The original documents are located in Box 34, folder "Swine Flu (4)" of the James M. Cannon Files at the Gerald R. Ford Presidential Library.

cc: Marsh
Johnson
Swine flu

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

JUN 2 1976

MEMORANDUM FOR THE PRESIDENT

Subject: The National Influenza Immunization Program -- Participation by Manufacturers of Vaccine

Since the passage of legislation authorizing the National Influenza Immunization Program, the Department has been negotiating with representatives of the manufacturers a contract for the purchase of the vaccine. We have been attempting to include provisions in the contract which will result in the manufacturers' being liable for injuries resulting from their negligence, while the federal government will be liable for injuries resulting from its failure to perform properly those aspects of the program over which it has control. We have also been trying to provide that the government will, short of indemnification, do everything possible to make the manufacturers whole for losses they may incur as a result of lapses in the government-controlled part of the program. We have developed a contract which three of the four companies have, up until now, agreed reduces their risks in this regard to an acceptable level. A fourth company, however, Richardson-Merrell, has informed us that it is unwilling to participate in the program unless its risk resulting from failures in the government-controlled part of the program is reduced to nothing. It has been advised by counsel, and our lawyers agree, that this cannot be done under existing legislation. The Anti-Deficiency Act prohibits our entering into an agreement specifically to indemnify the contractor against any loss that it may incur, even though that loss results from our failure to perform correctly our part of the program.

Richardson-Merrell has approximately 25% of the capacity necessary to manufacture the flu vaccine. We will not be able to purchase sufficient vaccine from the remaining companies to immunize the entire population without the participation of Richardson-Merrell. There is also, of course, a substantial risk that the other companies may reassess their positions if it becomes known that Richardson-Merrell finds the small risk they are assuming unacceptable. In short, I consider that if the program is to be successful, we must secure the participation of Richardson-Merrell. Further, I

feel that their request to be protected completely and unambiguously against losses resulting from the government's failure to carry out its responsibilities under the program properly is a reasonable one. Indeed, this is exactly what we have been trying to achieve by contract language under existing law, and what the Congress understood we would do.

I am submitting draft legislation to OMB that would give us the authority to enter into a contract with the manufacturers providing for indemnity of losses in the limited situation I have described. I hope that this can be promptly proposed to the Congress.

We in the Department are, of course, ready to provide whatever further information you or your staff may wish.

Secretary

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

JUN 2 1976

MEMORANDUM FOR THE PRESIDENT

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

ACCOMPLISHMENTS

1. Approximately 3,500 adults and 650 children have voluntarily participated in clinical trials. A few reactions have been observed, however, they are of a non-serious nature and their frequency is low and well within medical and scientific experience with previous influenza vaccines.
2. Delegation of authority has been granted to the Center for Disease Control (CDC) to award grants to States to help carry out the National Influenza Immunization Program. Grant applications totalling $32,893,000 have been received from 60 project areas (States, territories, and other authorized areas). To date, 22 applications have been approved and grants awarded.
3. CDC representatives reviewed the status of NIIP activities at the Annual Conference of State and Territorial Epidemiologists on May 26, at Cherry Hill, New Jersey. NIIP was generally well received by this major group.
4. A contract for the purchase of jet injector equipment from Vernitron Medical Products, Inc., was signed on May 18. These items will be available to grantees in lieu of cash.

PROBLEMS

1. Legal problems of vaccine manufacturers.
2. International aspects of NIIP.

ACTIONS TAKEN TO RESOLVE PROBLEMS

1. General Counsel of HEW under the guidance of the Department of Justice is continuing to meet with legal representatives of the four vaccine manufacturers in an effort to resolve issues that relate to potential tort liability. Consideration is currently being given to possible legislative approaches to this problem.
2. Discussions are continuing in an effort to develop the best possible solution to the problem of whether we share our uncertain and possibly limited supplies of vaccine with Canada, Mexico, and the rest of the world.

FUTURE EVENTS

1. HEW has scheduled major briefings on NIIP in its Auditorium during the first week of June with representatives from major medical and health professional organizations (June 3, 1:00 p.m.) other Federal agencies (June 4, 9:30 a.m.) and voluntary organizations (June 4, 2:00 p.m.).
2. Grant awards will be made by CDC to the remaining project areas as applications are reviewed and approved.

Secretary

MAY 25 1976

MEMORANDUM TO THE HONORABLE JAMES M. CANNON

Some weeks ago I suggested that perhaps the way to get out of the impass we seem to have on the Canadian--Mexican flu dilemma was to open up foreign suppliers so that the United States was not the sole source of vaccine in the case of a worldwide pandemic. Ted Cooper has given this his best effort and reports in the attached memorandum that he has such assurances as he feels are possible to that end. In particular, you will note that the Canadians are not now relying solely on us, but have themselves contacted sources in Australia and France. Further, Ted has made certain that we have laid before the World Health Organization our sense of their responsibility in helping to meet a potential world problem through developing sources for the supply of the vaccine in their countries.

As a result of these negotiations, I think it is now proper that we can give assurances to the Canadians, and later to the Mexican government if they request, that we will let them buy in our market. I would suggest, however, that we might want to consider letting this message go back informally through Dr. Cooper to his counterpart in Canada, rather than using formal diplomatic channels since one of the major purposes we hope to achieve is to keep this from becoming a diplomatic exchange in which the Canadians had to formally ask for our assistance.

If the President concurs in this matter, please notify me and we will proceed as indicated.

/s/David M.,

Secretary

Attachments

246-N

THE WHITE HOUSE

WASHINGTON

June 3, 1976

MEMORANDUM FOR: JACK MARSH

FROM: JIM CANNON

SUBJECT: Swine Flu Inoculation Program Report

Attached is a copy of the most recent of Secretary Mathews' bimonthly reports to the President on the status of the swine flu inoculation program.

Attachment

THE WHITE HOUSE

WASHINGTON

May 15, 1976

MEMORANDUM FOR: JIM CANNON

FROM: JACK MARSH

Would it be helpful to have a status report on how we are coming with the swine flu inoculation program. Perhaps a report to the President from Mathews would be helpful.

Many thanks.

THE WHITE HOUSE
WASHINGTON

Date 6-7-76

To: Jim Cannon

From: Spencer C. Johnson

____FYI

____For Appropriate Action

Comments:

Jim Cavanaugh indicated that he spoke to Dick Cheney about this and a report was not required.

Spence

THE WHITE HOUSE
WASHINGTON

June 7, 1976

TO: SPENCER JOHNSON

FROM: JIM CANNON

For handling.

cc: Dr. Cavanaugh

THE WHITE HOUSE

WASHINGTON

June 7, 1976

MEMORANDUM FOR: JIM LYNN
JIM CANNON

FROM: DICK CHENEY

SUBJECT: Swine Flu Program

The attached report seems to indicate we've got serious problems in our swine flu immunization program. It's vitally important we not let this one slip through the cracks, and that we do whatever is necessary to achieve the best record possible. The President has asked for a report on the issues raised in the attached memo of June 2nd from Mathews.

cc: Jim Connor

Attachment

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

JUN 2 1976

MEMORANDUM FOR THE PRESIDENT

Subject: The National Influenza Immunization Program
-- Participation by Manufacturers of Vaccine

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Secretary

MAY 25 1976

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/s/David M.

Secretary

Attachments

-246-N

Cannon file
file Health
Swine flu

THE WHITE HOUSE

WASHINGTON

DECISION

June 9, 1976

MEMORANDUM FOR THE PRESIDENT

FROM: JIM CANNON

SUBJECT: Purchase of Swine-Type Influenza Vaccine by Canada and Mexico

Secretary Mathews has requested authorization for Assistant Secretary Cooper to informally notify his counterpart in Canada that the United States will permit Canada to purchase some swine-type flu vaccine (Tab A).

The Canadian Government has requested authorization to purchase the vaccine from U.S. manufacturers to inoculate a "selected population," including essential services and high risk persons. Although normally dependent on the U.S. for influenza vaccine, Canada has arranged to obtain a portion of their requirement from other countries. It is anticipated that the remainder could be provided by U.S. firms without jeopardizing our own program. Our own capabilities, however, cannot be confirmed until June 21 when the clinical trial data can be evaluated.

The Mexican Government has not made any request.

RECOMMENDATION

I recommend that you approve the informal communication of assurances to the Canadian Government and, if asked, to the Mexican Government, that the United States will permit the purchase of swine-type influenza vaccine to inoculate their selected population. This commitment, of course, will be based on the assurances that sufficient supplies will be available to meet the U.S. demand for the vaccine. Secretary Mathews, OMB (O'Neill), and NSC (Scowcroft) concur.

DECISION

_____Approve

_____Disapprove

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

MAY 25 1976

MEMORANDUM TO THE HONORABLE JAMES M. CANNON

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If the President concurs in this matter, please notify me and we will proceed as indicated.

Secretary

Attachments

Sent 7/7

7/6/76

THE WHITE HOUSE

WASHINGTON

June 17, 1976

RT:
VP is meeting
Dr Cooper -
perhaps on
Tuesday.
PLS do
me
Wed.
7/7.

MEMORANDUM FOR: JIM CANNON
JIM CAVANAUGH
PAUL O'NEILL

FROM: ART QUERN

SUBJECT: Influenza Program

I continue to be concerned that we are without a full-time person here in the White House to serve as a coordinator on behalf of the President for the Swine Influenza Program.

While Ted Cooper's role is clearly the lead one on behalf of the Administration, I am concerned that there is a need for someone on the White House staff to coordinate related activities of other Federal agencies, assist in the inter-governmental aspect of this project, expedite decisions when necessary, and generally assist and monitor this massive project specifically on behalf of the President.

With all due respect, I believe that Jim Cavanaugh and Paul O'Neill both have so heavy a load and so broad a range of responsibilities that it is unfair to ask them to assume this critical function. Similarly, OMB and Domestic Council staff simply do not have the time available to do this job in the manner it needs to be done.

I, therefore, again urge the designation of a single person to be the full-time White House coordinator to provide HEW with full-time White House assistance.

I am thinking of someone like Pam Needham who would know how to get things done and might be interested in taking the responsibility for a few months. (I have not discussed this at all with Pam).

AQ

[July 1976]

THE DEPARTMENT'S POSITION

1. Shared responsibility for the respective government and manufacturers' obligations.

2. No government assumption of responsibility for manufacturers' negligence.

3. We are working now on the issue of the insurance to cover the legal costs of baseless suits.

4. The Administration is opposed to any "windfall" profits as a result of the way this insurance for baseless suits is provided.

652-0974 Home

ROGER A. CLARK

ROGERS & WELLS

200 PARK AVENUE
NEW YORK, N.Y. 10017
972-7000

1666 K STREET, N.W.
WASHINGTON, D.C. 20006
331-7760

[July 1976]

~~Jack~~ Miller — (Swine Flu File)
Mayor Clarke.

Definite Break in ~~Ins~~ vaccine

Pool Insurance — (for these purposes this period)

Rogers — good strong job

(Lee Hyde — Mayor Asst
Bill Bailey. Rec Actn
Will Draft

Bailey to call ~~to~~

~~2~~ Ins paid $50 ya
at that pt govt

govt + $50 ya

Indemnification

Fed'l women pay over

$50 yr all costs —

would in turn

clean up to

neighborhood —

Which mis cos would

in turn

---

not ~~[illegible]~~ profit basis

3:30 Monday

in Mathias office —

~~[illegible]~~

[illegible]

Motor worker - Coop
more
$50-50 ok
Prudential Insurance

---

15 or 20 coming

Bobbie Kilberg 7
Cum + Forbes.

Monday is annual
5 minutes to Midnight

+ Bill to come from Administration

Call to

Bill Bailey - Aetna

AM Report
Cavanaugh Action

Mr. Cannon:

SWINE FLU REPORT - July 13, 1976

Dr. Cooper phoned to say that Sec. Mathews hosted a meeting including manufacturers, their lawyers, and some of their insurers. They went over contract language and deficiencies in liability coverage from their viewpoint. Nothing was resolved. They promised to get back to the Secretary by the end of the week with a yes or no.

I relayed the message to Dr. Cavanaugh. He suggested that the Secretary report this in writing. Dr. Cooper indicated that the Secretary was trying to reach the President by phone and that if necessary he would send us a memo to relay to the President.

July 14: Dr. Cavanaugh spoke with Sec. Mathews and Dr. Cavanaugh will write memo to President tomorrow.

DRAFT

OPTIONS:

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

Should the options in the second and third category fail, we could be quickly thrown back into consideration of program curtailment or cessation. Several of the options in the second and third category could be selected in combination. For example, you could decide to consult with the Congressional leadership without finally deciding to pursue new legislation.

Category I: Modify or Abandon the Program.

Option 1: Partial program. Under this option, the federal government would seek to acquire some or all of the stocks currently in the possession of the manufacturers and would in turn seek to vaccinate some fraction of the population. Possibilities would include the high risk population or a "first come, first serve" basis.

PROS

- Would protect some Americans

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

CONS

- Would reverse the basic thrust of our public position in behalf of the national program
- Would raise undesirable precedent for the future in federaling immunizations for selected groups
- Would force a highly undesirable set of federal choices:
  - -- Selection of high risk group raises undesirable scientific, ethical and economic consequences for those left out
  - -- A "fast come, fast serve" virtually guarantees geographic and socio-economic discrimination.
- Manufacturers might be unwilling to release the vaccine to the federal government on the grounds that they were still subject to suit.

Option 2: Abandon the program. Under the option, the Executive branch would announce that the failure of insurers to underwrite on reasonable terms and the Congress to enact the

ecessary legislation now requires abandoning our program. esumably, flu shots would still be recommended if obtainable, nd the scientific element would continue. Manufacturers ould presumably sell the current 95 million doses in rmal markets, including foreign markets.

PROS

- Would probably result in some coverage of Americans, mainly middle and upper income.
- Might permit manufacturers to obtain some insurance (higher priced) since risks in purely private undertakings are considered somewhat less.

CONS

- Excludes much of populationwa and raises price of protection.
- Could be regarded as failure on the part of President.
- Could provoke a negative and unpredictable Congressional reaction.
- Could strengthen charges that the program was a political venture.

Catagory II: Continue Negotiations without further legislation

Option 3: Presidential Discussions With the Insurance Industry

The President could ~~elect to~~ intercede personally with the leadership of the ten largest insurers and urge them to provide adequate insurance coverage to the manufacturers of the vaccine. ~~He could emphasize the importance of this national health program and discuss the adverse effects of the failure of the Public Health Service to be able to carry out this and other preventive health programs such as Polio.~~

Pro:

This action would carry the weight

of the Presidency and demonstrate the importance that our leadership attaches to preserving the health of the American people. It would represent the ultimate attempt on the part of the Executive Branch to encourage the insurance carriers to provide coverage.

~~CON~~:

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

- Might be necessary to persuade Congress to reconsider its negative view of proposed legislation.

Option 4: Indemnification Fund, from Current Program Appropriations

~~It~~ A portion of current program appropriations ~~could~~ might be made available ~~in a fixed amount, in each contract~~, as an "indemnification fund" to reimburse manufacturers for costs of defending third party law suits arising for actions other than their own negligence. Vaccine manufacturers might then be persuaded to remain in the program. An "indemnification fund" could be created in one of two ~~major~~ ways: (1) a portion of the excess ~~program~~ funds in the program could be ~~simply~~ set aside by the government and made available, as suits ~~costs~~ arise, to a maximum limit to be negotiated by ~~in each~~ contract, or (2) by inclusion of an additional, fixed amount (e.g. 10 cents per dose) in the vaccine contract purchase price. These monies which ~~go toward~~ would creating an "indemnification fund" could be justified on the grounds that it is "a part of the costs of doing business" -- a program cost which we have the authority to pay.

Pro:

- ~~(1)~~ This provision might meet ~~what we believe to be~~ the manufacturers ^ processed greatest concern -- the cost of defending a large number of baseless law suits. Assuming an "indemnification fund" of about $5 to $10 million for each contract, manufacturers might be able to obtain insurance to cover the cost of defending claims above the amount available in the "indemnification fund."

- ~~(2) If the manufacturers successfully negotiated a substantial increase in the cost in vaccine, in an amount contigent upon estimated cost of defending law suits (method 2), this could result in a windfall to the manufacturers if fewer law suits are brought than expected.~~ If ~~on the other hand,~~ the "indemnification fund" were created under government control (method 1), the Government would be paying only for costs actually incurred by the manufacturers for defending such suits.

Con:

- ~~(1)~~ The Government would be bearing the cost of defending law suits against the manufacturer

even though the government fully discharged its responsibilities under the contract.

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

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

Option 5: Formal Contract with Two or Three of the Vaccine Manufacturers In an Effort to Effect Agreement With Hold-out Company(ies).

If we could get two or three of the vaccine producers to enter into contract, this would put public pressure on the remaining company(ies) to enter into contract and release their vaccine for use in NIIP. The most likely prospects are Wyeth and Merck-Sharpe-Dohme.

Pro:

- If successful, and all four manufacturers signed contracts this would ensure adequate

supplies of vaccine to meet our National needs.

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

~~CON~~:

- If unsuccessful, the decision ~~on the part of the Public Health Service~~ to implement a national program in the absence of assurances of adequate amounts of vaccine could result in a serious over-commitment, ~~if demand exceeds supply.~~ without a clear recourse to obtain more supplies.
- The least likely companies are the largest manufacturers and have given very little indication of flexibility.

Category III: Seek new legislation

Option 6: Consulatation With Congressional Leadership by the President and Re-introduction of Previous Legislation.

In view of the major and necessary role that the Congress has played in authorizing and appropriating monies for NIIP, ~~and in view of the fact that the House Subcommittee on Health rejected our initial proposal to resolve the liability issue by new legislation, an argument can be made for consulting with pertinent members of Congress and re-introducing previous legislation to indemnify manufacturers since it appears that the Subcommittee's belief that this national program could proceed without additional legislation was wrong.~~ the President would meet with both general and health leadership of the Congress to urge reconsideration of the Administration's previous bill.

Pro:

- ~~(a)~~ The Executive Branch would be taking a responsible role in informing the Congress as to the status of contract and liability aspects of the NIIP. It woud provide an opportunity to discuss the possibility of reconsidering our previous legislation to

indemnify manufacturers for liability other than that due to their own negligence.

- ~~(5)~~ Our previous legislative proposal had broad provisions which would permit us to address, if we elected, all of the concerns of the manufacturers, including the issue of baseless suits.

Con:

- ~~Politically Liable.~~ This action by the President could be misinterpreted by the Congress, and viewed by the public, as an admission of failure ~~on the part of the USPHS, HEW and/or the President~~ to implement a "Presidential program".
- The bill still lacks the specificity desired by the manufacturers as to whether and how the Secretary will exercise his authority to handle the major problems.
- The House Subcommittee's belief that the matter could be negotiated without legislation is seriously in doubt.
- Informal Congressional "feelers" have indicated a willingness to reconsider the matter.

11

Option 7: Urge legislation that make specific the use of authority to solve problem through reinsurance. The use of Federal dollars to cover legal costs of "baseless" suits (those other than where the manufacturer is found negligent) can be approached in two ways. Either the government can pay into an indemnification fund to cover costs of baseless suits up to a certain amount, leaving to private insurance any larger amounts or the government could cover any costs of baseless above some fixed amount (the "reinsurance" approach) with regular insurance covering costs up to that fixed point. This option would adopt the latter approach.

PRO

- Would limit outer liability of insurers thus making the risks limits explicit.

- Would likely keep Federal dollars from actual use if we are right about the real risks.

CON

- Manufacturers might not accept limits proposed by Federal government

- Insurance might not be made available or made available only at a prohibitive price (e.g. full cost of claims).

Option 8: Federal Compensation for Persons Injured as a Result of Receiving Nationally Recommended, Licensed Vaccine

We could request that Congress authorize the development of a Compensation scheme to cover liability for personal injuries that are incurred as a result of participation in the National Influenza Immunization Program.

PRO:

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

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

- ~~(3) Such an approach to the liability issue~~ Would be applicable to other preventive health programs.

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

Con:

- Would establish a cumbersome Federal bureaucracy to review, arbitrate, and settle claims* -- for what may likely be very few cases each year.

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

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

*Some have refuted the claim that there would be the need to develop a new bureaucracy, by pointing that the claims reveiw board for Black Lung Disease, which is currently being phased out, could be adapted for use in NIIP.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Washington, D.C. 20201

July 18, 1976

MEMORANDUM TO THE HONORABLE JAMES CAVANAUGH

Attached is a draft of our options memo which we will discuss with Secretary Mathews tomorrow morning. It discusses the present situation regarding insurance coverage for the four manufacturers participating in the National Influenza Immunization Program. A condensed, hand-written version of the options section is also attached.

In my judgement, resolution of this problem within the next two days is of the utmost importance to the future of the program. As you know, one company has already informed us that they will be phasing out of production as of Tuesday, and a second will make a similar decision in a few days.

Theodore Cooper

Theodore Cooper, M.D.

5 p.m.

National Influenza Immunization Program
Status Report
July 19, 1976

DRAFT

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

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

C. MAJOR PROBLEMS
1. Contract Negotiations
2. Insurance Coverage

D. OPTIONS
1. Discontinue Negotiations and Modify Program
   - Option 1: Partial Program: Adopt a Federally-supported Influenza Immunization Program of Limited Size--e.g. High-risk or "First Come, First Serve"
   - Option 2: No Program: Abandon Current Attempts to have a Federal Influenza Program of Any Size
2. Continue Negotiations
   - Option 3: Presidential Discussions with the Insurance Industry
   - Option 4: Indemnification Fund, from Current Program Appropriations
   - Option 5: Formal Contract with Two or Three of the Vaccine Manufacturers, In an Effort to Effect Agreement With Hold-out Company(ies).
3. Legislation
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Existing

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MEMORANDUM

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

TO : The Secretary DATE:

FROM : Assistant Secretary for Health

SUBJECT: The National Influenza Immunization Program: Status Report, July 19, 1976 -- Action

ISSUE:

In view of discouraging responses from vaccine manufacturers that they will be unable to obtain adequate insurance to cover the risks of their participation in the National Influenza Immunization Program (NIIP), and in view of the likelihood that manufacturers will cease production and not enter into contracts to sell A/New Jersey/76 vaccine for use in the NIIP, how should we proceed?

BACKGROUND

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

-- the infectiousness of the A/New Jersey/76 (swine influenza-type) virus and its Human-to-Human spread has been well-documented in an outbreak of influenza at Fort Dix, New Jersey, involving several hundred

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military recruits, in February of this year.

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

-- Influenza remains a lethal disease.

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

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

Clinical Trials and Vaccine Safety: Results of the first phase of clinical trials which involved 5,200 volunteers in the largest pre-certification field trials ever performed, have been very encouraging. The trials demonstrate that vaccine preparations from each of the four manufacturers

was effective in immunizing persons over age 24, at as low as 200 CCA units. The effectiveness was particularly pronounced in individuals over the age of 53, since they have been primed by exposure to swine influenza-type virus during the period between 1918-1929. Reactions to vaccine at the 200 CCA dosage level among all recipients over the age 24 were minimal. For example, only 1.9 percent of recipients experienced any fever during the 48-hour observation, a frequency not significantly different from that observed in the placebo control group where 1.7 percent had fevers.

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

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

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

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

Drug Company	Number of Doses (200 CCA Units)
Merrell-National	40 million doses
Merck-Sharpe-Dohme	21 million doses
Parke-Davis	10 million doses
Wyeth Laboratories	5 million doses

(Total: 76 Million doses)

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

On July 15, 1976, we were verbally notified that Merrell-National will not purchase any more eggs after Tuesday,

July 20, and therefore, will be going out of influenza vaccine production. We also learned that Parke-Davis will be making an "imminent decision" within the next few days as to the termination of their production.

MAJOR PROBLEM

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

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

In light of these developments, the Department sought legislation to indemnify the manufacturers against losses

resulting from the Government's failure to carry out its responsibilities under the program. On July 1, the House Subcommittee on Health and the Environment refused to take action on legislation and urged all parties to resolve the liability problem through agreement and contract language.

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

Insurance Coverage: The loss of liability insurance coverage has raised some serious problems for the vaccine manufacturers: (1) They would have to pay all Judgements rendered against them in injury suits except those attributable

to the Government's failure to carry out its responsibilities in the program; (2) They would also have to bear the costs of defending all suits -- even baseless, meritless, or frivolous suits -- a burden which insurance companies normally assume.

Review of testimony provided by the American Insurance Association on behalf of 138 insurance carriers and subsequent discussions with individual representatives of major insurance brokers and carriers, have led us to conclude that members of the industry are ill-informed and that their fears as to the safety of A/New Jersey/76 vaccine are grossly exaggerated. Nevertheless, manufacturers believe that they would be taking an unjustified business risk in entering into this Federally-initiated, Congressionally-approved national program, without insurance.

OPTIONS:

Three major categories of options address the current liability question. These major options and their subsets are outlined and discussed below:

Outline:

I. Discontinue Negotiations and Modify Program

Option 1: Partial Program: Adopt a Federally-supported Influenza Immunization Program of Limited Size -- e.g. High-risk or "First Come, First Serve"

Option 2: No Program: Abandon Current Attempts to have a Federal Influenza Program of Any Size

II. Continue Negotiations

Option 3: Presidential Discussions with the Insurance Industry

Option 4: Indemnification Fund, from current Program Appropriations

Option 5: Formal Contract with Two or Three of the Vaccine Manufacturers, in An Effort to Effect Agreement with Hold-out Company(ies).

III. Legislation

Option 6: Consulation With Congressional Leadership by President to Urge Reconsideration of Existing Proposed Legislation, H.R. ——

Option 7: Federal Compensation for Persons Injured as a Result of Receiving Nationally Recommended, Licensed Vaccine

Option 8: Federal Re-Insurance to Provide "top-dollar" Coverage

Discussion:

Option 1: Partial Program: Adopt a Federally-supported Influenza Immunization Program of Limited Size -- e.g. High-risk or "First Come, First Serve".

In anticipation of an insufficient supply of vaccine to meet our full, potential needs as a Nation, a program of limited size could be developed to vaccinate only the High-Risk members of our population, or a limited number of Americans on a "First Come, First Serve" basis.

Pro: (a) Would provide Federal monies to protect at least some Americans. ("Some Federal Support is better than None")

(b) Would demonstrate our intent and commitment to preserve the health and welfare of Americans.

Con: (a) Adoption of this option would be to reverse the arguments that we made to the Congress and the public in April and June of the need to inoculate all Americans in a National Program.

(b) The decision to use Federal funds to subsidize the costs of vaccinating the High-Risk group against A/New Jersey/76 -- would set a precedent for Federalizing the immunization of select groups in future years.

(c) A decision to subsidize the High-Risk group, a substantial proportion of which are elderly, to the exclusion of other susceptible members of our population for whom the vaccine is safe -- raises issues of science, ethnics, and economics:

Science: The presence of detectable levels of specific antibody against swine influenza-type viruses among persons over 50

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suggests that this group already has some immunity -- in contrast to younger segments of our society.

Ethics: The decision to categorically exclude the millions of people between ages 24 and 64 for whom the vaccine is safe and recommended, could be construed as arbitrary, capricious, and discriminatory.

Economics: The decision to vaccinate only the high-risk group would leave the most economically productive segments of our society unprotected.

(d) To offer vaccine on a "first come, first serve" basis risks denying access to the vaccine to those who live in remote areas, or those who are elderly or disabled. One could not ensure equitable geographic distribution, and competetive, anxious situations could develop in local settings of limited vaccine supply.

Option 2: No Program: Abandon Current Attempts to have Federal Influenza Program of any size

If the Federal Government ceases to negotiate a contract and thus abandons all efforts to purchase vaccine, the manufacturers would be stuck with 95 million doses, for disposal via normal marketing channels -- direct sales to private physicians, hospitals, and clinics and to via foreign markets.

Pro:

(a) The manufacturers could probably retain insurance coverage, albeit at a higher price, since responsibility for risks would be substantially assumed, in the normal manner, by private physicians and other providers.

(b) Manufacturers would be in a position to Price their vaccine to cover increased costs required to pay for higher insurance premiums.

(c) Manufacturers would be able to supply their regular customers -- especially foreign -- in a normal fashion.

Con:

Adoption of this option would automatically exclude large segments of our population who are unable, and/or unwilling, to pay the normal office fee of ~~$10 to $15~~ (plus the ~~smaller $1-$2~~ cost of the vaccine) in order to get protection. This option would be discriminatory on socio-economic grounds.

Option 3: Presidential Discussions With the Insurance Industry

The President could elect to intercede personally, and urge the leadership of the ten largest insurers to provide adequate insurance coverage to the manufacturers of the vaccine. He could emphasize the importance of this national health program and discuss the adverse effects of the failure of the Public Health Service to be able to carry out this and other preventive health programs such as Polio immunization.

Pro:

This action would carry the weight

of the Presidency and demonstrate the importance that our leadership attaches to preserving the health of the American people. It would represent the ultimate attempt on the part of the Executive Branch to encourage the insurance carriers to provide coverage.

Con:

Should the insurance industry refuse to provide adequate coverage, this could be construed ~~characterized~~ as a personal defeat for the President.

Option 4: Indemnification Fund, from Current Program Appropriations

If a portion of current program appropriations could be made available, as an "indemnification fund", to reimburse manufacturers for costs of defending third party law suits arising for actions other than their own negligence, vaccine manufacturers might be persuaded to remain in the program. An "indemnification fund" could be created in one of two major ways: (1) a portion of the excess ~~program~~ funds in the program could be ~~simply~~ set aside by the government and made available, as suits costs arise, to a maximum limit to be negotiated by ~~in each~~ contract, or (2) by inclusion of an additional, fixed amount (e.g. 10 cents per dose) in the vaccine contract purchase price.

Such an "indemnification fund" could be justified on the grounds that it is "a part of the costs of doing business" -- a program cost for which we have the authority to pay.

Pro:

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

(b) If the manufacturers successfully negotiated a substantial increase in the cost in vaccine, in an amount contigent upon estimated cost of defending law suits (method 2), this could result in a windfall to the manufacturers if fewer law suits are brought than expected. If on the other hand, the "indemnification fund" were created under government control (method 1), the Government would be paying only for costs actually incurred by the manufacturers for defending such suits.

Con:

(a) The Government would be bearing the cost of defending law suits against the manufacturer

even though the government fully discharged its responsibilities under the contract.

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

(c) The manufacturers may not feel that the amounts the government can commit are adequate.

Option 5: Formal Contract with Two or Three of the Vaccine Manufacturers In an Effort to Effect Agreement With Hold-out Company(ies).

Convincing two or three of the vaccine producers to enter into contract, this would put public pressure on the remaining (one or two) company(ies) to ~~enter into contract and release their vaccine for use~~ participate in NIIP. The most likely prospects are Wyeth and Merck-Sharpe-Dohme.

Pro:

(a) If successful, and all four manufacturers signed contracts this would ensure adequate

supplies of vaccine to meet our National needs.

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

Con:

If unsuccessful, the decision on the part of the Public Health Service to implement a national program in the absence of assurances of adequate amounts of vaccine could result in a serious over-commitment, if demand exceeds supply.

Option 6: Consultation With Congressional Leadership by the President and Reconsideration of of Existing Proposed Legislation, H.R. _____

In view of the major role that the Congress has played in authorizing and appropriating monies for NIIP, and its present interest in seeing the program continue an argument can be made for the President encouraging the Congressional leadership to urge reconsideration of our previous legislation to indemnify manufacturers which the House Subcommittee was unable to approve. The Subcommittee's belief that this national program could proceed without additional legislation appears to be wrong.

Pro:

(a) The Executive Branch would be taking a responsible role in informing the Congress as to the status of contract and liability aspects of the NIIP. It would provide an opportunity to discuss the possibility of reconsidering our previous legislation to

indemnify manufacturers for liability other than that due to their own negligence.

(b) Our previous legislative proposal had broad provisions which would permit us to address, if we elected, all of the concerns of the manufacturers, including the issue of baseless suits.

Con:

Politically Liable: This action by the President could be misinterpreted by the Congress, and viewed by the public, as an admission of failure on the part of the USPHS, HEW and/or the President to implement a "Presidential program".

Option 7: Federal Re-insurance to Provide "top-dollar" Coverage

If a Federal program could be developed to provide re-insurance, or "~~second~~ top-dollar" coverage, vaccine manufacturers might be persuaded to remain in the program. Although, similar to our current legislative proposal before Congress (H.R. ___) to indemnify, ~~except for~~ negligience, ~~at "any dollar" level including "first-dollar"~~ all liability costs except those due to the concept of reinsurance, specifically ~~sets the~~ sets a dollar level at which insurance becomes effective. The "deductible" then would be assumed either by the manufacturer or through normal "first-dollar", primary insurance coverage.

Pro (a) Federal re-insurance would provide excess, "~~second~~ top dollar" coverage which presently is being denied by insurance carriers.

(b) An unusually large number of suits is not anticipated. Therefore, while Federal monies are being made available for real insurance, they would be protected from normal "first-dollar" coverage.

Con (a) The manufacturers may not accept, as reasonable, the dollar level at which Federal re-insurance takes effect.

(b) They may still experience difficulty in getting primary, "first-dollar" coverage.

Option 8: Federal Compensation for Persons Injured as a Result of Receiving Nationally Recommended, Licensed Vaccine

We could request that Congress authorize the development of a ~~scheme~~ plan for compensation for personal injuries incurred as a result of participation in the National Influenza Immunization Program.

Pro:

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

(b) Would indicate a responsible Federal role since the Government would license, recommend usage, and support purchase of vaccine and implementation of programs of immunization.

(c) would be applicable to other preventive health programs.

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

Con:

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

(b) Would require a major legislative effort to develop a compensation ~~scheme~~ Plan. Furthermore, the time required to develop and pass legislation would be too long to benefit NIIP.

*Some refute the need to develop a new bureaucracy, by pointing that the claims reveiw board for Black Lung Disease, which is currently being phased out, could be adapted for use in NIIP.