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**MEMORANDUM OF INFORMATION FOR THE FILE**

DATE 9/22/76

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LETTER, MEMO, ETC. Agenda

TO: —

FROM: Jim Cannon

SUBJECT: Meeting with Sec. Mathews on Swine Flu

Cooper, Ted
Taft, William H.
O'Neill, Paul
NIIP

**CORRESPONDENCE FILED CENTRAL FILES – CONFIDENTIAL FILE**

THE PRESIDENT HAS SEEN

C.F.

THE WHITE HOUSE

WASHINGTON

July 22, 1976

MEETING WITH SECRETARY MATHEWS ON SWINE FLU

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

From: Jim Cannon

I. PURPOSE

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

II. BACKGROUND, PARTICIPANTS & PRESS PLAN

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

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

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

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

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

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

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

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

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

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

C. Press Plan: To be determined.

III. TALKING POINTS

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

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

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

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

JUL 20 1976

MEMORANDUM FOR THE PRESIDENT

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

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

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

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

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

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

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

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

Secretary

Attachment

National Influenza Immunization Program
Status Report
July 20, 1976

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

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

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

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

# MEMORANDUM

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

TO : The Secretary

DATE: July 20, 1976

FROM : Assistant Secretary for Health

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

ISSUE:

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

BACKGROUND

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

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

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

-Influenza remains a serious public health and economic problem.

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

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

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

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

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

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

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

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

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

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

MAJOR PROBLEM

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

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

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

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

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

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

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

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

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

OPTIONS:

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

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

Category I: Modify or Abandon the Program

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

PRO

-Would provide Federal monies to protect some Americans

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

CON

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

-Would force a highly undesirable set of Federal choices:

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

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

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

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

PRO

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

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

CON

-Excludes much of population and raises price of protection

-Could be regarded as a failure of the Administration

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

Category II: Continue Negotiations without Further Legislation

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

PRO

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

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

CON

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

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

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

PRO

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

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

CON

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

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

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

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

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

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

PRO

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

CON

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

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

Category III: Seek New Legislation

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

PRO

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

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

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

CON

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

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

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

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

PRO

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

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

CON

-Manufacturers might not accept limits proposed by Federal government

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

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

PRO

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

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

-Would be applicable to other preventive health programs.

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

CON

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

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

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

Category IV: Other Options

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

PRO

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

CON

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

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

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

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

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

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

July 20, 1976

MEMORANDUM FOR THE PRESIDENT

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

The insurance companies to be invited should include the following:

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

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

Secretary

MEETING WITH
SECRETARY MATHEWS ON SWINE FLU

Thursday, July 22, 1976

2:30 P.M.

THE PRESIDENT HAS SEEN....