

FOR IMMEDIATE RELEASE

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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.

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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 inoculation 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.

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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 that 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?

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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.

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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 out repeatedly. 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 epidemiologic base of planning, because we are not seeing a lot of cases now, would be completely normal. We do not usually see this.

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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.

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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 said 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 should have 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.

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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: In 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.

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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.

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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.

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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?

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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.

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(AT 1:45 P.M. EDT)