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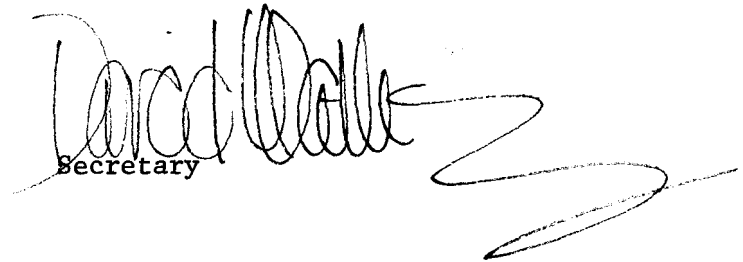


THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE
WASHINGTON, D. C. 20201

JUL 19 1976

MEMORANDUM FOR THE PRESIDENT

Attached is a paper developed by my staff concerning the status and problems of the National Influenza Immunization Program. We desire your guidance on how to proceed in resolving the key issues. This is the subject of a meeting proposed for Monday afternoon, July 19, 1976.


Secretary

Enclosure



National Influenza Immunization Program
Status Report
July 19, 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).
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 - Option 6: Consultation With Congressional Leadership by President and Reconsideration of Existing Proposed Legislation
 - Option 7: Federal Re-Insurance to Provide Top-dollar Coverage
 - Option 8: Federal Compensation for Persons Injured as a Result of Receiving Nationally Recommended, Licensed Vaccine
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 - 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.

MEMORANDUM

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

TO : The Secretary

DATE: July 19, 1976

FROM : Assistant Secretary for Health

SUBJECT: The National Influenza Immunization Program: Status Report,
July 19, 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.

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.

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 insurers 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.

Should the options in the second and third category fail, we could be quickly faced with the consideration of program curtailment or cessation. Several of the options in 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 raise undesirable precedent for the future in Federalizing the immunization of 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 "first come, first serve" program virtually guarantees geographic and socio-economic discrimination.
- Manufacturers might still 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 that the failure of insurers to underwrite on reasonable terms, and the Congress to enact the necessary legislation, now requires abandoning 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.

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

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- Excludes much of population and raises price of protection
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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 insurers 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 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.
- 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 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 would 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.

-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 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.

-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.

Option 7: Federal Re-insurance 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 (the Re-insurance 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 their risk limits explicit.
- Would likely protect Federal dollars from actual use if we are right about the real risks.

CON

- Manufacturers might not accept limits proposed by Federal government
- Insurers might not make primary, "first-dollar" coverage available to manufacturers at all, or make it available only at a prohibitive price.

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

- Would 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 available, 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.

Miscellaneous Options: In addition to the above, we considered, but excluded, other options:

- A. Purchase or Lease Vaccine Facilities
- 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
- C. Payment of Court Costs by Plaintiffs in Baseless, Frivolous Suits
- 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.

RECOMMENDATIONS

At a minimum, we offer:

- A. that you consider recommending to the President that he contact the Vaccine Manufacturers to encourage them to continue production of influenza vaccine.
- B. that you consider recommending to the President that he consult with the leadership of the Congress on the urgency of the situation.

In addition, we offer for your consideration the following, in priority order:

- C. That you Request Presidential Support for Continued Negotiations Without Further Legislation in order to Establish an Indemnification Fund from Current Program Appropriations (Option 4)
- D. That you Request Support to Seek New Legislation Through Presidential Consultation with the Congressional Leadership for the Purpose of Urging Reconsideration of Existing Proposed Legislation (Option 6)
- E. That you Request Presidential Approval to Seek New Legislation in Order to Propose a Program of Federal Re-Insurance to Provide Top-dollar Coverage (Option 7)
- F. That you Request Presidential Approval to Seek New Legislation In Order to Propose a Program for Federal Compensation for Persons Injured as a Result of Receiving Nationally-Recommended Licensed Vaccine (Option 8)
- G. That you consider recommending to the President that he contact the major insurance carriers to urge their coverage of the vaccine manufacturers so that they can participate in the program.





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/s/David Mathews

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- 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 would 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.

-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 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.

-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.

Option 7: Federal Re-insurance 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 (the Re-insurance 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 their risk limits explicit.
- Would likely protect Federal dollars from actual use if we are right about the real risks.

CON

- Manufacturers might not accept limits proposed by Federal government
- Insurers might not make primary, "first-dollar" coverage available to manufacturers at all, or make it available only at a prohibitive price.

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

- Would 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.

Miscellaneous Options: In addition to the above, we considered, but excluded, other options:

- A. Purchase or Lease Vaccine Facilities
- 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
- C. Payment of Court Costs by Plaintiffs in Baseless, Frivolous Suits
- 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.

RECOMMENDATIONS

At a minimum, we offer:

- A. that you consider recommending to the President that he contact the Vaccine Manufacturers to encourage them to continue production of influenza vaccine.
- B. that you consider recommending to the President that he consult with the leadership of the Congress on the urgency of the situation.

In addition, we offer for your consideration the following, in priority order:

- C. That you Request Presidential Support for Continued Negotiations Without Further Legislation in order to Establish an Indemnification Fund from Current Program Appropriations (Option 4)
- D. That you Request Support to Seek New Legislation Through Presidential Consultation with the Congressional Leadership for the Purpose of Urging Reconsideration of Existing Proposed Legislation (Option 6)
- E. That you Request Presidential Approval to Seek New Legislation in Order to Propose a Program of Federal Re-Insurance to Provide Top-dollar Coverage (Option 7)
- F. That you Request Presidential Approval to Seek New Legislation In Order to Propose a Program for Federal Compensation for Persons Injured as a Result of Receiving Nationally-Recommended Licensed Vaccine (Option 8)
- G. That you consider recommending to the President that he contact the major insurance carriers to urge their coverage of the vaccine manufacturers so that they can participate in the program.



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

July 20, 1976

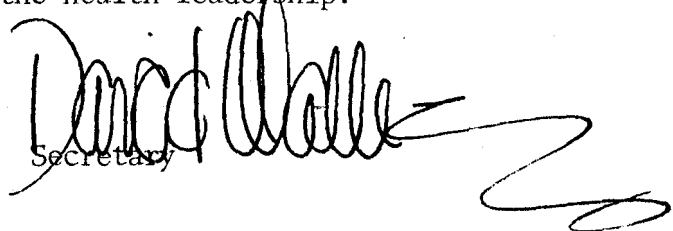
MEMORANDUM FOR THE PRESIDENT

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



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

JUL 20 1976

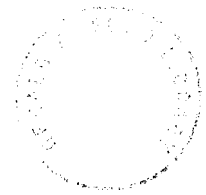
MEMORANDUM FOR THE PRESIDENT

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.

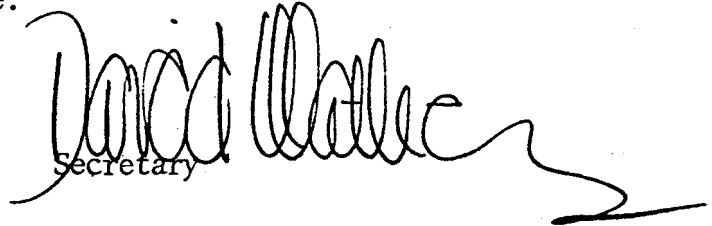
The liability problem, the underlying issue of the cost of baseless suits for supposed government negligence, and the immediate problem of keeping production going are the three issues we need to address.

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 insurers 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 insurers 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 insurers 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 insurers 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 insurers 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.

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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 insurers, 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
- Insurers 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.
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- 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 WHITE HOUSE
WASHINGTON

7/19/76

TO: JAMES CAVANAUGH



Robert D. Linder



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

JUL 19 1976

MEMORANDUM FOR THE PRESIDENT

RK
News reports that the Department of Defense has "rejected" two of the four swine flu vaccines incorrectly suggests that there is something wrong with them. Here are the facts:

Merrell-National and Merck Sharp and Dohme make "whole" virus vaccine. Parke-Davis and Wyeth Laboratories make "split" virus vaccine. Our clinical trials showed conclusively that both types produce high levels of immunity in persons over 25. People between 18 and 25, however, seem to get better protection from the "whole" virus vaccine. For this reason, the Defense Department elected to use "whole" virus vaccine rather than "split" virus vaccine because of the high number of military personnel between 18 and 25.

The Public Health Service is continuing research to determine the most effective vaccine dose in persons under 25.

The Department will issue a statement to clear up public misunderstanding on the safety and effectiveness of the four vaccines.


Secretary



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

JUL 19 1976

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/s/David Mathews

Secretary

THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE

WASHINGTON, D. C. 20201

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The President
The White House
Washington, D.C.

THE WHITE HOUSE

WASHINGTON

July 21, 1976

MEMORANDUM FOR: BILL NICHOLSON
FROM: MAX FRIEDERSDORF *m.f.*
SUBJECT: Swine Flu

Congressman Paul Rogers (D-Fla.) Chairman of the House Commerce Health Subcommittee which has jurisdiction over the President's Swine Flu vaccination program, called this afternoon with the following recommendations.

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cc: Jim Cannon, Jim Cavanaugh, Jim Lynn, Paul O'Neill, Jack Marsh
Phil Buchen



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

JUL 21 1976

MEMORANDUM FOR HONORABLE JAMES CAVANAUGH

Pursuant to my conversation of today, I am sending responses from three vaccine manufacturers. Parke-Davis does not intend to respond. The response of the American Insurance Association will be received by me and forwarded to you tomorrow, Thursday, July 22, 1976.


Theodore Cooper, M.D.

MERCK & CO., INC.

RAHWAY, NEW JERSEY 07065

July 21, 1976

RC
Reviewed
7/21/76

Honorable Theodore Cooper, M. D.
Assistant Secretary of Health, Education & Welfare
Department of Health, Education and Welfare
330 Independence Avenue, S. W., Room 5077
Washington, D. C. 20201

Dear Dr. Cooper:

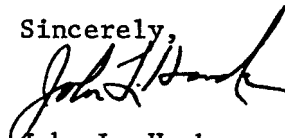
This is in response to the request from the Office of the President, which HEW transmitted to us, asking for a brief statement on why we feel we are unable to sign the proposed swine flu vaccine purchase contracts and why we feel we cannot get adequate liability insurance.

We feel we cannot sign the proposed contracts because to do so in the absence of protection against uninsured liability could involve risks too significant for us to assume. We have made 24 million doses of the vaccine thus far without contract and at our full expanded capacity. We expect to continue to make the vaccine as long as we are told by government that experts feel the vaccine is needed. We have told HEW and the Congress we will make it available on a nonprofit, cost-recovery basis. But we need, and should be accorded, appropriate protection against product liability risks. Thus far we have not been able to get such protection from the insurance industry. If that situation continues, we urge that some alternative modality be developed that will resolve the problem.

Despite our continuous approaches to the insurance companies, we have found only one company that has been willing to underwrite \$2.5 million of liability coverage. No other insurance company has been willing to underwrite liability insurance even to cover our own possible negligence. We understand that the reason for their unwillingness is their concern about accepting what they perceive to be an open-ended risk because of the unprecedented nature and dimension of the swine flu immunization program and their assumption that it will be accompanied by an unusually large number of law suits despite the relative safety of the vaccine.

I hope these brief comments will be helpful to the Office of the President. We will be happy to elaborate on them if that should be desirable.

Sincerely,



John L. Huck
Senior Vice President



cc: Wm. H. Taft, HEW

Statement by Wyeth Laboratories on the Swine Flu Vaccine Program

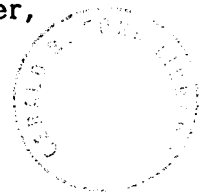
Wyeth Laboratories is still producing the swine flu vaccine and wishes very much to supply this vaccine for use in the planned nationwide immunization program.

Risk of potential liability, however, is holding up execution of the purchase contract, especially since shortly after this program was announced almost all of our product-liability insurance carriers withdrew coverage for this vaccine, leaving our insurance coverage grossly inadequate.

As soon as this program was announced, the industry advised the Congress of the liability problem and asked for legislation indemnifying the manufacturers from liability, except for any liability resulting from any negligence in manufacturing vaccine which does not meet Government specifications.

The manufacturers and the Department of Health, Education and Welfare have developed proposed contractual provisions which, according to HEW, go as far as it lawfully can without Congressional authorization, in having the Government assume such risks. However, there remain substantial liability risks which HEW has not assumed under this contract.

We have been asked to produce this vaccine on a high priority basis. Up until now, we have complied with the Government's



request for production, even though we have no contract obligating the Government to purchase the vaccine. The vaccine is intended to benefit all of the people of the country. It seems reasonable to request that the people, through the Congress, accept liability for risks other than those arising from negligent manufacture.

Rogers & Wells
1666 K Street, N.W.
Washington, D. C. 20006

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New York, N.Y. 10017

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"EURLAW" PARIS

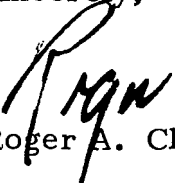
July 21, 1976

Bernard Feiner, Esq.
Assistant General Counsel
Department of Health, Education,
and Welfare
Washington, D. C. 20201

Dear Bernie:

Enclosed is the statement which you requested on behalf of Richardson-Merrell stating its views on what is necessary to consummate the contract for the purchase of the swine flu vaccine.

Sincerely,


Roger A. Clark

Enclosure

July 21, 1976

Because of the vital importance of the program in protecting the health of the American people, Merrell-National Laboratories has cooperated fully in the Government's nationwide immunization program by producing more than its share of high quality vaccine at great expense without a firm contract. Merrell wishes to continue to cooperate fully but cannot do so unless it obtains products liability insurance protection consistent with that which it has with respect to all its other products. The unacceptable risks involved are the following:

1. The present contract does not limit Merrell's potential liability to that arising out of its own negligence in failing to use due care in the manufacture and handling of the vaccine in accordance with contract specifications. Given the size of this program, many people receiving the vaccine undoubtedly will develop subsequent ailments which may bear no relationship to the inoculation other than having followed it in time. Many of these people may sue for damages and it is quite possible that a substantial number could recover even though Merrell was completely free from fault. This is the classic "deep pocket" exposure which permeates the whole area of products liability. Yet, Merrell could not recover from the Government if the Government could prove that it discharged its responsibilities under the contract. The risks of monetary judgments and legal costs cannot now be calculated or even estimated with any accuracy. These are risks inherent in the Government program and Merrell clearly should not be required to take them.

2. The contract would not allow reimbursement to Merrell for attorneys fees and other costs in successfully defending claims against it based in whole or in major part on an alleged failure to discharge properly a responsibility specifically assumed by the Government under the contract. For example, the law would permit a plaintiff to sue the manufacturer for failure to provide an adequate warning even though the Government has assumed that responsibility under the contract. The contract would also not allow reimbursement to Merrell for attorneys fees and other costs if the Government disputed its obligation under the contract and it was necessary for Merrell to obtain payment by suing the Government in the Court of Claims. In both instances, because of the size of the program the costs could be very substantial.

3. Finally, without normal insurance coverage, Merrell will not be protected against unforeseen and unanticipated "catastrophy" liability for its own negligence. This is the traditional risk-spreading function of insurance and is absolutely essential if Merrell is to participate in the program. Our insurance carriers have so far refused to provide this essential coverage. However, we continue to hope that such coverage will be made available if the Government can satisfactorily assure the insurance industry on the other points above.

In summary, it is simply not possible or fair for a private company to take on risks of possibly catastrophic loss when neither the insurance industry nor the Government is willing to assume such risks in connection with a program conceived and controlled by the Government.

THE WHITE HOUSE

WASHINGTON

July 21, 1976

MEMORANDUM FOR: BILL NICHOLSON
FROM: MAX FRIEDERSDORF *mf*
SUBJECT: Swine Flu

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cc: Jim Cannon, Jim Cavanaugh, Jim Lynn, Paul O'Neill, Jack Marsh
Phil Buchen

THE WHITE HOUSE
WASHINGTON

July 21, 1976

8:00
Health
O'Neil
Jung

MEMORANDUM FOR: JIM CAVANAUGH
FROM: SPENCE JOHNSON *sl*
SUBJECT: Congressional activities relating
to the National Influenza Immunization
Program.

This morning I had the opportunity to speak with House Health Subcommittee Chairman Paul Rogers and Lee Hyde, the staff member handling the Subcommittee's swine flu hearings. The tone of their remarks which represents the Subcommittee's attitude is quite disturbing.

Chairman Rogers, without being negative in any way, did express deep concern that the President should meet as soon as possible with the vaccine manufacturers and their casualty insurance companies. His concern was primarily that the President should be more visibly involved in seeking to break the apparent impasse which is threatening the program.

Dr. Hyde, on the other hand, was much more direct and critical. He indicated that many members of the Subcommittee had expressed concern that the Administration, especially the President and the Secretary, have not dealt strongly enough with the manufacturers and the casualty insurance companies. He indicated that it is still not clear that the Committee is willing to pass any indemnification legislation. Contrary to what the Secretary indicated in yesterday morning's meeting, although Chairman Rogers indicated to him that he wished to be helpful, this does not necessarily mean the automatic passage of legislative alternatives that the Administration might propose. In fact, it seems to me that the Congress wants to attack the attitudes and actions of the vaccine manufacturers and their insurance companies and exort the Administration to do the same.

Chairman Rogers is conducting another hearing on Friday at which the manufacturers and their insurance companies will be present, as well as Dr. Cooper. As best I can determine, his intention is to drag the body through the dust again. In the meantime, no positive legislative activity is taking place which could insure the production of the vaccine and the availability of eggs beyond Friday.

I think it is imperative that the President meet as soon as possible with the Congressional health committee leadership. It would be preferable to have the Administration and the Congress acting together for a common purpose in resolving the impasse with the manufacturers and insurance companies, rather, than having the Congress publicly berating the Administration along with the drug and insurance industries for not behaving responsibly.

In addition, there is a definite negative feeling from the House Subcommittee toward the lack of the Secretary's appearance in these forums. As might be expected, the attitude is that evidently the Secretary does not feel strongly enough about the program to come to the Congress himself and personally ask for the necessary legislation.

In my opinion, positive intervention on the part of the White House, with the Congress, is needed immediately.

Is there any action you wish me to take in this regard?

cc: Jim Cannon ✓
Art Quern

Copy sent to Spence

THE WHITE HOUSE
WASHINGTON

July 21, 1976

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