The original documents are located in Box 29, folder "Swine Flu" of the Ron Nessen Papers at the Gerald R. Ford Presidential Library.

EMBARGOED FOR RELEASE
UNTIL 5:00 P.M., (EST)

March 24, 1976

Office of the White House Press Secretary

THE WHITE HOUSE

FACT SHEET

SWINE INFLUENZA IMMUNIZATION PROGRAM

BACKGROUND

Last month an outbreak of swine influenza was isolated among recruits in training at Fort Dix, New Jersey. Although only 12 cases were confirmed, extensive blood testing has indicated that several hundred recruits were probably infected during this outbreak, and it was associated with the one death.

This flu strain, which had been dormant for almost half a century, was the cause of an epidemic in 1918-19 that killed an estimated 548,000 Americans.

The entire U.S. population under the age of 50 is susceptible. Hundreds of blood samples of individuals tested from various parts of the country show that approximately 80% of people over the age of 50 have swine-like virus antibodies in their blood from exposure to the influenza which circulated until 1930. However, the presence of these antibodies does not insure protection against the disease if it returns.

Prior to 1930, this strain was the predominant cause of human influenza in the U.S. Since 1930, the virus has been limited to transmission among swine with only occasional transmission from swine to man -- with no secondary person-to-person transmission.

Although there has been only one outbreak of swine influenza, person-to-person spread has been proven and additional outbreaks cannot be ruled out. Present evidence and past experience indicate a strong possibility that this country could experience widespread swine influenza in 1976-77. Swine flu represents a major antigenic shift from recent viruses and the population under 50 is almost universally susceptible. These are the ingredients for a severe epidemic, or pandemic. Pandemics of influenza occur at approximately 10-year intervals. In 1968-69, influenza struck 20 percent of our population causing more than 33,000 deaths (14 per 100,000) and cost an estimated $3.2 billion.

While there is no evidence that the flu has spread beyond the Army base, the reemergence of this strain has caused great concern in the medical community. Over the last few days the President has consulted with members of the Administration, health community leaders and public officials. On the basis of these consultations, the President believes that it is important to take effective counter-measures to avoid an outbreak similar to the one in 1918.

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DESCRIPTION

In view of these facts, the President has announced the following actions:

-- He is asking the Congress to appropriate $135 million prior to their April recess so that orders can be placed with the pharmaceutical industry to ensure the production of enough vaccine to inoculate every man, woman, and child in the United States.

-- He is directing HEW Secretary David Mathews, to develop plans that would make this vaccine available to all Americans during the three-month period from September to November of this year.

-- He is asking each and every American to receive an inoculation this fall.

Extraordinary measures are necessary because of the short time period available to assure adequate vaccine production and to mobilize the nation's health care delivery system. An extensive immunization program must be in full-scale operation by the beginning of September and should be completed by the end of November, 1976.

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FOR IMMEDIATE RELEASE MARCH 25, 1976

Office of the White House Press Secretary

THE WHITE HOUSE

TO THE CONGRESS OF THE UNITED STATES:

The nation faces a serious potential public health threat this winter from a strain of virus known as swine influenza.

One month ago this strain of influenza was discovered and isolated among Army recruits at Fort Dix, New Jersey. The appearance of this strain has caused concern within the medical community because this virus is very similar to the one that caused a widespread and very deadly flu epidemic late in 1918-19. Some Americans will recall that 548,000 people died in this country during that tragic period -- and 20 million people worldwide.

I have consulted with members of my Administration, leading members of the health community and public officials about the implications of this new appearance of swine flu. I have been advised that there is a very real possibility that unless we take effective counteraction, there could be an epidemic of this dangerous disease next fall and winter here in the United States.

The facts that have been presented to me in the last few days have come from many of the best medical authorities in this country. These facts do not suggest there is any cause for alarm. The scientific community understands what we are dealing with and they have developed a vaccine that will be effective in combatting it. The facts do suggest, however, that there is a need for action now -- action by the Government, action by industry and the medical community, and most importantly, action by all of our citizens.

Although no one knows at this time exactly how serious this threat could be, we cannot afford to take chances with the health of our people. Accordingly, I am taking the following action.

I am asking the Congress for a special supplemental appropriation of $135 million -- prior to their April recess -- to insure the production of sufficient vaccine to inoculate every man, woman and child in the United States.

I have directed HEW Secretary David Mathews, and the Assistant Secretary for Health, Dr. Theodore Cooper, to develop and implement plans that will make this vaccine available to all Americans.

Finally, I am asking each and every American to make certain he or she receives the vaccine this fall. Inoculations are to be available at schools, hospitals, physicians' offices, and public health facilities.

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Extraordinary measures are necessary because of the short time period available to assure adequate vaccine production and to mobilize the nation's health care delivery system. An extensive immunization program must be in full-scale operation by the beginning of September and should be completed by the end of November, 1976.

I urge the Congress to act immediately to pass this special supplemental appropriation separately. This $135 million appropriation, if acted on promptly, will be a key factor in putting this threat behind us before next winter.

GERALD R. FORD

THE WHITE HOUSE,
MARCH 25, 1976

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AMERICAN HERITAGE

THE MAGAZINE OF HISTORY

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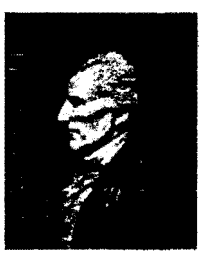

COVER: We pay tribute here to Richard Henry Lee of Virginia, who on June 7, 1776, introduced in the Continental Congress the resolution that led to the Declaration of Independence. Superimposed over the detail of Charles Willson Peale's 1784 portrait of Lee, it begins: "Resolved: That these United Colonies are, and of right ought to be, free and independent States...." The portrait is from Independence National Historic Park, Philadelphia, the resolution from the National Archives. *Back cover:* The jug is currently on loan to San Francisco's Wine Museum, from the Lowie Museum of Anthropology, University of California, Berkeley.

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FOR IMMEDIATE RELEASE JULY 9, 1976

OFFICE OF THE WHITE HOUSE PRESS SECRETARY

THE WHITE HOUSE

PRESS CONFERENCE
OF
DAVID MATHEWS
SECRETARY OF THE DEPARTMENT OF
HEALTH, EDUCATION AND WELFARE
AND
THEODORE COOPER
ASSISTANT SECRETARY FOR HEALTH
THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

THE BRIEFING ROOM

1:12 P.M. EDT

MR. NESSEN: Some of you had inquired earlier as to whether we would bring Secretary Mathews and Dr. Cooper down to see you after their report to the President. I relayed to them your request, and they agreed to come down and talk about their meeting.

The background is that the President requested today's meeting with Secretary Mathews and Dr. Cooper, so that he could hear from them an up-to-the-minute report on the status of the swine flu vaccination program. They gave him the report, and as far as I know, they are willing to pass on to you exactly what they told the President.

So, let me bring out now Secretary Mathews and Dr. Cooper.

SECRETARY MATHEWS: The President on Tuesday asked me if I and Dr. Cooper would come and give him a briefing on the flu program. We did meet with the President today and gave him a report on several aspects of the program, scientific data that had come in to date, the state of preparation at the State level for the program and most certainly the question of liability that has been much in the news.

The President's position, after hearing the report, was that we should go ahead as we planned, that it had his support, and that he would call on the interested parties to act in the public interest in this matter.

As to the matter of the question of liability, as you know, we did go to Congress to ask that the pharmaceutical companies not be held liable for our own actions in administering the program. We did not ask that they have any liability from their own negligence.

MORE

Chairman Rogers held a hearing, and after that hearing requested that we try to resolve this matter through contract negotiations with the pharmaceuticals. We are in the process of resolving that.

An additional question has arisen between the pharmaceuticals on the one hand and the insurance carriers on the other. The concern of the carriers in this case is for a different kind of liability; namely, the liability that they would incur for the cost and legal fees of baseless suits.

They have referred to this as a high risk. It is our concern that this term be properly understood because what they mean is a high financial risk. The scientific data indicate quite clearly that the medical risks that is in the side reactions to the immunization itself are little different from the risk involved in innoculation of placebos.

Our data shows that 1.9 percent of the people who got the flu shot had a fever with it, and that 1.7 percent of the people who had placebos got a fever with it, so the fever reaction to the inoculation itself is roughly the equivalent of that to placebos.

Q The placebo is like water?

SECRETARY MATHEWS: Not water, but a solution, that is right.

Q It is a nothing?

SECRETARY MATHEWS: It is a nothing.

DR. COOPER: It does not have the active agent in it.

SECRETARY MATHEWS: We are acting -- and I have offered to act -- as a mediator between the pharmaceutical companies on the one hand and the insurance underwriters on the other. We met -- our staff did -- with them on the 2nd and made certain proposals. They are to react to those proposals by close of business today.

I have offered to call a special session in my office and meet with the insurance underwriters and the pharmaceutical companies on Tuesday afternoon, if that is necessary.

The President has expressed an interest in that meeting and has asked me to give him a report on the results of that meeting on Wednesday morning.

Dr. Cooper may wish to elaborate on some of the technical and scientific data that he commands far more surely than I do.

MORE

Q Can we ask a question? One of the issues that has arisen apparently is a dispute between Drs. Salk and Sabin over the question of whether there should be this widespread inoculation or whether only certain people who might be very prone to difficulties should get it.

Now, how is that being resolved? Has the President been brought up to date on that?

SECRETARY MATHEWS: He has, and Dr. Cooper can elaborate on that discussion.

DR. COOPER: All these views were discussed at a recent two-day meeting of the advisory committees for immunization practices and the special advisory committees to the Bureau of Biologics of the Food and Drug Administration. Dr. Sabin's view on stockpiling -- and a few others who were at that meeting who had alternative proposals -- was thoroughly reviewed.

The recommendation of the experts, as well as our staff, is to take the view that for the adults in whom the vaccine has shown excellent serological response, indicating good protection as well as very low reaction rate should go on not only for the high risk population but also for the adult population.

The question that really arose at that meeting of substance was how to handle the children. The children's data indicated that we should do additional studies to find out if we could produce good serological conversion at a low reaction rate. Those studies are in progress now. The first phase of bleedings and studies are being completed today.

We will have some data on that toward the end of next week and the rest in August. But, the debate is not really between Dr. Sabin and Dr. Salk. Dr. Sabin's recommendation was that if we were going to run short and if the vaccine was not strong enough to last long enough, perhaps we should stockpile it and use it only for the high risk population.

It was the opinion of the others in the group, with which I concur, that we had the capability of insuring good protection for a long period of time for the entire adult population. That is currently the recommendation tht we are forwarding to the Secretary at the moment.

Q Dr. Cooper, with respect to the question of liability, can you amplify on the number of insurers that are involved in writing the coverage for these four licensed companies and how many of them are coming to this meeting and so on and so forth with regard to the meeting next week?

DR. COOPER: As I understand it, the insurance coverage for the major manufacturers involves a very large group of insurance companies. I am not aware of the exact number that are covering each of the four manufacturers. It is our hope that after the manufacturers have the opportunity to review the latest proposed language for contracts with their lawyers and with their underwriters, that they will select out their prime underwriters for the discussion that the Secretary has indicated that he is willing to invite them to. I don't really know the number.

Q But you are inviting all that are involved to this meeting, both insurers and manufacturers?

SECRETARY MATHEWS: Pharmaceuticals will have to indicate to us the appropriate people to call.

Q Mr. Secretary, I think a great many people wonder, having seen the initial news conference when the announcement was made of distribution of the vaccine, whether or not you are going to meet your schedule, given the problems you are having, the liability problems, the problems of production, unexpected problems, and where does it stand now as to where it stood in March when it was first announced?

SECRETARY MATHEWS: From the data we collected in these trials, we have no reason to alter the schedules that we announced initially. As a matter of fact, we have had some good fortune in that the dosage for adults now looks to be about 200 units as opposed to some 400.

DR. COOPER: Our original planning was probably at a higher level. As you know, because of the wrong batch situation, there have been some delays. This may put us somewhat off our initial start schedule, if we can produce the vaccine.

To my knowledge -- and I have been told by each of the presidents of these companies involved -- that the production schedule is continuing. I don't know what would happen if the negotiations were not able to be completed, or taken a very long time, as to what impact that might have on the schedule.

But, if we could resolve the liability issues and get on with the program, we may be delayed from what we wish to start for the high risk population by a few weeks, but we have every hope that we could meet our total target of by the end of the year reaching all those in the population for whom it is recommended.

MORE

Q So you would hope that people in nursing homes, for example, could still be inoculated possibly in August?

DR. COOPER: If we can resolve the contractual issues, yes. Late August or early September.

SECRETARY MATHEWS: Based on the hope we would indeed be able to resolve the issues before us. When I said reach our target, we announced that by December, our initial announcement, that we should be able to have some 200 million plus doses available, and we still anticipate that, although as Dr. Cooper points out, we should not underestimate and we don't mean for anything we say to underestimate the difficulties we could run into if we did not resolve the liability problem.

Q In other words, the liability problem, not the medical problem is the key to resolution of this whole sphere?

SECRETARY MATHEWS: I think that is a fair statement.

Q Even more so than production as well?

DR. COOPER: Yes, I think the technical problems of production have been well worked out. The Bureau of Biologics and the Center for Disease Control have been excellent in their quality control activities. As I understand it, from the reports that I am getting about potential here, the product production technically is in good shape. The problem here is if we will in fact write the contracts.

Q What is your definition of children agewise?

SECRETARY MATHEWS: Under 18.

Q Dr. Cooper, are you as satisfied now as you were six months ago of the need for this mass immunization program?

DR. COOPER: Yes. We discussed that again with the advisory group that gave us the original advice and the other sources. It is true that we have not seen any additional spread. This has been pointed outrepeatedly. We wouldn't expect it in this hemisphere in this season.

We did not see the Victoria strain spreading through this country until December or January last year, so that the notion that we would change our epidemilogic base of planning, because we are not seeing a lot of cases now, would be completely normal. We do not usually see this.

Now, we have stepped up our surveillance. We are seeing a few cases of flu in certain areas in the northern hemisphere. None of it is swine flu. But, this is not what we would anticipate. We would not anticipate seeing this until next flu season, if it occurs.

Q As you see it now, will the swine flu impact on the health of Americans, if nothing is done, if there is no vaccine made available? What are you talking about in terms of deaths and serious illnesses?

SECRETARY MATHEWS: To follow up on Dr. Cooper's remarks, we have never said that we are preparing against the certainty of a swine flu epidemic, and I think it is very important to keep in mind what we have tried to say over and over again about not overselling.

We are simply saying that the data we have seen from the scientific community suggests that there is a possibility that we might have a pandemic and that the virus causing that pandemic might be related to the swine-type influenza with which we have had serious problems before.

I think it would be instructive to point out that with the more common forms of virus infection, not in the pandemic state, I believe the figure was we have had 33,000 deaths a year at one point.

DR. COOPER: In 1968-1969, with the peak spread of "Hong Kong," there were several excess deaths, 33,000 approximately.

SECRETARY MATHEWS: Our statement to the public has been that if this were of the type that we had in 1918 and 1919 in its lethal effect and in its pandemic spread, that one would anticipate deaths in the hundreds of thousands, but we have never said that that would occur for certain.

DR. COOPER: We have no indication -- I would like to make this clear -- that this particular virus that did spread at Fort Dix caused a disease any more serious than the kinds we were seeing in the rest of the population this winter --"A Victoria."

But, I would call to your attention that between January and May of this year there were already over 11,000 excess deaths from influenza in this country without this new variant, so that although we don't want to use a scare tactic, I completely get frustrated when people think that flu is a trivial disease. Flu is not a trivial disease.

MORE

Now,a lot of people call any cold or any intestinal upset the flu. "I stayed home for the flu." We are not proposing a vaccination to prevent everybody from getting a cold. We are proposing a vaccination of a new variant, in which the population or for which the population has very low resistance. This is just good preventive medicine. Even if it did not occur, it has great benefits.

Q Gentlemen, could I get one thing straight? Perhaps I misunderstood you, but I thought Secretary Mathews ssaid earlier that you have no reason to alter your schedule.

SECRETARY MATHEWS: We have no reason to change the statement that we made initially, which was that by December we shouldhave available some 200 million plus doses. As Dr. Cooper said, that, of course, is contingent on how these negotiations go next week. It also -- as he pointed out, what we have experienced so far -- may mean that we may not start in the exact week that we predicted but we still anticipate starting in August.

Q So, at this point -- if I can paraphrase what you have said -- then you do not now expect to start giving the vaccine until toward the end of August, which would be a few weeks later than you had anticipated.

DR. COOPER: About a month later than we had hoped to start.

Q That situation seems clear.

DR. COOPER: We won't start at all if we don't get the vaccine.

Q That is assuming everything works out?

DR. COOPER: That is right.

Q Dr. Cooper, just an explanatory thing. Is the swine flu different from the A Victoria flu and is one flu worse than the other, and does it take a different vaccine for every type of flu?

DR. COOPER: There are different variants of the virus that causes influenza, and they are called different things by the scientists. There is a type A and a type B. In the type A there are also variations because the virus undergoes changes when it comes in contact with certain environmental situations.

Now, we have virus vaccines that are made to respond to the change to offer protection. They have been used for many years,and they are getting better all the time. The one we are using now is a very good vaccine of low medical risk for the adult population when administered properly.

That is why I get repeatedly concerned when we talk about liability and the insurance industry or the other industries or the lawyers say this is a high risk situation. What they are talking about -- high risk -- is that there may be lots of suits because a lot of people are involved, but that does not mean that the vaccine is of low quality. It is an excellent quality vaccine.

Q What are the prospects for resolving this liability question? You are going to have these meetings. Do you think you can resolve it?

SECRETARY MATHEWS: I always begin any negotiations hopefully.

Q But can you go beyond that?

SECRETARY MATHEWS: Not until we have the meetings.

DR. COOPER: Tn the early meetings this week we have made progress. There are some unresolved questions which I don't know how they will go. The Secretary has repeatedly offered to help to mediate those. If we have reached the place where we can no longer technically resolve it, we are delighted that he has offered to mediate the unresolved issues.

Q Are any negotiations going with the local agencies who are going to have to administer a lot of those shots? Some of those people were not too happy with the whole idea of the immunization program. They have to lay out some monies and some of them are dubious about the value of the vaccine. Are you getting a good response?

SECRETARY MATHEWS: Dr. Cooper's report this morning was he was pleased with the progress in the States overall. There are questions of money. There are questions of liability at the State level. One State has indicated it has some questions about whether it will immunize the whole of its population.

On the whole, we are well pleased with the state of readiness at the local level where we are going to depend for the administration of this program.

Dr. Cooper made a remark earlier on in this campaign that I thought was very appropriate. He said it was never anticipated that this could not be done without sacrifice on everybody's part, nor was it anticipated that this could be done at the Federal level alone.

Q Secretary Mathews, given the possibility that you start late, if you resolve the liability question, you would expect to have enough time to get everyone inoculated by December?

SECRETARY MATHEWS: By December. We have not changed that projection.

I might say to the question you raised earlier, it is very important, I think, to say to the American public, "You can take this vaccine that we are prescribing, developing, and still get the flu because you can take the inoculation against a swine and still get the old form," and I think we need to be extraordinarily candid with the American public because we wouldn't want people to say, "Gee, I took the vaccine that my Government recommended and I still got the flu."

There are, as Dr. Cooper said, a lot of different forms of the flu.

Q Is this the first time that you have disclosed the delay you now anticipate in starting the program?

DR. COOPER: No. After we began to report the impact that we were asked, after the delay, because of the production of the two and one half million doses of the wrong variant, and reported our schedules at that time, we have been well aware that we would have to adjust our initial starting date and probably adjust some of the age grouping administrations between the period of September 1 and the end of December.

It is still our anticipation, if the vaccine is available--with the good cooperation we are getting from the State and local systems and the volunteer agencies and the professional groups--that this can be administered within that time frame, although there will have to be changes in the starting date and changes in the rates.

Q The only thing I am trying to establish is that some of us, myself included, have not perhaps followed the day-to-day developments, so in fact you are saying that the starting date now probably would be a month later?

DR. COOPER: That is correct. If we run into additional delays because we cannot resolve the contractual issue, that could have impact on this. That is important at this point in time. As of yet, as of the moment, I am not aware that this is in jeopardy, but it may be if we cannot resolve the issue soon.

Q But the delay is a technical delay, is that right?

DR. COOPER: That was due to technical features in our original scientific and production planning.

SECRETARY MATHEWS: I believe when we made the original announcement we did not give a firm starting date because there were several questions.

One, we did not know much about the length of protection, and that would determine when we would start. We did not know much about production schedules. We did not know how many units it was going to take. We did not know whether we would get one or several doses out of an "A."

We said at the time that we would hope to start in August, that that would be the earliest, and that was the reason we asked Congress.

Q Mr. Secretary, if the liability issue is not resolved, what happens to the program?

SECRETARY MATHEWS: Quite frankly, if it were no longer possible to get protection for the pharmaceuticals for this particular vaccine, not only would it mean that this program would not be possible, but I think it would have very and negative connotations for all public immunization programs.

Q Mr. Secretary, could I ask you a couple of questions on another subject? We have heard rather detailed accounts here of how the President was irritated and displeased with this whole father-son thing, and according to Nessen, his irritation meter was about an 8 that day, and the President indicated it today.

I wonder if you could give an account from your end of the telephone how irritated the President was and if you agreed with his unhappiness with it all?

SECRETARY MATHEWS: I think the President and I got the news of this about the same time -- maybe I got it late in the afternoon beforehand -- but I would say our reactions were almost identical, as were probably the reactions of most people in the country.

It does not take a lot of thought to sense that this is not quite what we intended. As a matter of fact, this is not the first time we have had this particular problem in the department.

Some two or three months ago I issued a similar ruling when a preliminary ruling threatened Boys' State and Girls' State American Legion.

Q Mr. Secretary, how about the protests of some of the feminist groups that this sort of thing is nickle and diming the civil rights, anti-sex discrimination features of that bill?

SECRETARY MATHEWS: It is my belief that this is not what Congress intended to either protect or prohibit. We are analyzing the situation and the law, as well as our regulation, to see if that is not born out. If we have misjudged the case -- and this was indeed the clear intent of Congress -- as the President has indicated, we will go to Congress immediately to ask relief for this.

Q Mr. Secretary, you have a middle level bureaucrat, as he has been referred to here around the White House. The President, through his Press Secretary, has been very critical of this bureaucrat, a man by the name of Palimino, I understand, and apparently he was just trying to do his job.

He made a rather reasonable statement. He said you would be using Federal funds to sponsor an event where a child without a father or a mother couldn't attend, which is a reasonable thing to say, and yet he has been jumped on by the President of the United States. The Secretary of HEW says he agrees with the President, at least on the issue involved here.

I am wondering about the morale of all these bureaucrats that are getting jumped on in the election year. How do you feel about it?

SECRETARY MATHEWS: I have said, on the question of the bureaucracy, that I have questioned the results, but I have also said that I don't think that we can explain the difficulties that we are having by appealing to some devil theory.

I remember quoting to the Lieutenant Governors an old saying that came out of the south. There was a famous Confederate General who went into battle, and he was supposed to give back the usual report: "We have met the enemy and they are ours."

He was not successful in the battle, and sent back the report, "We have met the enemy and we are theirs." That was later transcribed by Pogo to say, "We have met the enemy and they are us."

We tend to react to the bureaucracy as if it were a Martian imposition of foreign origins of late. The fact of the matter is we created the bureaucracy through the legitimate processes of our Government over a long period of time.

I think if we want to correct it, what we need to do is try to understand it, and I think in this case the President did what Presidents are supposed to do, or what Cabinet members are supposed to do; that is, there are hundreds and thousands of rulings that come out of the departments or various levels of department interpretations.

People will very often ask for a reconsideration, and it is my job and the President's job to look at those interpretations and make a judgment; that is, to know enough about how the bureaucracy works and to know enough about what good policy intent is to make a second judgment, and we did in our role what seemed to be quite normal.

Q If I may follow that up, my question really was, how about the morale of these people who are out there trying to make these decisions on the basis of limited information?

This fellow, I understand, works out of San Francisco, and he read the statute involved here and maybe he does not know Congressmen well enough to know what their intent is.

SECRETARY MATHEWS: That is why I said there is a review mechanism in Government, and it isn't inappropriate for me or for the President to do our job, and it doesn't mean that because we do our job and disagree with a regulation that is sent up or disagree with a preliminary ruling in some way, that the person involved is at fault. It seems to me that is the proper workings of the system.

Q I always thought it was considered poor leadership to criticize an underling.

SECRETARY MATHEWS: I don't know that anybody has criticized anything --

Q Yes, the White House.

Q Can I get back to something? I have one economic question.

SECRETARY MATHEWS: -- but I think the question is on the validity of the interpretation. I think the interpretation was too literal and we are reviewing it for that purpose.

Q Dr. Cooper, one more question with regard to the flu situation. In your preliminary negotiations with the insurers and the pharmaceuticals, do you get the indication that the insurance industry is going to be able to resolve this problem reasonably both with regard to scope of coverage and range of premium?

DR. COOPER: Let me make it clear, I personally have not negotiated with the insurance industry. I have negotiated with the pharmaceutical industry. I have participated in discussions with Mr. Lesley Cheek, who represents the American Insurance Association. It is my hope, in answer to your question, yes, that we can resolve the question and, as the President said, he wants all of us to act in the public interest. I think if we do, we ought to be able to resolve it.

Q As I can understand it, there is no objection from the industry about us paying 50 cents a shot for this stuff?

DR. COOPER: This has never been an issue. We have not even negotiated anything further on that at this point in time.

Q If they can make three doses for a shot, this might turn into a great big rip-off.

DR. COOPER: There is no way that can happen. We monitor those preparations, we know the process, we have people on-site at frequent times monitoring it. Our original estimates were based on our complete familiarity with the process involved. So, there is no ability here for them to rip us off.

Q Wasn't it also, in giving this 50 cent a shot, as an estimate of what the insurance would cost them?

DR. COOPER: No, sir. I think at various times the basis for the quotes that we get on a bid have been of different make-up. Now, I have not seen myself, because it is improper for me until this other issue is resolved and the contractual negotiators have completed their legal responsibilities, the make-up of each bid, so that usually operating costs, overhead costs are included in some of these.

Our estimates were based on that we have not negotiated their specific bids. All companies have bid, but we haven't answered the bids because of the contingency question about liability.

Q I wonder why they didn't include in their cost the cost of insurance?

DR. COOPER: Because they were told, at least as they reported to us, that the companies that were insuring them wouldn't cover them for this product of that program.

THE PRESS: Thank you.

END (AT 1:45 P.M. EDT)

FOR IMMEDIATE RELEASE AUGUST 4, 1976

Office of the White House Press Secretary

THE WHITE HOUSE

TEXT OF A LETTER BY THE PRESIDENT
TO THE SPEAKER OF THE HOUSE
AND PRESIDENT OF THE SENATE

Dear Mr. Speaker: (Mr. President)

On March 24, 1976, after meeting with a distinguished group of physicians, scientists and public health experts, I asked the Congress to appropriate $135 million dollars for the production of sufficient swine flu vaccine to inoculate every man, woman and child in the United States. I also directed the Secretary of Health, Education, and Welfare to develop plans that would make this vaccine available to all Americans. The Congress moved quickly on my appropriation request, and I was pleased to sign it into law April 15.

Since that time HEW, working with the medical profession, State and local health officials, vaccine manufacturers, and other groups, have developed extensive plans to see to it that our original goal of making this vaccine available to all Americans can be met.

We continue to be faced, however, with a major problem in meeting our goal. Although experience indicates that there is a very low risk of untoward reactions to the vaccine, the drug manufacturers producing this vaccine for HEW need some form of appropriate liability protection.

On June 16, in anticipation of this situation, I directed HEW Secretary Mathews to immediately submit legislation to the Congress to enable the government to assume a proper share of risks so that this important program might move ahead.

This morning I received a report from the Secretary that after seven weeks of discussions and negotiations, the Health and Environment Subcommittee of the House Interstate and Foreign Commerce Committee acted last night to report legislation that would, if enacted by the House and Senate, correct this problem, which has unnecessarily delayed this vital program.

I am writing to you this afternoon to urge that the House of Representatives move quickly to enact this legislation so that the vaccine can be made available without further delay.

In conclusion, let me reiterate a point that I made in March and again to Chairman Paul Rogers on July 23: The threat of swine flu is genuine. Data from both the scientific and medical communities support the need for an inoculation program. Clinical tests conducted to date show that the vaccine is both safe and effective. There is no excuse now to let this program -- a program that could affect the lives of many, many Americans -- be delayed any longer. Let's work together to get on with the job.

Sincerely,

Gerald R. Ford

# # #

THE WHITE HOUSE

WASHINGTON

August 4, 1976

MEMORANDUM FOR: JIM CANNON
JIM CAVANAUGH
DICK PARSONS
DAN McGURK

FROM: SPENCE JOHNSON

SUBJECT: Influenza Immunization Program Legislation

Last evening the House Health Subcommittee, chaired by Congressman Rogers, reported the attached bill.

This is similar to the Administration's draft to provide indemnity under the Federal Tort Claims Act. The only amendment made in subcommittee was to change the term "agent of the government" to "program participant".

Currently, it is the intention of the Chairman to try to pass this measure before the recess. Full committee action could occur any time between now and next Tuesday, and Floor action shortly after.

However, prior to full committee action Chairman Rogers will hopefully clear the measure with the Judiciary Committee so that sequential referral is not necessary. Also, the reaction of the manufacturers and insurance companies will be evaluated to see if further amendments at the full committee are necessary to satisfy any additional concerns.

It is important to note that this legislation was pushed through the subcommittee by the Chairman and two other members by the use of proxies over the objections of four other subcommittee members. This could result in a heated session in the full committee. HEW legislation liaison is preparing to seek support of the full committee members. It might be well for the White House Congressional Relations to do the same.

The Subcommittee on Health and the Environment, of the House Interstate and Foreign Commerce Committee reported a measure last evening that would establish a mechanism to compensate persons injured as a result of inoculation with vaccine under the National Influenza Immunization Program. The bill, very similar to a proposal presented to the subcommittee by Secretary Mathews, would provide that persons injured as a result of inoculation under the Program would have as their exclusive remedy a suit against the Federal government under the Federal Tort Claims Act.

Under this bill, the Federal government would be liable for claims against "program participants", including the vaccine manufacturers and distributors who participate in the Program, the public and private agencies or organizations that participate in the Program without charge for the vaccine or its administration, and the medical and paramedical personnel who, without charge for the vaccine or its administration, administer or assist in administering inoculations with such vaccine.

At the same time, the government retains the right to recover for any negligent act of a "program participant" that results in a settlement or court judgement.

Physicians who administer the vaccine in their normal practice for a fee would be covered by their regular malpractice insurance and would not be included in this Program.

FOR IMMEDIATE RELEASE AUGUST 4, 1976

Office of the White House Press Secretary

THE WHITE HOUSE

TEXT OF A LETTER FROM THE
PRESIDENT TO THE SPEAKER OF THE
HOUSE OF REPRESENTATIVES
AND THE HONORABLE MIKE MANSFIELD

August 4, 1976

Dear Mr. Speaker: (Senator Mansfield:)

On March 24, 1976, after meeting with a distinguished group of physicians, scientists and public health experts, I asked the Congress to appropriate $135 million dollars for the production of sufficient swine flu vaccine to inoculate every man, woman and child in the United States. I also directed the Secretary of Health, Education, and Welfare to develop plans that would make this vaccine available to all Americans. The Congress moved quickly on my appropriation request, and I was pleased to sign it into law April 15.

Since that time HEW, working with the medical profession, State and local health officials, vaccine manufacturers, and other groups, have developed extensive plans to see to it that our original goal of making this vaccine available to all Americans can be met.

We continue to be faced, however, with a major problem in meeting our goal. Although experience indicates that there is a very low risk of untoward reactions to the vaccine, the drug manufacturers producing this vaccine for HEW need some form of appropriate liability protection.

On June 16, in anticipation of this situation, I directed HEW Secretary Mathews to immediately submit legislation to the Congress to enable the government to assume a proper share of risks so that this important program might move ahead.

This morning I received a report from the Secretary that after seven weeks of discussions and negotiations, the Health and Environment Subcommittee of the House Interstate and Foreign Commerce Committee acted last night to report legislation that would, if enacted by the House and Senate, correct this problem, which has unnecessarily delayed this vital program.

I am writing to you this afternoon to urge that the House of Representatives (Senate) move quickly to enact this legislation so that the vaccine can be made available without further delay.

more

In conclusion, let me reiterate a point that I made in March and again to Chairman Paul Rogers on July 23: The threat of swine flu is genuine. Data from both the scientific and medical communities support the need for an inoculation program. Clinical tests conducted to date show that the vaccine is both safe and effective. There is no excuse now to let this program -- a program that could affect the lives of many, many Americans -- be delayed any longer. Let's work together to get on with the job.

Sincerely,

GERALD R. FORD

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FOR IMMEDIATE RELEASE AUGUST 6, 1976

OFFICE OF THE WHITE HOUSE PRESS SECRETARY

THE WHITE HOUSE

STATEMENT BY THE PRESIDENT

THE BRIEFING ROOM

3:38 P.M. EDT

I have been following with great concern the investigations into the cause of the tragic outbreak of illness in Pennsylvania this past week. All Americans join me in their sympathy for the families of more than 20 people who have died and their hope for the speedy recovery of those currently under treatment.

I am greatly relieved, of course, that these tragic deaths were not the result of swine flu. But let us remember one thing, they could have been.

The threat of swine flu outbreak this year is still very, very genuine. Data from the scientific community clearly supports the need for a full-scale inoculation program. Clinical tests conducted to date clearly demonstrate that the vaccine is both safe and effective. There is no excuse to let the legislative program that I proposed seven weeks ago -- a program that could safeguard the lives of many, many Americans -- be delayed any longer.

HEW Secretary Mathews and the leaders of Congress reported to me on Wednesday that after long hours of hearings, discussions, negotiations, Congress would finally act yesterday to pass legislation to provide swine flu vaccine to all American people.

Needless to say, I was keenly disappointed to learn last evening that the news from the doctors in Pennsylvania had led to another slowdown in the Congress. I am frankly very dumbfounded to know that the Congress, which took the time and effort to enact ill-advised legislation to exampt its own Members from certain State income taxes, has failed to act to protect 215 million Americans from the threat of swine flu.

Drug manufacturers have produced over 100 million doses of swine flu vaccine in bulk form. But that vaccine has not been prepared in suitable dosage form pending action by the Congress.

MORE

Because of these legislative delays, we are, at this moment, at least, six weeks away from beginning an effective inoculation program.

Had Congress acted promptly after I submitted my proposal, we would have been in a position to dispatch the shipments of vaccine today.

Further delay in this urgently needed legislation is unconscionable. I call on the Congress to act now before its next recess, so that the health of the American people will be fully protected.

Thank you very much.

END (AT 3:41 P.M. EDT)

FOR IMMEDIATE RELEASE SEPTEMBER 2, 1976

OFFICE OF THE WHITE HOUSE PRESS SECRETARY

THE WHITE HOUSE

PRESS CONFERENCE
OF
DAVID MATHEWS
SECRETARY OF HEALTH, EDUCATION AND WELFARE
AND
DR. THEODORE COOPER
OFFICE OF SECRETARY OF HEW

THE BRIEFING ROOM

5:40 P.M. EDT

MR. CARLSON: As you know, Secretary Mathews and Dr. Cooper just spent about 45 minutes with the President, bringing him up-to-date on the swine flu program, and here to answer your questions and summarize the meeting are Dr. Cooper and Secretary Mathews.

SECRETARY MATHEWS: We did meet with the President, as we have done periodically. You will recall that I appeared before you about every four to six weeks in the process of making a report to the President. What we are doing is accounting for the delay that was occasioned by the problem of liability insurance.

That necessarily forces some adjustments in the schedule that we announced here in August of roughly six weeks. The State associations that had geared their programs to that schedule and announced in August are going to have to delay the administration of the program until the time that we get the vaccine, which we anticipate to be in the first week of October. In addition to that, we have been in contact with the manufacturers to discuss their program to date and the schedule for the delivery of the doses.

I did write the manufacturers on August 31 to indicate that the information I had about the schedule for the availability of the doses seemed to me to be off the pace more than it should be, and I would appreciate, I said in the letter, if they would revise those schedules upward.

Dr. Cooper has been in conversation with each of the manufacturers today and they tell him that there has been no delay -- other than for the obvious one that we all know about -- no delay in their manufacturing or bottling -- they use the term "flat-out" to describe their work.

MORE

We thanked them for that, and we encouraged them to consider overtime or even a faster schedule if necessary, so that we could begin this program the first week in October.

That, as you know, is the date when the legislation calls for the claims system to go into effect. Quite frankly, we would like to get delivery on those doses beforehand. We did not anticipate there would, even under the best circumstances, be much before September 15. We said at the time we had the delay, I testified on the Hill that if we got a resolution on the date of the testimony, that it would be five to six weeks for us to go through the bottling period.

Well, that would have run us to about September 15 anyhow. But we would like to get delivery then or as soon thereafter as possible.

There is some hesitation, I understand, on the part of the legal advisers to the manufacturers because they interpret the October date to be the permissible date for starting the program. It is our view, and I believe it is the view of the Congress, that is simply the date which one may file a claim under the program. We hope that we can clarify that so that we can get delivery.

We do now have manufactured already enough dosage to supply the needs of the adult population at the expected rate of use of the vaccine. A recent poll indicates that most Americans are aware of the program. About 56 percent have indicated that they plan to take the shots. Another 20 percent are undecided.

Let's assume that between 70 and 80 percent of the adult population of about 150 million poople will want the dosage. That would mean that we would have to have about 110 to 115 million doses. We already have manufactured that amount.

Dr. Cooper reminds me to say in bulk form.

So, we are concerned about the delivery schedule, we are concerned that we encourage the manufacturers and work with them any way we can to make sure that the schedule for delivery is as early as possible. We do have a six-weeks delay that we discussed in July. That was the delay that occurred then, and we do have assurances from them that they are working, as they put it, "flat-out" in the production and the bottling of the vaccine.

MORE

Q Mr. Mathews, you said you encouraged them to work overtime, or you said something else?

SECRETARY MATHEWS: As fast as necessary.

Q What response did you get?

SECRETARY MATHEWS: They indicated they would consider that. Dr. Cooper actually talked to them, but their report to us was that they had no intention of doing anything other than being cooperative and that they were, to use their phrase, working flat-out in the production and the bottling of the vaccine.

Q And the September 15 date, as far as they are concerned over liabilities, have their concerns been assuaged and are they now ready to deliver, if it is ready?

SECRETARY MATHEWS: We are not in a position to say that.

Q Mr. Secretary, I am wondering why you were so surprised, as people in your Department indicated, with their delivery schedule being so far below what you expected? Secondly, if they are now working seven days a week and 24 hours a day, how can they do any more?

DR. COOPER: Not all are working 24 hours a day. Most are working seven days a week. Some have indicated to me that they have double shifts. So, that is not really a round-the-clock necessarily, all the way. Every one of the manufacturers has in good faith continued to work every day on this and have indicated to me today that they will reassess the rate at which they can provide the early supply.

Now, let me respond to the other part of your question by saying we were not surprised about the total numbers because we knew what the total numbers were when the Secretary testified in August. What we were concerned about was the shape of the curve of delivery of it, from the early part, the skewing of the curve, what its delivery would be, because there had been testimony about whether or not -- you know, if the indemnification legislation was passed, it would take weeks and so on.

So, we expected the larger peak early and it was on this regard we were somewhat concerned. The manufacturers have indicated they are going to study the possibilities for improving that early delivery.

There was the problem of October 1 for delivery. You also have to recall in that law, as the Secretary has pointed out, that there are certain cost responsibilities that are involved.

Q In that context, you are talking about the possibility of overtime, and you do not yet have any contracts between the drug firms and the vaccine manufacturers. Now, it would seem to me probably that if these people are going to work overtime, it is going to cost even more.

And what about this contract thing? As I understand it, there is a controversy about what "reasonable" profit shall be, not for the swine flu vaccine, but for the A-Victoria, of which 45 million doses are to be combined.

SECRETARY MATHEWS: I don't think you should put too much literal emphasis on the word "overtime." That is to say, we contacted them and said we really hoped they would work at maximum effort to give us the vaccine on a schedule that, as Dr. Cooper said, shifted more of it toward the front than the present profile indicated.

Now, obviously, a contract cannot be completed until we have the price. Obviously, too, the price is set by law to be a not-for-profit price. So, we now have the auditors in the companies making a determination of what that price is.

How to expedite the contract--we have indicated to them verbally, and will indicate in writing this week the general form of the contract. Dr. Cooper has talked to them about the general form of the contract in the manner of a letter of intent. They have indicated on the basis of what they have heard about it, and they will have a chance to see it in writing this week, that they feel comfortable with signing that. So, we don't anticipate the inevitable auditing that would set the precise price to limit coming together on an agreement on the contract.

Q You didn't answer my question about the "reasonable" profit of the 45 million doses.

DR. COOPER: They have verbally agreed to accept a letter of contract, which will allow us to continue the auditing and determination without impeding production and bottling and delivery of the vaccine.

Q In other words, they might start to deliver even though there are no contracts?

DR. COOPER: Yes.

Q Is delivery being held up more because of supply or because of concern over liabilities?

SECRETARY MATHEWS: If you mean by supply is the bulk form of the vaccine there, obviously it is there.

Q Can they get it into vials fast enough -- but is it because of their concern over liabilities that they won't deliver by October 1?

SECRETARY MATHEWS: Even by our estimates they couldn't get it into vial form before about September 15 in any significant amount.

DR. COOPER: We have cleared, as a matter of fact, the first 2 million today.

Q Is the liability thing a real problem?

SECRETARY MATHEWS: The question of what that October 1 date means is problematic.

Q Well, what is your answer to them so they can deliver?

SECRETARY MATHEWS: Our answer is that the legislation in our judgment and the judgment of Congress did not mean that they were prohibited from delivering before October 1.

Q Those numbers you gave yesterday and the letters to the manufacturers, generally interpreted as 20.4 million doses, would be available on October 1. The way that broke down was 5 million would be doses for the general public and 15.4 million doses for high risk people, which leads me to ask you this: Originally your program was, if you had started in July and August, you were going to vaccinate high risk people and get them out of the way, and then vaccinate the general public. Then you blended those two programs when you started running into delays.

What are you going to do now? Are you going to now reassign priorities and reconfigure this program?

DR. COOPER: I think it was never the intention that you could make it clear cut only high risk, because the combination in the pool -- as the products, both the A-Victoria and the swine, come off the assembly line -- it would indicate that we couldn't necessarily put them all together at the same time, so that in an efficient way some of the monovalent and general application could go as well as the high risk. This reflects the same intent that we want to make available, when it is available for, as soon as possible, that area. That shows the emphasis.

Q It would be nice to have something done in this program in an efficient way.

My question was, are you going to put high risk people out front?

DR. COOPER: Sure.

Q When are you going to make these formal announcements?

DR. COOPER: The high risk people are out front in all the guidelines, in all the State plans. The law says that you can't file a claim before October 1. This has been interpreted to mean -- despite my interpretation, or the Secretary's interpretation that we could deliver it and get it out before that -- that in order to assure that there is protection, that doses can't be given before that.

Q Okay, but on October 1 or about October 1 when you start this, according to your present delivery schedules, you are going to have three times as much bivalent vaccine as you have monovalent vaccine. How are you going to make sure the right people get the right vaccine at the proper time?

DR. COOPER: Because there are criteria set out which identify the high risk population between the State plans and community plans, identify that those are the people that get the bivalent vaccine first.

Q How long will it be before the last person in the country that wants this vaccine will be able to have the shot?

DR. COOPER: The last adult or last child?

Q The last person that wants it. How long before it is packaged in individual bottles and distributed to health centers?

DR. COOPER: It is our estimate that by Christmas and certainly by the end of the calendar year, the adult demand -- that is, the 18 and above group -- can be met well within the production schedule. It is the shift of the curve that was identified earlier -- we would like it earlier in order to make sure that we have maximum protection available.

We feel that with the knowledge that we have right in hand at the moment now, without any extraordinary efforts, the total amount will allow us to conclude that the expected adult demand can be met by Christmas. That is not to say -- suppose there was an epidemic early on, that that demand might not go up, we would have to revise our estimate. Or if the studies on the children are complete, we have a larger expected demand for that. The whole thing would have to shift by the four to six weeks that the Secretary mentioned earlier.

Q When are the children going to be able to get all the dosage they need?

Q What did the President ask you to do?

SECRETARY MATHEWS: The President asked me to give him a status report on where we were. We do this, as I say, about every four to six weeks.

Q Did he express satisfaction or did he say he was a little bothered by these delays?

SECRETARY MATHEWS: No, he simply asked for a status report.

Q Mr. Nessen said this morning at his briefing that the President said, "It damn well better run right," which would indicate there was a certain amount of dissatisfaction on his part. Did he voice any of this to you or impart any idea that it wasn't being run right?

SECRETARY MATHEWS: None whatsoever.

Q Is there a problem? Is it serious?

SECRETARY MATHEWS: This program has been problematic from the time it started.

Q Why?

SECRETARY MATHEWS: Because of about 600 different factors that range all the way from the six weeks it took to solve the liability problem to the question of how many doses you could get out of an egg, to the question of what kind of shots the children would have.

It seems to me that we are being surprised by the obvious. A program of this magnitude in this time frame is bound to occasion these kinds of problems. I don't see why we are surprised that a program of this scale of this boldness --

Q When the President announced this program, he said this would be the greatest mass medical experiment in the Nation's history, or of any country. He said 200 million shots and we would beat the threat of swine flu, and we haven't.

In Congress they say they are going back to investigations because there is a big snafu. Is it a snafu or isn't it?

SECRETARY MATHEWS: There is no evidence I have seen of a snafu. Why are we surprised that a program of this unprecedented magnitude, that has raised all of the problems that have been raised, is a difficult one to accomplish in this period of time?

Q Are you happy and satisfied with the program, Mr. Secretary?

SECRETARY MATHEWS: Yes, I am.

Q You are happy and satisfied with it as it stands right now?

SECRETARY MATHEWS: I believe that we have done a good job of meeting the problems that are attendant to a program of this kind.

Q The problem, as stated by the President on the 25th of March in his message to Congress, as I recall it, was to start vaccinations by the first of September and have them all completed by November. Are you satisfied --

DR. COOPER: He didn't say November.

SECRETARY MATHEWS: No. The President did say he hoped to start and I said, some time in August, as a matter of fact, and end up by Christmas.

Now the only difference in that schedule is the six weeks delay that was occasioned by the liability question. The President didn't cause the liability question.

Q I didn't say the President did. I was just asking you -- you say you are happy with this program that has not met the --

Q Is there any slowdown on the part of the manufacturers until they get something in writing?

SECRETARY MATHEWS: We called and had a confirmation verbally that there is not.

It seems to me the standard for judging this program is not whether it encounters the inevitable difficulties of a program of this newness and this magnitude. The standard for judging it is whether it can in fact resolve those difficulties, and I would remind you that six weeks ago we were not even sure we could resolve some of those difficulties.

We have done that and I think that all of the partners, which includes not just the Federal Government, not just the Executive Branch, but the Congress and the manufacturers and the liability people -- we have, on the whole, faced up to those problems.

DR. COOPER: Could I comment on that? Every year the United States Public Health Service has recommended influenza shots for the high risk population. A good year's performance for the people of the high risk population who actually take it, which may be between 25 million and 40 million, has been about 15 percent.

That is not a good performance. I think we have run into some difficulties in a very large effort here, as the Secretary has explained, but in my view it is inevitable that we will do better this year.

I would call to your attention that already from influenza, irrespective of the variant that we are talking about, it has claimed in excess deaths of over 10,000 to 12,000 lives since January, already. It is not a trivial disease.

Q Why didn't you and the Government ask the manufacturers to start putting the bulk vaccine in vials as soon as it was produced instead of letting it sit in the barrels?

DR. COOPER: That is easy. First off, we had to have the right dose to put in the vials.

Q You had that in July.

DR. COOPER: All right, we had it in July.

Secondly, there was some question about whether the program would go forward at all because of the liability question. The companies had gone through and produced 100 million doses in the bulk form with no contract or assurance whatsoever. So, I don't think that they have been unresponsive to our needs.

We had to agree on both the dose and subsequently the labeling and the packaging amounts and the liability question.

Q But that all was done by August 1, all those except the liability. The questions that said what the package is going to look like and what ought to go in and what the labeling is had been resolved. Indeed, if they had started putting them in vials on August 1 when those questions were resolved, we would not be facing the problem right now of this shortfall.

SECRETARY MATHEWS: No, sir. We said then if they did exactly what we said and we finished that program out, it would be five to six weeks, which would be September 15.

Q But they took two more weeks before they started putting the stuff in vials.

SECRETARY MATHEWS: No, they testified to Dr. Cooper verbally that they did not delay putting it in vials. We asked them to start putting it in vials in July. We were discussing bottling it then because that is when the questions were raised about how can we bottle it if we don't know the dosage or whether it is going to be a Government or private program.

Q They haven't put it in vials.

DR. COOPER: Not since July.

Q Since the day they had the labeling and the dosage?

DR. COOPER: Well, they began the recognition that they had the pool for bottling right after the July period. I cannot say yes, you will have to get from them when they began doing it in the actual packaging. In fact, the actual packaging determination was not agreed upon until there was an agreement about the liability and that was signed, as you know, subsequent to that.

Q Mr. Secretary, I don't quite understand what happens to the children. You said you cannot get the parents inoculated until December or late December possibly, when the flu is already a problem around the country.

SECRETARY MATHEWS: No, we did not say that.

Q Well, they are the last ones. Just tell us what the kids are going to get.

SECRETARY MATHEWS: We do not know at the present time what the proper way is to administer the doses to the children under 18 until we have the completion of the tests that are underway.

We will have the completion of these tests fairly soon. The latter part of September, I would imagine, we would be able to make a decision about how best to approach the children. So that means that, since that determination won't be possible until September, probably October, that the inoculation of the children will come later in the fall.

Q Will they all be inoculated in time so that if there is a danger, they will escape the danger?

SECRETARY MATHEWS: The flu season, the normal pattern for the flu season, is a January-February peak and we anticipate, we anticipated all along when we made our announcement, that we could wind this program up Christmas.

We have said, because of the liability question, we have a six-weeks delay. That means that you can add six weeks to Christmas, which means the total program should wind up the latter part of January or the first part of February.

Q But you think that by the time you get ready to inoculate the children, you will have enough stuff to do it?

SECRETARY MATHEWS: Yes.

DR. COOPER. Let me add that on September 8, there will be a meeting with the proper committee of the American Academy of Pediatrics to discuss the appropriate dosage for what are called high risk children, which are regularly recommended every year. These are children that have chronic lung disease, cystic fibrosis, chronic heart disease, probably children under immunotherapy for leukemia, that sort of thing. These are recommendations.

We expect to have them, that is, a few million children, potentially, I expect, in this country.

Q That will be here in Washington?

DR. COOPER: No, the meeting will be in Atlanta on September 8. The completion of the studies on the normal children is, as the Secretary indicated, later in September. That means at the completion of those studies, we will then determine whether it is appropriate to recommend the dosage in consultation with the virologist, the immunologists and the pediatricians.

In any case, it is likely to be not a single shot because children immunologically do not respond the same way as adults, and they do not respond the same way in response to side effects. They are more fever-sensitive and so on. That is not unusual.

As you know, even in polio, it is in divided doses. In DPT, it is in divided doses, and the studies going on now are oriented toward what would be the best to offer them in divided doses.

The high-risk children recommendations will be discussed on September 8.

Q You say there are several million high-risk children?

DR. COOPER: My guess would be a few million, a few million children.

Q What you are telling us is that you don't even know yet whether you can give this stuff to kids, you won't know until September?

DR. COOPER: We know we can give it. In the first studies, we had children in it. We want to decide on what the right schedule and dosage is so that they can get the immunization without high fevers, and within an acceptable level of sore arms and other effects.

Q Can we go back to something I tried to ask earlier?

SECRETARY MATHEWS: Sure.

Q You were talking about the fact it is not surprising that you have had problems.

SECRETARY MATHEWS: Yes.

Q The day after the press conference that CDC held in which they compared this to the 1918 flu epidemic, there was an influenza workshop at NIH at which Dr. Hellman, who is the vaccine expert, raised the question of wasn't there a possibility of running into the very liability problem that you ran into.

I am wondering why, when he raised this on February 20, it was June before the thing really steamed up?

SECRETARY MATHEWS: I think Dr. Cooper could give you some information on that, but even as late as the date that we had the meeting with the President, when we had the manufacturers there, people who had the liability problem, there was no indication that the problem would reach the magnitude that it did.

We talked about delays in the program. The only delay I know of, by the way, is the delay occasioned by that liability program that lasted six weeks.

Q Why is the program two-plus months behind?

SECRETARY MATHEWS: It is six weeks behind.

DR. COOPER. Let me answer Judy's question. Hellman was not the first one to raise the possibility of the liability question. Ever since the Reyes case, we have been concerned with all our vaccines and these were regularly discussed.

Now, we thought that we could deal with this in contract language in which we assigned our own responsibilities very clearly. That did not turn out to be acceptable. That was the reason it took so long to resolve it.

We first thought we could negotiate it by contract. It was raised at that meeting by the President, as a matter of fact -- was this going to be an issue? Representatives of industry were there. We thought we could negotiate this, but it did not prove out to be the case.

Q But on March 31, again on April 31, C. Joseph Stetler, the President of the Pharmaceutical Manufacturers Association, very specifically went into detail about the liability issue, how legislation would be required, indicating clearly that it could not be done in an administrative way. This was 2-1/2 months before you came to grips with the problem that you had a problem.

DR. COOPER. It was not that we came to grips with it. Dr. Stetler felt we should go the legislative route. Some others felt we should go, other good legal counsel, said this was a manageable proportion if we could negotiate it in specific language and even the companies entered into that discussion with good faith.

We always recognized that one recourse would be the legislative route and, when it was not possible to do it, even the Congress, when we first raised it to them, sent us back to do it again by the administrative route.

So, it was not at all our insensitivity to the possibilities of solving it by legislation. It eventually was done and not by the legislation that was originally proposed.

Q If it was solved by legislation then, Dr. Cooper, why is it we still haven't gotten contracts signed?

Representative Rogers -- I spoke to him today -- is very much disturbed by the fact that it has been over three weeks and still no contracts.

DR. COOPER: That is right, but that hasn't got anything to do with the liability question. The law requires that we not allow them to make any profit on the swine portion and, when there is a bivalent, only on the Victoria portion, you recall that.

Now the criteria on which you assign costs in a program in which the manufacturers in good faith have already spent 60 percent of their cost, requires that we send auditors in to do the full audit at that time, and you can't do that in one day.

Q They are trying to maximize their costs in order to get an attractive contract; is that right?

DR. COOPER: I didn't say that. I don't have any indication that they are trying to maximize.

SECRETARY MATHEWS: You see, what you haven't associated is the contract problem with any delay. There is no evidence that the manufacturers of the vaccine are in any way not performing because they do not have a contract. They have already produced 100-some-odd million doses without a contract.

Q We are talking about a delivery. As Dr. Sabin says, it doesn't do any good until it gets in the person's arm.

DR. COOPER: Dr. Salk.

SECRETARY MATHEWS: The delivery question does not turn on the contract issue. The delivery question turns on the October 1 date, and its implications in the legislation. So, it is not accurate based on any information we have discussed here today.

Q So, the delay is Congress' fault for writing that in; is that right?

SECRETARY MATHEWS: I have simply said the delay is a result of the liability problem.

Q I don't understand your reasoning when you say it is a six-week delay when the first injections were to begin in July.

SECRETARY MATHEWS: No, sir, nobody said injections were to begin in July.

Q In July and August for high risk people?

SECRETARY MATHEWS: We talked about August in those conversations.

DR. COOPER: In the first discussions we indicated that we would like to begin in late July or the first of August.

Q Here we are, it has got to be at least two months. If you take everything at best, you have a two-month delay, and if you take at worst, you have a three-month delay.

DR. COOPER: We never said the first of July.

Q So, say two months.

DR. COOPER: We said the studies would be done June 21. If you take the four to six weeks after that, it is possible we could have had delivery under the best of circumstances by late July or the first of August. So, at the worst, it would be two months.

In realistic terms, even if we finish the studies -- and that is not their liability fault because, as the original study showed, they were not adequate for all the children, as you know, so more were needed. All right, so we are really talking on an average of six weeks that set us back, of a serious nature in delay of the States' plans. The July to August differential was not a critical feature and if you look at the States' submissions that was never a critical issue in that regard.

SECRETARY MATHEWS: Nor was there any statement that we planned to do this in July.

Q You said July, mid-July.

SECRETARY MATHEWS: Spencer may have said that is what he would like to do.

Q I am a little confused about how the October 1 date in the legislation is the cause of the delivery problem. Is it that the manufacturers don't want to deliver it before then because, even if they did, they don't have enough ready to deliver?

SECRETARY MATHEWS: We don't know that.

Q They said that.

DR. COOPER: One manufacturer told me that their storage capacity --

Q Could you tell us which manufacturer?

DR. COOPER: I am not trying to be coy; I am just trying to remember which one. I am reluctant to say.

But, one manufacturer said that their storage capacity under the proper storage conditions is limited. When they make a certain amount and they store it, if they could deliver it on the 20th, they could make room for more, so that is a limitation.

Now not every company has a limitation in storage capacity. Most of them have acknowledged that the legal interpretation of the October 1 date is a determinant of when they would make it available. So it depends on how you calculate whether it is October 1 or October 2 or October 3, depending on what is available.

Now I asked them, are there any technical problems that have changed your ability, your estimates of your ability to put this in the context of your original bid, which is what these percentages were originally measured against. To my knowledge, there are no technical problems that have been involved.

What they were saying in June -- you know, the bids were due on June 15 to 20, something of that order -- when they were making their original estimates, is that if they were able to get an order under full indemnification by the end of that period, by say around June 25, they could have met the time schedule that would have been 100 percent of what the Secretary is talking about 74 percent.

Q Isn't there some way they can ship it in bond or something to clear out the storage area?

DR. COOPER: Believe me, we have asked them to look at all possibilities, to move it as fast as possible. You know, I don't want to risk the possibility that this season can't shift. We would like to have it as early as possible. That is what the original plan was.

Q Have you thought of going back to Congress and asking them to eliminate the Brock amendment from that --

DR. COOPER: I talked to Mr. Rogers today about it and asked him what the interpretation of that was. I think, yes, we have considered if it is necessary. Tomorrow we expect to get, in response to the Secretary's letter -- all of them are aware of the data in the letter, all of them have said they will make every effort today to look at every possible way to do this.

They have verbally assented to signing a letter contract and we hope to have some time tomorrow or the next day their assessments of any revision of schedule that will help us skew that curve backwards.

You know in reality I am delighted that everybody is now concerned whereas before everybody was saying, what do you need it for. Now that there seems to be some difficulty and a short supply, I am delighted that everybody is concerned that we get it early enough. I think that is fine, and I would be delighted to have your help in getting it done that way.

Q Maybe a lot of people are concerned about the availability of the Victoria vaccine which, through your doing, is all tied up with the swine vaccine?

DR. COOPER: The Victoria vaccine will be three times, as you yourself have said, in greater amounts available, and it will be available in greater amounts than originally planned because of this program. If we can get a better performance than that 15 percent that we got last year, this also will be greatly to the benefit of each.

So, I am a believer in giving the Victoria but you will be pleased to know that our estimates of the serology of the general population shows that because of last year's spread of Victoria over half the population already has antibodies to Victoria. That is much less of a problem at the present time. We think it needs to be addressed particularly in the high risk population and all of it will be greatly beneficial.

THE PRESS: Thank you.

END (AT 6:17 P.M. EDT)

MEMORANDUM

THE WHITE HOUSE

WASHINGTON

December 16, 1976

MEMORANDUM FOR: PRESS OFFICE STAFF

FROM: RON NESSEN

HEW will be announcing later today temporary suspension of the Swine Flu program pending an investigation of any connection between the shots and nerve disorders.

If the White House Press Office has any inquiries on this matter, we should acknowledge that the President met earlier today with Secretary Matthews and Dr. Cooper and was brought up to date on the situation. The President concurred in the judgement and decision by HEW to suspend, temporarily, the Swine Flu program.

All further questions on the matter should be referred to the press office at the Public Health Service (245-6867).