Such a situation now exists in the United States. In February 1976, an outbreak of influenza occurred among military recruits at Ft. Dix, New Jersey. The virus identified as the cause of that outbreak is Swine Influenza Virus, known technically as "A/New Jersey/8/76 (HSW 1 N 1)." This strain has not been prevalent in the United States for nearly 50 years. The strain shows sharp antigenic differences from strains which have appeared in the U.S. in the interim.

Antibody surveys among the U.S. population suggest that only persons over 50 years of age have had any immunologic experience with a similar virus. Thus, essentially those under 50 years are presumed to be fully susceptible to it. Previous experience with other influenza strains has shown that even among those over 50 who have antibodies to swine influenza, little residual resistance to the infection can be expected. In other words, they, too, are vulnerable to infection with swine influenza virus.

Though typical influenza illness is moderate and self-limited, epidemics produce large numbers of excess deaths among persons who are aged or afflicted with chronic diseases. For them, influenza is, as it were, a final insult pushing them over the brink. The last pandemic, of Hong Kong influenza in 1968, produced nearly 30,000 deaths and incurred

costs estimated at $3.9 billion. The Great Pandemic of 1918-1919 which is thought to have been due to a virus similar to the recently isolated swine influenza virus, produced over half a million deaths in the United States alone; costs of that pandemic have not been adequately estimated.

Because of a short incubation period and a high degree of infectiousness, influenza spreads with remarkable speed during the season of intense transmission, September to March. In the past, pandemic strains have spread around the world in less than a year. Vaccines are about 70 percent effective in preventing influenza but 4 to 6 months is required for their preparation from newly emergent strains. Thus, frequently in the past, vaccines have not been available soon enough to significantly alter the course of pandemics. Immunization which only begins after occurrence of an epidemic is too late to effect significant control.

The United States now faces a complex situation. Swine influenza virus has been isolated and some outbreak activity has occurred near the end of the current transmission season. The population is extremely vulnerable to rapid spread of swine influenza because such a large proportion of persons in the population has no previous immunologic experience with similar viruses. A pandemic is clearly possible. However, intense transmission is not expected to occur until next fall and winter, leaving 6 months (if action is immediate) in which to develop a vaccine and administer it to U.S. citizens.

The solution to the problem facing the United States is universal vaccination of U.S. citizens with swine influenza virus vaccine in a period of about 6 months. There is no precedent for such a program. The proposed strategy rests on the simultaneous execution of large-scale vaccination campaigns in each State, under the general direction of the State Health Officer, covering every significant population aggregate. Private medicine will be involved by the official health agency to the extent appropriate to assure universal coverage of all citizens. Clearly, however, because of the time constraints, large-scale community-wide mass vaccination programs will be the backbone of the activity.

Major tactical elements in this approach are: (1) operations of mass vaccination campaigns, (2) assessment to assure adequate coverage of the population, (3) surveillance of influenza disease (due to swine influenza virus or other etiologic agents) and of vaccine-associated reactions.

To accomplish these tactical ends will require specific supporting activities including (a) production and evaluation of the necessary vaccines, (b) Federal financial support of official State health agencies, (c) State planning and community organization, (d) training, (e) public and professional information and education.

No reasonable alternative to this course can be justified on epidemiological ground. There is no basis for selective immunization of any part of the populace. The only other alternative is to ignore the threat, do nothing, and gamble that a pandemic will not occur. A decision to take action against the threat is a decision to immunize all citizens. Based on the most recent pandemic, cost benefit ratios of widespread immunization will exceed 20 to 1 if a pandemic is averted.

It must be remembered that in addition to swine influenza, influenzas of other etiology, especially influenza A-Victoria, will be occuring in the population. As usual, it is recommended that "high-risk" groups be vaccinated against the prevalent influenza strains. Therefore, persons in the "high-risk" group will receive a bivalent vaccine, comprised of influenza A/Victoria antigen and A/swine influenza vaccine, as part of the national program addressed in this OPS objective.

OPERATIONAL PLANNING SYSTEM

ORGANIZATION: Center for Disease Control

OBJECTIVE AND OPERATING PLAN
FISCAL YEAR 1976-77

RESOURCES REQUIRED
CDC Direct Operations: $101,851
Project Grants to States: $ 26,000

OBJECTIVE NO. 1: NATIONAL INFLUENZA IMMUNIZATION PLAN - Establish an integrated, comprehensive immunization delivery system utilizing official health agencies and private medicine, capable of making swine influenza immunization available to every person in the U.S. for whom it is not contraindicated.

OVERALL EVALUATION:

STATUS REPORT FOR MONTHS OF _____

MILESTONES	COMPLETION DATE
	JAN | FEB | MAR | APR | MAY | JUN | JUL | AUG | SEP | OCT | NOV | DEC
A. PROFESSIONAL EDUCATION	
1. Initiate a continuing information program directed at health professionals, including the established professional media, direct communications, and a Speakers Bureau for medical and health related meetings.	△
B. PRODUCTION AND EVALUATION OF VACCINE	
1. Initiate vaccine evaluation field trials with first lots of vaccine.	△
2. Contingent on Bureau of Biologics (FDA) approval of vaccine formulations, initiate vaccine distribution:	
a. Bivalent vaccine for immunization of high-risk groups (20-25 million doses).	△
b. Monovalent (swin- only) vaccines for mass campaign (first 100 million doses).	—△
C. OPERATIONS	
1. Design strategy to reach total population and develop for presentation to State Health Officers.	△
2. Develop grant guidelines.	△
3. Provide technical assistance to States in development of program plans and in organization of community resources, including volunteers, civic groups, etc.	—△
4. Negotiate and contract with manufacturors for procurement of total production of influenza vaccine, additional jet guns, cold chests for field transport of vaccine, and other equipment needed for campaign.	△

ORGANIZATION: Center for Disease Control

OBJECTIVE NO.: 1
continued

MILESTONES	COMPLETION DATE											
	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
5. Work with other Federal agencies involved to achieve necessary level of interagency preparedness.						△						
6. Receive and review grant applications, make grant awards to States, and notify States of proposed vaccine allocations.					—	△						
7. Implement a comprehensive system for (a) surveillance of influenza disease due to swine influenza virus and other etiologic agents and (b) monitoring vaccine-associated reactions.							△					
8. Mobilize community resources and initiate campaign among highest risk (aged and others) population, using initial (bivalent) vaccine distribution.								△				
9. Initiate mass campaign to reach total population, using monovalent vaccine.									△			
10. Develop a plan for dealing with significant focal outbreaks of influenza.									△			
11. Monitor disease trend and outbreaks in order to direct additional immunization efforts toward epidemic control.									—	—	—	—
D. PUBLIC AWARENESS												
1. Establish information contacts at State and other operating levels and begin continuing information exchange with individuals responsible for State and local programs.				△								
2. Develop theme, strategy, and informational tools for use in multi-media campaign to coincide with availability of vaccine.						△						
3. Work with established media to assure continuing flow of information to the public through all appropriate mass media channels.				—	—	—	—	—	—	—	—	△
4. In cooperation with grantees, begin mass media campaign to stimulate action by the public.								△				

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ORGANIZATION: Center for Disease Control

OBJECTIVE NO.: 1
continued

MILESTONES	COMPLETION DATE											
	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
E. PROGRAM ASSESSMENT AND EVALUATION												
1. Develop methodology to assess program status.						△						
2. Implement assessment mechanism to coincide with initiation of immunization campaign.							△					
3. Provide feedback of assessment data to State and local health officers and other interested parties.								—	—	—	—	△
4. Evaluate program accomplishments.												△
F. TRAINING												
1. Define tasks State and local employees and volunteers will undertake in immunization campaign, and potential deficiencies in the skills and knowledge needed to complete them -- including, but not limited to:				△								
a. Jet gun operation					△							
b. Jet gun maintenance												
c. Shipping and storage of vaccine												
d. Contraindications												
e. Organizing community immunization campaign												
2. Select training solutions and develop teaching materials, checklists, manuals, practice sessions, etc. needed to achieve a properly trained work force.							△					
3. In cooperation with grantees, identify persons needing training and provide courses, practice sessions, or other skill development training as required.						—	△					

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OPERATIONAL PLANNING SYSTEM

RESOURCES REQUIRED

NIZATION: Bureau of Biologics

OBJECTIVE AND OPERATING PLAN
FISCAL YEAR 197 6-77

DRAFT

CTIVE NO. 1 : National Influenza Immunization Plan - To establish the requirements for a vaccine prepared against swine influenza which will be consistent with the need to immunize the U.S. population; to establish a smoothly functioning system which will allow vaccine assessment and official release of commercial vaccine lots to proceed smoothly and rapidly.

OVERALL EVALUATIO

STATUS REPORT FOR MONTHS OF

MILESTONES	COMPLETION DATE
	JAN | FEB | MAR | APR | MAY | JUNE | JULY | AUG | SEPT | OCT | NOV | D
Communication	
1. Dissemination of information to manufacturers and coordination of their vaccine production schedules with NIAID as it concerns clinical studies and with the CDC as it concerns mass immunization programs. This will be accomplished through frequent meetings between the manufacturers, the involved governmental agencies, members of the scientific community and the public.	— — — — — — — — — — — — △
Production and Evaluation of Vaccine	
1. Testing and distribution of virus and seed strains including original isolates and recombinants.	— — △
2. Testing of pilot lots for safety and potency in laboratory test systems.	— △
3. Clinical testing of pilot tests of swine influenza vaccine to establish optimum formulation of swine influenza vaccine in collaborative studies with CDC, NIH and military.	— — △
4. Development of guidelines for production of swine influenza vaccine.	△
5. Control testing of commercial monovalent swine influenza vaccine lots; this will be done concurrently with the manufacturers' tests in order to speed release.	— — — — — — — — — — — — △
6. Clinical testing of pilot lots of polyvalent vaccine.	— △
7. Development of guidelines for production of polyvalent vaccine.	△
8. Control test of commercial polyvalent influenza vaccine; concurrent testing will be performed.	— — — — △

ANIZATION: Bureau of Biologics

OBJECTIVE NO.: 1
continued

MILESTONES	COMPLETION DATE
	JAN | FEB | MAR | APR. | MAY | JUNE | JULY | AUG | SEPT | OCT | NOV | DEC
9. Apply new potency tests to both polyvalent and monovalent swine pilot lot vaccines and to a sample of commercial vaccines.	
10. Develop and apply new approaches to the assessment of clinical reactivity.	
11. Evaluation of experimental inactivated influenza virus vaccines used in clinical trials by other involved agencies.	
12. Evaluation of experimental live virus vaccines used in clinical trials by other involved agencies.	
C. Operations	
1. Implement system for monitoring flow of completed released vaccine lots for reliably estimating the timetable on vaccine availability and for disseminating this information to the other agencies involved.	
2. Develop in coordination with CDC, NIH, and the Armed Services information systems concerning vaccine reaction monitoring.	
3. Schedule and provide additional teams to inspect licensed vaccine manufacturers.	
4. Implement program for post-distribution monitoring of both monovalent and polyvalent vaccines.	
5. Equip facilities for expanded testing workload.	

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April 2, 1976.

National Institute of Allergy and Infectious Diseases

Fact Sheet

Supplemental Request for Influenza Research

Current Funding

FY 1976 $3,400,000

FY 1977 $4,300,000 estimated

On-going efforts are directed toward development of an improved, live vaccine which could be administered intranasally. Such a vaccine has the potentiality of being produced more rapidly and economically than a killed one. In addition, we are investigating a vaccine made from a component chemically split off from the whole influenza virus. Grant funded studies are primarily in epidemiology, virus structure, genetics and virus growth. The NIAID has an influenza research center at Baylor University and 5 vaccine evaluation centers. Influenza surveillance is also being conducted at these centers.

Supplemental Request

$4,000,000 and 9 positions

The threat of swine type influenza creates several urgent needs for research. These are 1) intensive study of the influenza viruses circulating in the pig population and of changes in these viruses related to increased transmissibility to man, 2) the determinants of pig to man transmission and later dissemination in man, 3) studies on the antigenicity and reactogenicity of the vaccines to be commercially produced to provide the data needed for

determination of dosage and usage, 4) determination of the efficacy of amantadine and other drugs in prevention and treatment of swine type influenza viruses, 5) determination of the efficacy of protection of influenza vaccines against this type of disease in volunteers and, if outbreaks occur, in population groups, 6) further research and development on experimental vaccines including live, attenuated and subunit vaccines, 7) establishment of special surveillance facilities to give us early warning of influenza activity 8) additional highly specific reagents for immunologically dissecting the influenza virus strains, 9) expanded grant supported activities in epidemiology, virus structure, genetics and virus growth.

C

ASSISTANT ATTORNEY GENERAL
ANTITRUST DIVISION

Department of Justice
Washington, D.C. 20530

APR 5 1976

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Honorable Theodore Cooper, M.D.
Assistant Secretary for Health
Office of the Secretary
Department of Health, Education
and Welfare
Washington, D. C. 20201

Dear Dr. Cooper:

This is in response to your letter of April 5, 1976, requesting our opinion as to whether the planned program for production of sufficient "Swine Flu" vaccine to inoculate virtually every American to counter a possibly serious health threat would create a situation in conflict with the antitrust laws. According to your letter, potential manufacturers of vaccine will negotiate separately with your Department with respect to its purchase of vaccine, but certain joint action regarding the use of manufacturing facilities and technology may be necessary to maximize production in this emergency.

Based upon the description of the program contained in your letter, the limitation of any joint action found necessary to the meeting of the exigencies of the current emergency, and the serious health hazard that the program is designed to avoid, we do not believe that it would present a situation in conflict with the antitrust laws.

Sincerely yours,

Thomas E. Kauper

THOMAS E. KAUPER
Assistant Attorney General
Antitrust Division

TRACER 31569

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

APR 5 1976

Mr. Thomas E. Kauper
Assistant Attorney General
Antitrust Division - Room 3109
U.S. Department of Justice
Washington, D. C. 20530

Dear Mr. Kauper:

On March 25 the President, in a special message to the Congress, announced, "The nation faces a serious potential public health threat this winter from a strain of virus known as swine influenza." Accordingly, he asked the Congress for a special supplemental appropriation of $135 million to ensure the production of sufficient vaccine to inoculate every man, woman and child in the United States, and directed Secretary Mathews and me to "develop and implement plans that will make this vaccine available to all Americans."

In seeking to carry out the President's instructions, we must call upon the drug industry to manufacture more than 200 million doses of swine influenza vaccine by the fall. To succeed in this unprecedented industry effort, licensed vaccine manufacturers may find it necessary to cooperate with each other in some aspects of the vaccines' manufacture and distribution. Accordingly, we wish to assure ourselves that no conflict with the antitrust laws will arise.

In bare outline, the Department will contract with licensed manufacturers to purchase all of the swine influenza vaccine that they can produce (subject to certain maximums) during a specified period, and will arrange to grant those vaccines to State and local public health authorities under cooperative arrangements through which those authorities will provide for the vaccines' administration.

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Specifically, we are moving now to determine our contract specifications: the vaccine quantities required, the packaging, and the delivery dates. When the specifications are established, we shall deliver them to all licensed manufacturers and invite their separate bids. Upon receipt of their bids we would expect to enter into separate negotiations with each manufacturer to improve the terms of those bids. We do not intend to negotiate with the manufacturers as a group, and do not expect them to consult with each other in formulating their bids.

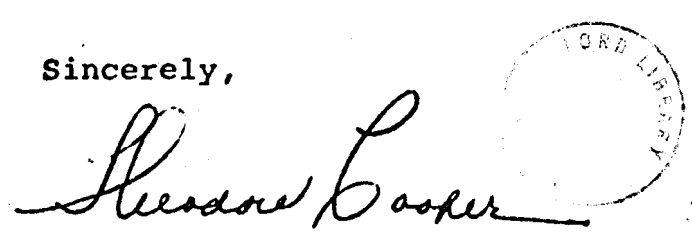
Upon completion of the negotiation process we would expect to enter into contracts that, barring an unanticipated technological breakthrough, would obligate the Department to purchase the manufacturers' entire output for a certain period.

During the course of vaccine production there are various points at which the manufacturers may consult among themselves. First, in order to maximize production they may find it necessary to pool certain of their manufacturing facilities and compare their respective technologies. Second, in light of the relative efficiency of each manufacturer, it may be necessary, after their consultation with each other and the Department, to reallocate production quotas. Finally, under Department supervision, the companies may be asked to cooperate with each other in undertaking aspects of the actual national distribution of the Government-owned vaccine.

Joint action by these companies will, of course, be limited to meeting the exigencies arising from the current nationwide public health emergency.

Please advise us whether, in your opinion, the described activities will create a situation in conflict with the antitrust laws.

Sincerely,



Theodore Cooper, M.D.
Assistant Secretary for Health

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April 5, 1976

MEMORANDUM

Need for Special Provisions Concerning Manufacturers' Liability for Swine Influenza Vaccine Produced and Labeled in Accordance with Government Specifications

Legislation to authorize the Department of Health, Education, and Welfare to initiate a program to inoculate all Americans against swine influenza is presently pending before Congress. The necessary vaccine would be purchased and made available by the federal government for use by federal, state, and local health authorities and private physicians. Recent judicial decisions concerning mass immunization programs*/ suggest that courts may impose on manufacturers a duty to warn all persons receiving the vaccine of any risks that may be associated with its use. Failure to provide warnings deemed adequate by the courts may subject manufacturers to liability for any injuries or adverse reactions that may result from use of the vaccine. This liability could be imposed even though the vaccines supplied to the federal government met the highest standards of purity, quality, and effectiveness and were labeled and manufactured in compliance with all Food and Drug Administration

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*/ E.g., Reyes v. Wyeth Laboratories, 498 F.2d 1264 (5th Cir.), cert. denied, 419 U.S. 1096 (1974).

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requirements and HEW contract specifications. Because the scope of the proposed vaccination program greatly exceeds that of any prior mass immunization effort, manufacturers are confronted with incalculable, but potentially overwhelming, exposure to damage judgments in state or federal courts.

It has been suggested that HEW could relieve manufacturers of liability for injuries caused by properly manufactured vaccines if it agreed, in its contracts with the manufacturers, to assure that adequate warnings were provided to all persons receiving the vaccine or to indemnify manufacturers for any loss they may sustain because of HEW's failure to assure proper warnings. In the absence of legislative authorization, neither approach can be counted on to protect manufacturers from liability for inadequate warnings.

If a duty to warn is imposed by the courts, it rests in the first instance on the manufacturer. According to one court, the manufacturer of a vaccine for use in mass immunization programs "is required to warn the ultimate consumer, or see to it that he is warned."*/ It is not clear

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*/ Reyes v. Wyeth Laboratories, supra, at 498 F.2d 1276.

from reported decisions that the manufacturer can discharge its duty simply by contracting with another party to provide warnings to recipients. This is especially so if the manufacturer knows, or has reason to know, that the contractual assurances may not be carried out in practice. The proposed vaccination program for swine influenza will be carried out at the federal, state, and local levels by government agencies, private organizations, and physicians. It is at least probable that HEW will be unable to control the exact manner in which each of 200 million doses of vaccine is administered. Courts may impute knowledge of this fact to manufacturers who contract with the government to supply vaccines.*/

Even if HEW assures that warnings are given to each recipient of the vaccine, courts in each state will be free to second-guess the adequacy of the warning given. They may assess its content (e.g., whether it fairly informs recipients of the risks and benefits of vaccination), the clarity of its language, and the conspicuousness of its presentation. No one can know in advance whether warnings agreed on by the government and the manufacturers will, in later damage suits, be deemed adequate by the courts. Moreover, different courts may apply different standards of adequacy. Absent special federal

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*/ In Reyes v. Wyeth Laboratories, supra the Court stressed that Wyeth could be "presumed to know" the manner in which vaccines were dispensed. 498 F.2d at 1277.

legislation, damage suits against manufacturers are governed by state law and are for the most part reviewable only by the highest court in each state.

Thus, even if HEW agrees to "assume" the duty to warn vaccine recipients, manufacturers will still face the prospect of damage judgments for injuries resulting from the vaccination program, even though their products conform fully with federal specifications. Absent special legislation, it is extremely unlikely that HEW can contract with manufacturers to indemnify them for losses sustained under such judgments. The so-called "Anti-Deficiency Act"*/ prohibits government agencies from entering into contracts or obligations for the payment of money "in advance of appropriations" unless such an obligation is "authorized by law." In California Pacific Utilities Co. v. United States, 194 Ct. Cl. 703 (1971), the Court of Claims held that

> "The United States Supreme Court, the Court of Claims, and the Comptroller General have consistently held that absent an express provision in an appropriation for reimbursement adequate to make such payment, section 665 proscribes indemnification on the grounds that it would constitute the obligation of funds not yet appropriated. Chase v. United States, 155 U.S. 489 (1894); Hooe v. United States, 218 U.S. 322 (1910); Sutton v. United States, 256 U.S. 575 (1921); Leiter v. United States, 271 U.S. 204 (1926); Goodyear Co. v. United States, 276 U.S. 287 (1928); Shipman v. United States, 18 Ct. Cl. 138 (1883); City of

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*/ 31 U.S.C. § 665(a).

Los Angeles v. United States, 107 Ct. Cl. 315, 68 F. Supp. 974 (1946); 33 Comp. Gen. 90 (1953); 35 Comp. Gen. 85 (1955)."

For these reasons special provisions must be incorporated in the swine influenza vaccine legislation to protect manufacturers against the risk of essentially unlimited liability for injuries that may result from the government's mass immunization program.

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MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Deputy Assistant Secretary for Health DATE: April 9, 1976

FROM : Director, Bureau of Biologics
Food and Drug Administration

SUBJECT: Production Estimations of A/Swine-like Influenza Virus Vaccine.

You asked that we make certain estimates relating to the production of A/swine-like influenza virus vaccine for the proposed national immunization program.

The vaccine is a licensed biologic, and the entire domestic supply is produced by several large pharmaceutical firms located in the United States. Manufacture of the vaccine requires, in addition to a license, a reliable supply of fertile eggs, specialized production facilities and equipment and trained personnel. The tooling-up process involves a series of manipulations designed to adapt the new influenza virus to optimum growth in fertile eggs. As soon as the manufacturer has prepared a supply of egg-adapted seed virus suspensions, he can institute the vaccine production cycle. The cycle for production of a particular batch of vaccine takes about two months. Seed virus is inoculated into large numbers (thousands) of fertile eggs, and after several days the virus-rich embryonic fluids are harvested. The virus is purified, concentrated and inactivated. Finally, the inactivated virus concentrate is diluted so that the end product will contain a specified amount of viral antigen per 0.5 ml. of volume human dose. This proper amount of antigen, for a new type of influenza virus vaccine, is determined by clinical trials conducted during the tooling-up process. In these trials one measures the protective antibody response of volunteers given a range of amounts of viral antigen.

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Two important variables in producing a new type of influenza virus vaccine are the degree of adaption of the seed virus to growth in eggs and efficiency of the new virus antigen in evoking a protective antibody response in recipients. Hard information becomes available only after one has adapted the virus seed, produced a series of trial vaccine batches and tested these batches in volunteers. We expect to have this type of information on the new A/swine-like vaccine by early June. However, in the absence of hard data, one can make reasonable estimates by comparing the experience with type A influenza virus vaccines produced in earlier years with the preliminary information

about the new vaccine. This sort of comparison suggests, at present, that manufacturers should be able to obtain the equivalent of about two human doses of vaccine from each fertile egg.

With full commitment, industry has the capacity of processing about 12 to 15 million eggs per month in the preparation of vaccine. Assuming that full production could be reached by June, one could then anticipate from that time on the delivery of 24 to 30 million doses of vaccine each month for as long as full production was continued.

One needs to recognize that the needs of the delivery system in the United States (actual reaching the population and inoculating the vaccine) are also estimates. There will not be 100% coverage - the inoculation of every person. No immunization program to date has reached more than 75 to 80% of the target population. Also the time required to inoculate the public (even if vaccine is available) is an estimate. Blending these production system and delivery system estimates, we come out with the impression that it might be possible to reach those "reachable" Americans by the end of November 1976 but it could require another month or two.

This ties into the question of vaccine for Canada. We will in this memo only deal with certain logistical considerations. In a normal year when the U.S. would be using 20 million doses of influenza vaccine, Canada would be using about 2 million doses. Canada has only one domestic influenza vaccine manufacturer and this firm normally supplies less than 100,000 doses; the remaining 95% or so of their supply comes from U.S. manufacturers. If Canada attempts large scale vaccination this year, its single domestic firm will be able to tool-up to produce about 300,000 doses, thus they would need 10 million or more doses from the U.S. Our production output is likely to be such that supplying Canada could extend by 10 to 15 days the time required to meet domestic needs in the U.S.

For a number of reasons not dealt with in this memo we feel it would be wise to consider Canada as an extension of the U.S. program and see that they are supplied vaccine on the same schedule as the 50 states.

Harry M. Meyer, Jr., M.D.

F

Health
Industry
Manufacturers
Association

1030 FIFTEENTH STREET, N.W., WASHINGTON, D.C. 20005 • TELEPHONE (202) 452-8240

President
Harold O. Buzzell

April 8, 1976

James F. Dickson, M.D.
Deputy Assistant Secretary for Health
Department of Health, Education
and Welfare
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Dickson:

Thank you for the opportunity to discuss briefly the equipment aspects of the swine flu vaccination program with you last week. This letter confirms the willingness of the medical device industry to make the vaccination program successful and to bring to your attention the outstanding questions which must be resolved -- and resolved quickly -- for the equipment aspects of the program to be successful.

Two preliminary comments are in order. First, the Association's members are 160 corporations including more than 235 operating companies making all varieties of medical device and diagnostic equipment. Among our members are five -- virtually all -- manufacturers of syringes and needles and the major manufacturer of injection guns. Second, all of our questions assume that the equipment needs for the swine flu program will be in excess of those required for supplying the customary needs of hospitals, physicians, and patients and that no diversion or interruption in supplying these recipients is contemplated.

The first group of questions relate to the vaccine itself. The answers here will all have a direct bearing on the nature of the equipment required by the program and whether it is possible to supply it.

1. How will the dosage be administered, orally or by injection?

2. If injected, will it be by subcutaneous or intramuscular injection?

3. How large will the dosage be? Will there be a range in dosage size, for example, for different ages?

4. How many innoculations will there be per dose, i.e., will one patient dose require two or more innoculations or a booster shot?

5. If there will be more than one innoculation per dose, what will the length of time between doses be?

The next group of questions relate to the nature of the administration and distribution system to be employed. (They assume that the vaccine will be administered by injection.)

6. What per cent of total vaccinations will be administered by injector guns? What per cent by syringes/needles? Will the Federal Government make state-by-state determinations of equipment needs or gather information about them?

7. In what geographic locations or institutional situations will each (injector gun/syringes) be used?

8. To the extent syringes are used, will different sized syringes be permitted for the same dose (e.g., will it be permissible to use a 3 cc. syringe for a 1 cc. dose)? This may be the most significant question bearing on syringe supply. The ability to utilize syringes of different sizes for the same size dose will be necessary to assure adequate supply.

9. Who will select and procure the equipment and in what quantities? Will all injector guns be purchased by the Federal Government? Will all syringes be purchased by State and local officials? If so, in either case, under what circumstances could this change?

10. How will equipment be distributed? If Federal procurement is not involved, are supplies expected to move through normal distribution channels, e.g., distributors, dealers or directly, depending upon an individual manufacturer's practice?

11. Who are the ultimate recipients of injector guns and syringes expected to be and in what locations? How will these recipients relate to the Federal or State administrators of the program in their requirements for equipment? Will private physicians be involved?

12. If normal distribution channels are not used, what provisions for security against diversion and misuse and, in the case of syringes, disposal after use are expected?

13. Are non-standard packaging or labelling requirements contemplated?

14. What sort of reporting system will be established? What records of distribution and ultimate recipients will equipment manufacturers be expected or required to keep?

15. What other equipment or supply items figure in planning for the program? To the extent the foregoing questions may be relevant to them, how will they be treated?

16. Depending on the nature of the procurement arrangements for the swine flu program, legal antitrust, product liability, and indemnity issues may arise. We expect to consult the Department's General Counsel's office on such questions.

17. A final question relates to possible international swine flu vaccination programs and their attendant demands on U.S.-produced equipment. What is now known about such programs? Would U.S. demands for equipment be Federally coordinated, if necessary, with foreign demand and, if so, how?

The foregoing questions must be answered soon. Obtaining new materials and components prior to production and effecting actual shipping and distribution after production will take from two to three of the months between now and September. Actual production time, in other words, is not the sole consideration in determining whether a given number of injector guns or syringes can actually reach the hands of users by September and October. Now, in early April, it is almost too late to be assured that the requisite equipment to administer a nationwide vaccination program for a large percentage of our citizens can be delivered in a timely fashion.

We urge, therefore, prompt resolution of these issues and the others which are sure to arise in the course of the program. We know that you and the Department share our awareness of the necessity for quick action, and we will do whatever we can to help.

We shall be in touch with appropriate officials at the Center for Disease Control and the Bureau of Biologics in order to bring our concerns to their attention and to obtain their guidance. Any information and counsel which you could provide to us on the matters raised in this letter will be appreciated.

Sincerely,

Harold O. Buzzell
President

HOB/bjo

cc: Theodore Cooper, M.D.
David J. Sencer, M.D.
Harry M. Meyer, Jr., M.D.

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MEMORANDUM

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

TO : Director, Office of Management and Budget DATE:

FROM : Assistant Secretary for Health

SUBJECT: Biweekly Status Report on Nationwide Influenza Immunization Program

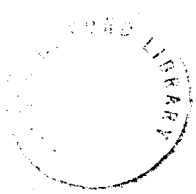
Accomplishments

Problems

Actions Taken to Resolve Problems

INFLUENZA TIMETABLE

	VACCINE PRODUCTION	STATE AND COMMUNITY PROGRAMS	NATIONAL ACTIONS
March	Vaccine Formulations Prepared		Policy Decisions on National Program
April	Vaccine Evaluation Trials Initiated	Program Planning	Program Guidelines Professional Education Appropriations Enacted
May		Professional Education Community Organization	Vaccine Contracts Awarded Award Grants
June	First Lots of Vaccine Approved		
July		Immunization of High Risk Groups	First Distribution of Vaccine Implementation of Surveillance System
August		Public Awareness Community Mobilization	Public Awareness
September		Immunization of General Population	



FEDERAL EFFORT

Biweekly Dates	CDC											
	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												
June 11												
June 25												
July 9												
July 23												
Aug. 6												
Aug. 20												
Sept. 3												
Sept. 17												
Oct. 1												
Oct. 15												
Oct. 29												
Nov. 12												
Nov. 26												
Total	4			200,000,000			62			44		

FEDERAL EFFORT

Biweekly Dates	FDA						NIH					
	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												
May 14												
May 28												
June 11												
June 25												
July 9												
July 23												
Aug. 6												
Aug. 20												
Sept. 3												
Sept. 17												
Oct. 1												
Oct. 15												
Oct. 29												
Nov. 12												
Nov. 26												
Total	20			630			9			20		

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						
June 25						
July 9						
July 23						
Aug. 6						
Aug. 20						
Sept. 3						
Sept. 17						
Oct. 1						
Oct. 15						
Oct. 29						
Nov. 12						
Nov. 26						
Total	200,000,000			2,000		

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									
May 28									
June 11									
June 25									
July 9									
July 23									
Aug. 6									
Aug. 20									
Sept. 3									
Sept. 17									
Oct. 1									
Oct. 15									
Oct. 29									
Nov. 12									
Nov. 26									
Total	62			200,000,000			200,000,000		