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94TH CONGRESS
2D SESSION

S. 3735

AN ACT

To amend the Public Health Service Act to authorize the establishment and implementation of an emergency national swine flu immunization program and to provide an exclusive remedy for personal injury or death arising out of the manufacture, distribution, or administration of the swine flu vaccine under such program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

That this Act may be cited as the "National Swine Flu Immunization Program of 1976".

SEC. 2. Section 317 of the Public Health Service Act (42 U.S.C. 247b) is amended by inserting after subsection (i) the following new subsections:

"(j)(1) The Secretary is authorized to establish, conduct, and support (by grant or contract) needed activities to carry out a national swine flu immunization program until August 1, 1977 (hereinafter in this section referred to as the 'swine flu program'). The swine flu program shall be limited to the following:

"(A) The development of a safe and effective swine flu vaccine.

"(B) The preparation and procurement of such vaccine in sufficient quantities for the immunization of the population of the States.

"(C) The making of grants to State health authorities to assist in meeting their costs in conducting or supporting, or both, programs to administer such vaccine to their populations, and the furnishing to State health authorities of sufficient quantities of such swine flu vaccine for such programs.

"(D) The furnishing to Federal health authorities of appropriate quantities of such vaccine.

"(E) The conduct and support of training of personnel for immunization activities described in subparagraphs (C) and (D) of this paragraph and the conduct and support of research on the nature, cause, and effect of the influenza against which the swine flu vaccine is designed to immunize, the nature and effect of such vaccine, immunization against and treatment of such influenza, and the cost and effectiveness of immunization programs against such influenza.

"(F) The development, in consultation with the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and implementation of a written informed consent form and procedures for assuring that the risks and benefits from the swine flu vaccine are fully explained to each individual to whom such vaccine is to be administered. Such procedures shall include the information necessary to advise individuals with respect to their rights ~~and remedies~~ ^{and remedies} arising out of the administration of such vaccine.

Such consultation shall be completed within two weeks after enactment of this Act, or by September 1, 1976, whichever is sooner.

"(G) Such other activities as are necessary to implement the swine flu program.

"(2) The Secretary shall submit quarterly reports to the Congress on the administration of the swine flu program. Each such report shall provide information on --

"(A) the current supply of the swine flu vaccine to be used in the program;

"(B) the number of persons inoculated with such vaccine since the last report was made under this paragraph and the immune status of the population;

"(C) the amount of funds expended for the swine flu program by the United States, each State, and any other entity participating in the program and the costs of each such participant which are associated with the program, during the period with respect to which the report is made; and

"(D) the epidemiology of influenza in the United States during such period.

"(3) Any contract for procurement by the United States of swine flu vaccine from a manufacturer of such vaccine shall (notwithstanding any other provision of law) be subject to renegotiation ^{to eliminate any} ~~to limit the~~ profit realized from such procurement to an amount not exceeding a

reasonable profit), as determined pursuant to criteria prescribed by the Secretary, and the contract shall expressly so provide. Such criteria shall specify that any insurance premium amount which is included in the price of such procurement contract and which is ^{refunded} ~~refunded~~ to the manufacturer under any retrospective, experience-rating plan or similar rating plan shall in turn be refunded to the United States.

"(4) No funds are authorized to be appropriated to carry out the activities of the swine flu program authorized in subparagraphs (A), (B), (D), (E), and (F) of paragraph (1) of this subsection in addition to the funds appropriated by Public Law 94-266.

(except that with respect to vaccine against the strain of influenza virus known as influenza A/Victoria/75 profit shall be allowed but limited)

"(k) (1) (A) The Congress finds that --

"(i) in order to achieve the participation in the program of the agencies, organizations, and individuals who will ^{manufacture,} ~~manufacture~~ distribute, and administer the swine flu vaccine purchased and used in the swine flu program and to assure the availability of such vaccine in interstate commerce, it is necessary to protect such agencies, organizations, and individuals against liability for other than their own negligence to persons alleging personal injury or death arising out of the administration of such vaccine;

"(ii) to provide such protection and to establish an orderly procedure for the prompt and equitable handling of claims by persons alleging such injury or death, it is necessary that an exclusive remedy for such claimants be provided against the United States because of its unique role in the initiation, ^{planning,} ~~and~~ and administration of the swine flu program; and

"(iii) in order to be prepared to meet the potential emergency of a swine flu epidemic, it is necessary that a ^{procedure} ~~procedure~~ be instituted for the handling of claims by persons alleging such injury or death until Congress develops a permanent approach for handling claims arising under programs of the Public Health Service Act.

"(B) To --

"(i) assure an orderly procedure for the prompt and equitable handling of any claim for personal injury or death arising out of the _____ administration of such vaccine; and

"(ii) achieve the participation in the swine flu program of (I) the manufacturers and distributors of the swine flu vaccine, (II) public and private agencies or organizations that provide inoculations without charge for such vaccine or its administration and in compliance with the informed consent form and procedures requirements prescribed pursuant to subparagraph (F) of paragraph (1) of this subsection, and (III) medical and other health personnel who provide or assist in providing inoculations without charge for such vaccine or its administration and in compliance with such informed consent form and procedures requirements,

it is the purpose of this subsection to establish a procedure under which all such claims will be asserted directly against the United States under section 1346(b) of title 28, United States Code, and chapter 171 of such title (relating to tort claims procedure) except as otherwise specifically provided in this subsection.

submitted after September 30, 1976
"(2) (A) The United States shall be liable with respect to claims for personal injury or death arising out of the administration of swine flu vaccine under the swine flu program and based upon the act or omission of a program participant in the same manner and to the same extent as the United States would be liable in any other action brought against it under such section 1346(b) and chapter 171, except that --

"(i) the liability of the United States arising out of the act or omission of a program participant may be based on any theory of liability that would govern an action against such program participant under the law of the place where the act or omission occurred, including negligence, strict liability in tort, and breach of warranty;

"(ii) the exceptions specified in section 2680(a) of title 28, United States Code, shall not apply in an action based upon the act or omission of a program participant; and

(iii)

"(iv) notwithstanding section 2401(b) of title 28, United States Code, if a civil action or proceeding for personal injury or death arising out of the administration of swine flu vaccine under the swine flu program is brought within two years of the date of the administration of such vaccine and is dismissed because the plaintiff in such action or proceeding did not file an administrative claim with respect to such injury or death as required by such chapter 171 the plaintiff in such action or proceeding shall have 30 days from the date of such dismissal in which to file such administrative claim.

"(B) For purposes of this subsection, the term 'program participant'

as to any particular claim means the manufacturer or distributor of the swine flu vaccine used in an inoculation under the swine flu program, the public or private agency or organization that provided an inoculation under the swine flu program without charge for such vaccine or its administration and in compliance with the informed consent form and procedures requirements prescribed pursuant to subparagraph (F) of paragraph (1) of this subsection, and the medical and other health personnel who provided or assisted in providing an inoculation under the swine flu program without charge for such vaccine or its administration and in compliance with such informed consent form and procedures requirements.

or two years from the date the claim arose, whichever is later

Administrative
participant

vaccine
form

"(3) The remedy against the United States prescribed by _____ paragraph (2) of this subsection for personal injury or death arising out of the _____ administration of the swine flu vaccine under the swine flu program shall be exclusive of any other civil action or proceeding for such personal injury or death against any employee of the Government (as defined in section 2671 of title 28, United States Code) or program participant whose act or *omission gave rise to the claim.*

"(4) The Attorney General shall defend any civil action or proceeding brought in any court against any employee of the Government (as defined in such section 2671) or program participant (or any liability insurer thereof) based upon a claim alleging personal injury or death arising out of the _____ administration of vaccine under the swine flu program. Any such person against whom such civil action or proceeding is brought shall deliver all process served upon him (or an attested true copy thereof) to whoever is designated by the Secretary to receive such papers, and such person shall promptly furnish copies of the pleadings and process therein to the United States attorney for the district embracing the place wherein the civil action or proceeding is brought, to the Attorney General, and to the Secretary.

“(5) (A) Upon certification by the Attorney General that a civil action or proceeding brought in any court against any employee of the Government (as defined in such section 2671) or program participant is based upon a claim alleging personal injury or death arising out of the administration of vaccine under the swine flu program, such action or proceeding shall be deemed an action against the United States under the provisions of title 28, United States Code, and all references thereto. If such action or proceeding is brought in a district court of the United States, then upon such certification the United States shall be substituted as the party defendant.

“(B) Upon a certification by the Attorney General under *subparagraph* ~~subparagraph~~ (A) of this paragraph with respect to a civil action or proceeding commenced in a State court, such action or proceeding shall be removed, without bond at any time before trial, by the Attorney General to the district court of the United States of the district and division embracing the place wherein it is pending and be deemed an action brought against the United States under the provisions of title 28, United States

Code, and all references thereto; and the United States shall be substituted as the party defendant. The certification of the Attorney General with respect to program participant status shall conclusively establish such status for purposes of such ^(initial) removal. Should a district court of the United States determine on a hearing on a motion to remand held before a trial on the merits that an action or proceeding is not one to which this subsection applies, the case shall be remanded to the State court.

“(C) Where an action or proceeding under this subsection is precluded because of the availability of a remedy through proceedings for compensation or other benefits from the United States as provided by any other law, the action or proceeding shall be dismissed, but in that event the running of any limitation of time for commencing, or filing an application or claim in, such proceedings for compensation or other benefits shall be deemed to have been suspended during the pendency of the civil action or proceeding under this subsection.

“(6) A program participant shall cooperate with the United States in the processing or defense of a claim or suit under such section 1346(b) and chapter 171 based upon alleged acts or omissions of the program participant. Upon the motion of the United States or any other party, the status as a program participant shall be revoked by the district court of the United States upon finding that the program participant has failed to so cooperate, and the court shall substitute such former participant as the party defendant in place of the United States and, upon motion, remand any such suit to the court in which it was instituted.

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"(7) Should payment be made by the United States to any claimant bringing a claim under this subsection, either by way of administrative settlement or court judgment, the United States shall have the right to recover for that portion of the damages so awarded or paid, as well as any costs of litigation, ~~attributable to~~ any negligent conduct on the part of any program participant in carrying out any obliga-

notwithstanding
any provision
of State law,

resulting from the failure of any program participant to carry out any obligation or responsibility assumed by it under a contract with the United States in connection with the program or from ~~the~~

tion or responsibility in connection with the swine flu program.

The United States may maintain such action against such program participant in the district court of the United States in which such program participant resides or has its principal place of business.

"(8) Within one year of the date of the enactment of the National Swine Flu Immunization Program of 1976, and semiannually thereafter, the Secretary shall submit to the Congress a report on the conduct of settlement and litigation activities under this subsection, specifying the number, value, nature, and status of all claims made thereunder, including the status of claims for recovery made under paragraph (7) of this subsection. and a detailed statement of the reasons for not seeking such recovery

"(1) For the purposes of subsections (j) and (k) of this section --

the District
of Columbia,
Puerto Rico,
the Virgin
Islands

"(1) the phrase 'arising out of the administration' with reference to a claim for personal injury or death under the swine flu program includes a claim with respect to the manufacture or distribution of such vaccine in connection with the provision of an inoculation using such vaccine under the swine flu program;

"(2) the term 'State' includes Guam, American Samoa, and

7/

"(3) the term 'swine flu vaccine' means the vaccine against the strain of influenza virus known as influenza A/New Jersey/76 (Hsw 1N1), or a combination of such vaccine and the vaccine against the strain of influenza virus known as influenza A/Victoria/75."

SEC. 3. The Secretary of Health, Education, and Welfare shall conduct, or provide for the conduct of, a study of the scope and extent of liability for personal injuries or death arising out of immunization programs and of alternative approaches to providing protection against such liability (including a compensation system) for such injuries. Within one year of the date of the enactment of this Act, the Secretary shall report to the Congress the findings of such study and such recommendations for legislation (including proposed drafts to carry out such recommendations) as the Secretary deems appropriate.

Passed the Senate August 10, 1976.

Attest:

Francis R. Vales
Secretary.

Chamell J. Blum
Assistant Secretary

94TH CONGRESS
2D SESSION

S. 3735

AN ACT

•To amend the Public Health Service Act to authorize the establishment and implementation of an emergency national swine flu immunization program and to provide an exclusive remedy for personal injury or death arising out of the manufacture, distribution, or administration of the swine flu vaccine under such program.

94th Congress -
2d Session

Mr. Rogers

A B I L L

To permit the United States to provide indemnification against claims for injury related to inoculation with vaccine under a comprehensive nationwide influenza immunization program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,
That (a) The Secretary of Health, Education, and Welfare may agree, as part of any contract for the purchase of a vaccine for the comprehensive nationwide influenza immunization program for which funds were appropriated under Public Law 94-266, to indemnify the manufacturer of such vaccine against losses on account of claims by third persons for any failure of the Secretary or manufacturer to perform any obligation assumed by the

Secretary under such contract, including the obligation to--

(1) investigate and determine the risks and benefits of inoculation with such vaccine,

(2) develop adequate statement of information respecting such risks and benefits, or

(3) take steps to assure that each individual to be inoculated (or, where appropriate, a parent or guardian of such individual) is informed of such risks and benefits.

(b) Nothing in subsection (a)--

(1) authorizes the Secretary to indemnify a manufacturer against any loss (A) attributable to negligence of the manufacturer in the manufacture or handling of a vaccine, or (B) arising from the failure of the manufacturer to discharge properly any of its obligations under a contract with the Secretary for the purchase of a vaccine, or

(2) shall be construed as creating or changing any rule of liability under any law of the United States or of any State.

Sec. 2. The Secretary of Health, Education, and Welfare shall make quarterly reports to the Congress on the administration of the comprehensive nationwide influenza immunization program for which funds were appropriated under Public Law 94-266. Each such report shall provide information on--

(1) the current supply of the vaccine to be used in the program,

(2) the number of persons immunized since the last report was made under this section,

(3) the amount of funds expended for the program by the United States, each State, and other entity participating in the program and the costs of each such participant which are associated with the program, during the period with respect to which the report is made, and

(4) the epidemiology of influenza in the United States during such period.

Sec. 3. The Secretary of Health, Education, and Welfare shall conduct, or provide for the conduct of, a study of the scope and extent of liability for personal injuries arising out of immunization programs and of the means to provide protection against such liability and compensation for such injuries. Within one year of the date of the enactment of this Act, the Secretary shall report to the Congress the findings of such study and such recommendations for legislation as the Secretary deems appropriate.

THE WHITE HOUSE
WASHINGTON

March 24, 1976

FILE
CALLS MADE
SEE LAST PAGE.

MEMORANDUM FOR: MAX FRIEDERSDORF

FROM: JIM CAVANAUGH

SUBJECT: Congressional Notification of
the President's Program on Swine
Influenza Immunization

On Monday the President met with Secretary Mathews and others about a possible outbreak of swine influenza this coming winter. The President, concerned with the potential seriousness of this situation, has convened a panel of influenza experts, medical professionals, public health officers, pharmaceutical executives, and public officials to discuss his plans for a Federal initiative to immunize all Americans against the swine influenza.

The meeting will take place in the Cabinet Room at 3:30 p.m. today. Following his discussion with the group, the President will announce his decision. You may want to notify key members of the Health Authorization and Appropriation Committees of the President's decision at 4:00 p.m. this afternoon. The members include Congressmen Rogers, Carter, Flood, and Michel, and Senators Kennedy, Schweiker, Magnuson, and Brooke.

TALKING POINTS

1. I am calling to inform you that the President and Secretary Mathews are now meeting with influenza experts, medical professionals, public health officials, pharmaceutical executives, and public officials to discuss a possible swine influenza epidemic next winter.
2. This meeting is a result of a briefing on Monday by HEW detailing the potential seriousness of this situation.
3. The President will announce his decision to give the go-ahead to industry to produce enough vaccine to immunize every American.

3:30 P.M.
Hirologist

4. The President will send up a \$135 million supplemental appropriation request for the FY 1976 budget to support this necessary effort in the

Morning.

3/24/76

CALLS MADE TO:

- ✓ SPEAKER - CL
- ✓ O'NEILL - CL
- ✓ MCFARLANE - CE TL
- ✓ RHODES - TL
- ✓ MICHEL - TL
- ✓ ANDERSON - TL

OFFICE OF THE WHITE HOUSE PRESS SECRETARY

THE WHITE HOUSE

STATEMENT BY THE PRESIDENT

THE BRIEFING ROOM

4:50 P.M. EST

I have just concluded a meeting on a subject of vast importance to all Americans and let me report to you the results of that meeting.

One month ago a strain of influenza, sometimes known as swine flu, was discovered and isolated among Army recruits at Ft. Dix, New Jersey. The appearance of this strain has caused concern within the medical community because this virus is very similar to one that caused a widespread and very deadly flu epidemic late in the first World War. Some older Americans today will remember that 548,000 people died in this country during that tragic period.

During the last few days I have consulted with members of my Administration, Secretary Mathews and Dr. Cooper and leading members of the health community and public officials about the applications of this new appearance of swine flu. I have been advised that there is a very real possibility that unless we take effective counter-action, there could be an epidemic of this dangerous disease next fall and winter here in the United States.

Let me state clearly, at this time no one knows exactly how serious this threat could be. Nevertheless, we cannot afford to take a chance with the health of our Nation. Accordingly, I am today announcing the following actions.

First, I am asking the Congress to appropriate \$135 million prior to their April recess for the production of sufficient vaccine to inoculate every man, woman and child in the United States.

Secondly, I am directing the Secretary of HEW, David Mathews, and Assistant Secretary Dr. Cooper, to develop plans that would make this vaccine available to all Americans during the three-month period from September to November of this year.

MORE

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

The reaction to the shot, I am told, may mean a few sore arms for a day or two--a very small price to pay for this vital protection.

The facts that have been presented to me in the last few days have come from many of the best medical minds in this country. These facts do not suggest there is any cause for alarm. The scientific community essentially 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.

We are taking the first steps this afternoon, and before next winter I hope we will have put this threat behind us.

I would like to thank the very outstanding group of technicians who came in and met with me for an hour or so this afternoon -- Dr. Salk, Dr. Sabin and others here who have convinced me beyond any doubt whatsoever that this is the right course of action, and tomorrow I will submit to the Congress a Message and a budget supplement so that this money will be available and available as promptly as possible.

We discussed how the supplemental should be handled, whether it should be a part of the supplemental that is now going through the Congress or a separate supplemental that would be identified only for this purpose and passed by both the House and the Senate for this purpose and this purpose alone.

It is my recommendation that the Congress take this item for \$135 million, act promptly on it and not tie it up with a broader supplemental appropriation bill.

Now it is my pleasure to ask Dr. Mathews, Secretary of HEW, and Dr. Cooper and the other distinguished scientists who are here who can answer your technical questions.

Thank you very much.

END

(AT 4:56 P.M. EST)

FOR IMMEDIATE RELEASE

MARCH 24, 1976

OFFICE OF THE WHITE HOUSE PRESS SECRETARY

THE WHITE HOUSE
PRESS CONFERENCE
OF
FORREST DAVID MATHEWS
SECRETARY OF THE DEPARTMENT OF
HEALTH, EDUCATION AND WELFARE
JONAS SALK
SALK INSTITUTE FOR BIOLOGICAL STUDIES
ALBERT B. SABIN
MEDICAL UNIVERSITY OF SOUTH CAROLINA
THEODORE COOPER
ASSISTANT SECRETARY FOR HEALTH
DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
AND
DAVID SENCER
DIRECTOR, CENTER FOR DISEASE CONTROL
DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

THE BRIEFING ROOM

4:57 P.M. EST

SECRETARY MATHEWS: I will discuss the history of virology and Dr. Cooper will discuss its current effects.

We have no additional statements. We are ready for any questions you may have.

Q Dr. Mathews, the President said flatly that he is asking each and every American to receive an inoculation of this this fall. If this is grown on an egg substrain, what are you going to do about people who are allergic to that and cannot handle it?

SECRETARY MATHEWS: Dr. Cooper, Dr. Sabin and Dr. Salk are experts in that field. I shouldn't answer that question in their presence.

DR. SALK: The only caution that should be exercised is to inquire whether or not a person is sufficiently allergic to eggs to develop asthma or hives.

Q And if so?

MORE

DR. SALK: If so, they should avoid being vaccinated and they will be protected as part of the effect by virtue of the beneficial vaccination of the rest of the population. The purpose of vaccinating on a mass scale is to offer community protection, nationwide protection, as well as individual protection.

DR. COOPER: I would add to that that it is part of our intention in the campaign, therefore, as part of the necessary awareness activity, to make a full disclosure of the sensitivities, what the expected adverse reaction would be, including the sore arms that the President talked about, since it is inevitable as we deal with 207 odd million injections that we have to alert the public to this in a responsible way. This also is the proper way to deal with the question of liability.

Q One other question, to follow up, if I may. Do you have any rough estimates of how many people are sufficiently allergic to egg to make this an unwise procedure for them?

DR. COOPER: When I asked about this, the best estimate I could get on this was about one per 100,000 --

DR. SALK: And they know it.

DR. COOPER: -- and usually they know it, as Dr. Salk points out.

Q Are you going to recommend a monovalent vaccine, what CC level and how many doses?

DR. COOPER: We are recommending monovalent vaccine for this particular activity, one dose.

Q How many doses totally are you going to tell the drug companies to manufacture, 215 million?

DR. COOPER: Enough for every citizen until we have completely covered the population.

Q Dr. Cooper, are there going to be monies available so that people who could otherwise not afford it will have it available? Will there be outreach, in other words?

DR. COOPER: Yes. As part of our proposed activity, there are three main parts. One is the production and certification of high quality vaccine. We have been assured by the experts it is efficacious.

MORE

Secondly is the organization of the system so that the capability of delivering it is present in any setting, including the financial barrier system that you just described, and thirdly is having the capability there, without the public awareness and willingness to participate, would not be as successful campaign and, as was pointed out to the President, I believe by Dr. Sabin earlier, the previous campaigns that did not include an important awareness activity of this type were only 50 or 60 percent effective. So, the program that is proposed has all three elements.

Q Can I follow up, if I may. I understand that this means--this will mean the holding of the vaccines for the present strain of flu so that the entire production effort can be devoted to this.

DR. COOPER: No, this is not to be done at the expense of all other production of vaccines.

Q Other production of flu vaccines?

DR. COOPER: Even other flu vaccines because there is a need -- particularly for certain high-risk groups -- to have the other flu vaccines that are being produced all the time, even now. That would not be set aside. This will continue.

Dr. Sencer might want to comment.

DR. SENCER: The production cycle for the Victoria strain, which is going to be in the vaccine, recommended for high-risk has already been completed, as has the production of the B virus, so that we are not displacing any of that.

SECRETARY MATHEWS: I think this might be a good point to make this observation. It was made several times in the meeting. There are many different kinds of flu. Even though we will inoculate, hope to inoculate, 200 million people to protect them against this particular kind of flu, that does not mean that they are protected from flu in general.

I think all of us have a difficult problem before us even conveying to the public the seriousness of the problem and yet, with some precision about what we are doing, as both Dr. Salk and Dr. Sabin will tell you. Flu is almost a generic disease. It is a term for a disease that covers many varieties, and I think we need to be very precise because we would not want to have 200 million people inoculated feeling they were protected from flu and then come down with some other form of it and be surprised.

MORE

Q Was there anything said at the meeting by the representatives of organized medicine about their cooperation in keeping down the cost of injections? Did they say they would give them for nothing or cut their office visit charges in half or anything like that?

DR. COOPER: We did not discuss that specific question specifically, but there was discussed the previous experience where the people were mobilized, physicians did donate their time and capability. The representatives of organized medicine did offer full cooperation from both the American Medical Association, the National Medical Association, the pediatricians, the family practice physicians, the State and territorial health officers and the American Public Health Association.

They all described with great enthusiasm their willingness to participate, as they have in previous campaigns.

Q What is this likely to cost a patient?

DR. COOPER: In many cases it will not be much at all. It depends on what locus that he eventually elects to have his inoculation. Some people will choose to go to their own physician's office, and although he will not have to bear the cost of the vaccine, it is their, maybe, Administration cost.

Others who go to public facilities may not have to pay, depending on what the arrangement is in a selected area. All this has not been worked out.

Q The Government is paying for the vaccine.

DR. COOPER: The vaccine. It is not a completely federalized campaign in which the Administration costs in totality are being borne by the Federal Government.

MORE

Q Mr. Secretary, are you aware that some scientists and public health officials oppose this program on the basis that with only one death and only a few hundred cases, that it may not be an epidemic and may never become one, and if you are aware of it, what is your answer to that?

SECRETARY MATHEWS: We had the advice of our own scientific advisory committees on this point. We explored this question with them. It was their firm recommendation to us that even though they could not give us a probability description, they felt that the possibility was such that they could do nothing other than recommend to us in the strongest terms that we proceed with the action that the President just announced. Moreover, the purpose of the meeting today which involved a wide range of people from the scientific community, including the two eminent, distinguished gentlemen who are on the platform with me today, reviewed that evidence just as we received it and came to the same unanimous conclusion to the President.

DR. SABIN: This is a very important thing for the public to understand and I would like to have an opportunity to comment.

It is very important to realize that this is a most difficult decision that has an aspect of your damned if you do and you're damned if you don't. Let me explain this. Supposing you do nothing and along comes Labor Day and schools are open and you have one of those big forest fires that can take place with a virus for which most of the population has no immunity. You have done nothing. You have done nothing because you can't be sure -- and nobody can be sure -- that it will really produce an epidemic.

Now then, you decide, well, we have got to do something. Then it is going to cost a tremendous amount of money. It is going to take a tremendous amount of effort. And then nothing happens, or what is even worse, there is going to be a lot of influenza-like disease and other acute respiratory disease because every year now over 400 million days of bed disability are due to acute respiratory disease of all kinds.

So you can visualize the situation in which this vaccine is administered and people are getting influenza and they will say, "What good was all this, we are getting sick anyway." Influenza represents this difficult situation.

What then is the crux of the disease. This particular virus has raised up an image of potential seriousness that was not created, for example, by this in influenza that caused a lot of disease this year.

MORE

It has a bad history. Now just because it was bad in 1918, 1919, 1920, doesn't mean that it is going to be bad again, as was brought out during the meeting by Dr. Kilbourne. We don't know. But the point is can we take a chance. And this is the important thing to realize. It is a very difficult thing.

Q Doctor, what about the people that might possibly get the illness from the inoculation? Is there no risk there?

DR. SABIN: It is not a question of getting the illness from the inoculation in this particular case. They may get some reactions, although this is a highly purified vaccine that is now being used by zymosthenigation which most of the egg material has cleared out.

I think the experience in large numbers of people have shown that reactions, perhaps in younger children -- a fever and things like that -- may be encountered, but again they are not all that serious if one keeps in mind the potential.

In other words, you are preparing for a potential attack that might never happen. This is what the Defense Department is doing, too. We are spending a lot of money and a lot of effort against something that may never happen. But should we do it?

DR. COOPER: In the common parlance it would be called a dead virus so it is really not active to cause the disease.

Q Dr. Cooper, the drug companies have said if they have to manufacture high potency vaccine they would have a very difficult time in manufacturing 200,000,000 doses. Here you are talking about 600 CCA. What are you going to make a recommendation for, a less potent vaccine, something a little below that?

DR. SABIN: Absolutely not.

DR. SENCER: The formulation has not been determined. There is another workshop tomorrow at the Department of Biologics to get to the full formulation of the vaccine, but we would not sacrifice potency.

I think the problem is going to be a production problem rather than changing the potency.

MORE

Q Dr. Cooper, the President mentioned a vaccination period from September to November of this year. But the 1918-19 flu was very unusual in that it appeared in this country in August and peaked in October.

Now if you should have a replay of that at this time, what would be the effect of a September-November vaccination period, and by the same token, is there any possibility of getting 215 million doses of this vaccine ready to put into people as early as July so it would be effective for an August appearance?

DR. COOPER: Let me take the last first. After the workshop and the potency questions and the production questions are addressed, the lead time for production of the vaccine and its testing and certification, as was discussed with the President, takes six or so weeks. Some, of course -- depending on how much is available, how much could be done -- could be ready in the summer.

It is true that the reporting of the 1918 pandemic did peak somewhat earlier than recent experience. But as reviewed with the President by people from the Armed Forces as well as other recent epidemiological history inoculation early in the fall usually has been quite effective in completely warding off expected activities by November.

Q For a typical virus, but this is not a typical virus and that is the whole point of my question.

DR. COOPER: We do not know that it is a completely atypical virus.

MORE

Q Excuse me, I will amend that. The 1918-1919 was not a typical virus, and I ask if you were to have a replay of 1918, what would be the effect of having a vaccine ready for mass use in September?

DR. COOPER: I think we would obviously miss some people and we would begin our inoculation on the high-risk groups as early as possible and continue until we have covered the population.

SECRETARY MATHEWS: I might say at this point this is one of the reasons the President is asking Congress for a most expeditious handling of this matter because time is of the essence and the decision about the time frame and when the inoculation begins, of course, is conditioned on when the industry gets the charge to go ahead.

Q Did Dr. Salk agree with the decision that was made, and did all the others agree, and have we ever had an immunization program of this size before?

SECRETARY MATHEWS: On the question of agreement, the President paused in about the middle of the conversation and looked around the room and asked if there was anybody in the room who disagreed with the recommendation that was before them. No one disagreed. As a matter of fact, everyone there, including Dr. Salk and Dr. Sabin, pointedly subscribed to the decision.

Q You are not saying there is also agreement outside of that group, are you? Not full agreement, are you?

SECRETARY MATHEWS: We have polled, one, the regular advisory group to the scientific organization within the Government. We secondly polled outside of that group, prior to this meeting, to check for concurrence. Third, we have taken this additional step of polling the principals, both in the medical profession, in the pharmaceutical profession and in this particular field, and in all of those cases we have not found anyone who would recommend any course of action other than that the President is taking.

Q Secretary Mathews, are you asking the pharmaceutical houses which will be making this large amount of vaccine -- ten times the normal supply for a year -- to make any sort of financial concessions or sacrifices in terms of the amount of profit they will get out of the product?

MORE

SECRETARY MATHEWS: We made no specific recommendations to them. The President I think made it clear this was the kind of effort that would take the cooperation of everybody in the country. The Federal Government, the Administration, by asking Congress for \$135 million, we are prepared to pay for the serum that we are asking for.

Q How much do you normally pay for flu vaccines in the course of a normal year when you don't have something like this?

DR. SENCER: We have not purchased influenza vaccine as a Federal effort, so we don't have any comparable figures. I think the going retail price is around 75 to 90 cents a dose, but that is with a bivalent vaccine.

Q Dr. Sencer, how long does it take to get the full, up to speed, on your titer? If you get a vaccine on a Monday, how long is it before you have immunity?

DR. SENCER: You begin to have protective antibodies within two weeks. We have not had any experience with this particular strain of virus in human trials. We will be getting that within the next few weeks and can give you a better answer then.

Q Dr. Sencer, are you going to be using Edwin Kilbourne's strain, and have you produced any vaccine at all yet?

DR. SENCER: There are production lots that are derived from the recombinant that Dr. Kilbourne has made. I don't think any of those have been put into human subjects as yet.

Q Mr. Secretary, have we ever had as large an immunization program as this in the country before?

SECRETARY MATHEWS: Not to my knowledge. The closest I guess you would be most familiar with.

DR. SABIN: One hundred million people received oral polio vaccine within a matter of about a year and a half. But, that provided a form of volunteer participation by the community, by the medical profession, by lay people, which made it possible to do this in the shortest possible time with the minimum of cost because if you are going to have to pay for administering every dose of this vaccine, you are going to end up with a bill that is going to be much larger than the cost of the vaccine.

Q What year was that, Dr. Sabin?

MORE

DR. SABIN: It began in 1962 and went on to 1963. This was the special vaccine -- on Sunday when people didn't go to work, the people came to school, the vaccine was brought to them. It was a remarkable organization which I think may have some value.

Q Would you like to see that done this time, and do you think it is feasible to do it this time?

DR. SABIN: You see, the problem here is that we are faced with something for which we don't have enough knowledge, and the only reason it is being done now and was not done a year ago or was not done, let's say, in 1968 is a double one. One is the potential danger of this particular strain, and secondly, that because of new knowledge which makes it possible to develop more quickly a recombinant that will grow enough in eggs, now there is a possibility of making vaccine well in advance.

I must go along with the fact that if that vaccine is not going to be ready by the time the schools open -- if it is going to be ready only for one part of the country, and if that virus does spread and is as bad an actor as it was in 1918, we are going to have an awful lot of bad influenza and you will have a control.

Q Dr. Sabin, what I was really trying to ask was whether you would advocate doctors and nurses volunteering their services, turn out in schoolyards and parking lots the way they did in 1962 and 1963 and get this done? Do you think that is feasible?

DR. SABIN: I would certainly recommend it because I think if this is not done, merely encouraging people to go to their doctor or go to the Health Department and get it will get a very limited response, as done in the past.

Q Dr. Sabin, are you thinking of doing anything about prevention? For instance, how is this passed on to someone?

DR. SABIN: What we know at the present time is that the most important way in which influenza virus and other respiratory viruses is transmitted is by way of the hands rather than droplets, and I have a particular kind of handshake for people with common colds. Give me your hand, Ted. Don't clasp the hand. (Laughter)

MORE

This is the acute respiratory disease handshake and it may be as important as anything else because you don't put that part in your nose or mouth.

Now the reason school children spread so much is because they have it on their hands, and then another thing, too many people you see -- watch the President or King or anybody -- when he coughs he goes (gesturing) and then he shakes your hand. (Laughter)

MR. NESSEN: Why don't we knock it off there and the more technical questions I think Sandy will help you with over at HEW.

END (AT 5:25 P.M. EST)

April 1, 1976

Office of the White House Press Secretary

THE WHITE HOUSE

March 31, 1976

MEMORANDUM FOR THE HEADS OF DEPARTMENTS AND AGENCIES

Last week I announced plans for a national immunization program to inoculate Americans against a swine-type influenza virus. Because of the serious nature of this virus, it is my hope that every man, woman, and child in the country can be inoculated before the end of this calendar year.

Since there are no precedents for an endeavor of this magnitude, I am issuing this directive to assure completion of the task in an appropriate, orderly, and timely manner. The Secretary of Health, Education and Welfare, David Mathews, will take the lead in this effort, but it is essential that all federal department and agency heads give him their full cooperation in carrying out this program.

I have asked the Congress for a supplemental appropriation of \$135 million for this program. The Public Health Service, under the direction of HEW Assistant Secretary for Health, Dr. Theodore Cooper, will proceed with the planning and implementation efforts to make the vaccine available to all Americans. This activity will be carried out in close coordination with the Center for Disease Control, the Bureau of Biologics of the Food and Drug Administration, and the National Institutes of Health.

These efforts will include utilization of State and local health agencies in conducting immunization programs, and as distribution centers for vaccine. It will be necessary to have the full cooperation and participation of the private sector, as well as government, to assure the immunization of the total population in the brief time available. In particular, we will need to mobilize the vast resources of private sector health professionals and facilities.

NATIONAL INFLUENZA IMMUNIZATION PLAN OBJECTIVES

- The vaccine must be tested in field trials for efficacy and effectiveness, and 215 million doses produced to immunize the entire population.
- The nation's health professionals must be encouraged to fully support this effort to increase the effectiveness of the immunization program.
- The public must be made aware of the importance of inoculation against this type of influenza virus through a nationwide citizen awareness program.

more

- The vaccine, along with sufficient medical supplies and equipment, must be distributed through the State agencies. Every opportunity for inoculation must be maximized including mass immunization and the utilization of delivery points already in place, such as physicians' offices, health department clinics, community health centers, and public facilities.
- Epidemiologic and laboratory surveillance will be maintained to evaluate the effectiveness of this effort and to determine disease trends and outbreaks so that any necessary additional immunization and health efforts may be directed toward epidemic control.

Initial efforts are now underway by the Public Health Service.

Our goal is to ensure that the flu vaccine is available at public health facilities, hospitals, schools, and physicians' offices throughout the country and that a maximum number of Americans avail themselves of it. Clearly we have the scientific and medical resources to undertake this action. We will only succeed, however, by effectively mobilizing all units of government, including Federal, State, and local officials, the medical profession, hospitals, clinics, and the manufacturers of the vaccine.

Because the health of our nation is at stake, I intend to give this matter my direct and continuous attention, and I am asking each of you to make a similar commitment within your own organization.

GERALD R. FORD

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

JUN 16 1976

The Honorable Carl Albert
Speaker of the House of
Representatives
Washington, D. C. 20515

Dear Mr. Speaker:

Enclosed for the consideration of the Congress is a draft bill "To permit the United States to provide indemnification against claims for injury related to inoculation with vaccine under a comprehensive nationwide influenza immunization program."

The draft bill would enable the Secretary of Health, Education, and Welfare to agree, in contracts for the purchase of, vaccine in connection with the National Influenza Immunization Program, to indemnify the vaccine manufacturers against claims attributable to inoculation with the vaccine, except claims arising out of the negligence of the manufacturers.

The Department has been negotiating with vaccine manufacturers concerning the terms of the contracts under which the Federal government will purchase influenza vaccine for use in the National Influenza Immunization Program. We and the manufacturers agree that the manufacturers should be responsible for possible injuries resulting from their negligence, if any, in manufacturing the vaccine, whereas the Federal government should be liable for injuries arising from any failure to perform properly those aspects of the program over which it has control. Principally, this is the duty to inform individuals of the risks associated with inoculation. The vaccine manufacturers believe that, under recent court decisions, the possibility exists, in the absence of this proposed legislation, that a vaccine manufacturer could be successfully sued for injuries resulting solely from the Federal government's activities in the Immunization Program. Although we think the possibility of

any such injury occurring, or the vaccine manufacturers being held liable for such injury, is extremely remote, the manufacturers are concerned that they could be required by courts to pay considerable sums for such injuries. The Anti-Deficiency Act now bars the Federal government from agreeing to indemnify the manufacturers for losses stemming from such injuries even though the injuries are not the fault of the manufacturers. The enclosed draft bill would amend existing law to enable this Department to provide assurance of such indemnification.

It is essential to conclude agreements for vaccine production as soon as possible to have sufficient vaccine available in the fall, when the national inoculation effort will occur. There are only six licensed vaccine manufacturers and of these only four are able to produce the influenza vaccine. Sufficient vaccine will be available only if all four of these manufacturers agree to produce vaccine. In order to assure that all four manufacturers will enter into contracts for the needed vaccine, we find it necessary to have authority to indemnify them against any liability they may incur for injuries not their fault. We therefore urge prompt and favorable consideration of the draft bill.

We are advised by the Office of Management and Budget that enactment of this proposal would be in accord with the program of the President.

Sincerely,

/s/ David Mathews

Secretary

Enclosure

A B I L L

To permit the United States to provide indemnification against claims for injury related to inoculation with vaccine under a comprehensive nationwide influenza immunization program.

Be it enacted by the Senate and the House of Representatives of the United States of America in Congress assembled, That section 311 of the Public Health Service Act is amended by adding at the end of that section the following new subsection (d):

"(d) The Secretary of Health, Education, and Welfare may agree, as part of any contract for the purchase of a vaccine for a comprehensive nationwide influenza immunization program, to indemnify the manufacturer of the vaccine against claims attributable to inoculation with the vaccine except claims for failure of the manufacturer to exercise due care in the manufacture or handling of the vaccine in accordance with the contract specifications or for failure to discharge properly any other obligation under the contract. Nothing herein shall be construed as creating or changing any rule of liability under any law of the United States or of any State."

*We'll indemnify you for anything except what
we specify in the contract not to create
a presumption*

THE WHITE HOUSE

WASHINGTON

July 23, 1976

Dear Paul:

I want to convey to you once again the strong commitment of this Administration to a National Influenza Immunization Program.

Almost four months ago to the day, I announced the initiation of this program after a panel of the country's top health, medical and scientific leaders unanimously recommended to me that we move forward. Those leaders convinced me that a strain of virus, popularly known as "swine flu", could threaten the health of our citizenry unless a massive, extraordinary program of national inoculations was immediately undertaken.

I requested a special appropriation of \$135 million from the Congress to ensure the production and distribution of sufficient swine-type influenza vaccine. I was gratified by the rapid response of the Congress in acting on my request and I signed it into law on April 15.

Since that time we have made significant progress toward our goal of making this vaccine available to all Americans before the onset of an influenza season this fall. Nearly 90 million doses of vaccine have already been produced; organizational efforts at the state and local levels for delivery of inoculations are well advanced; voluntary groups have been identified, briefed, and organized; and results of the largest pre-certification clinical field trials ever performed are very positive for the safety and effectiveness of the vaccine.

Despite these accomplishments, however, we now face a growing problem in making this public health program available to the American people.

Secretary Mathews reported to me yesterday afternoon that the providers of liability insurance for the vaccine manufacturers continue to resist our efforts to work out an agreement to provide insurance through normal commercial

channels. It is their position that the inordinate size of this program makes it difficult if not impossible to accurately assess, and thereby reasonably insure, the potential hazards of administering the vaccine to everyone.

Although experience indicates that there is a very low risk of untoward reactions to influenza vaccine, we will continue to pursue an agreeable compromise with these companies. Without essential product liability coverage, the vaccine manufacturers are unwilling to release the vaccine for use in this national program. Secretary Mathews reported to me that unless this liability problem is resolved in the next few days, the manufacturers will terminate their production of swine flu vaccine. All of us would be derelict in our responsibilities to the American people if this program comes to a screeching halt.

In anticipation of just this situation, I directed Secretary Mathews on June 16 to submit legislation to the Congress to enable the government to assume a proper share of risks for the program, but not those resulting from negligence of the manufacturer. This measure is still under consideration by the Congress, but further delay, regardless of the reason, could result in the failure of this program to meet this essential public health need for all Americans.

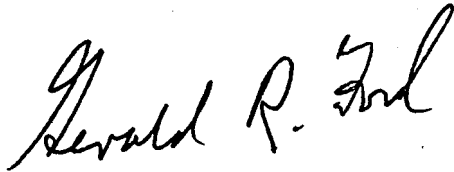
I share the concern of the Congress that the vaccine manufacturers and insurers be held accountable. But my first concern is that a safe and effective vaccine be available to all Americans who want it during the flu season.

I am pleased that the Health and the Environment Subcommittee of the House Interstate and Foreign Commerce Committee will hold another hearing on this important matter. I urge you to act immediately on my legislative proposal. We cannot accept the fact that the health of all Americans can be placed in jeopardy by a failure to take action on this important legislation.

While we await Congressional action -- and I trust that the Congress will act quickly with due regard for the Nation's health and safety -- I have directed Secretary Mathews to ask for the cooperation of the manufacturers again to ensure that they do not terminate their production of this vital vaccine while negotiations continue.

In conclusion, let me reiterate a single point: The threat of swine flu is very 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 -- bog down in petty wrangling. Let's work together to get on with the job.

Sincerely,

A handwritten signature in cursive script, reading "Gerald R. Ford". The signature is written in dark ink and is positioned below the word "Sincerely,".

The Honorable Paul G. Rogers
Chairman
Subcommittee on Health
and the Environment
Interstate and Foreign Commerce
Committee
House of Representatives
Washington, D.C. 20515

THE WHITE HOUSE

WASHINGTON

August 5, 1976

MEMORANDUM FOR: JOE JENCKS
BILL KENDALL
CHARLIE LEPPERT
TOM LOEFFLER
PAT RAWLINS *Rowland*
FROM: JIM CAVANAUGH
SUBJECT: Swine Flu Vaccination Program

Attached is a fact sheet that the President referred to in this morning's leadership meeting. Also attached is a copy of the President's letter to Senator Mansfield and Speaker Albert.

These were distributed to the members of Congress who attended this morning's leadership meeting.

Attachments

THE WHITE HOUSE

WASHINGTON

August 5, 1976

FACT SHEET

Swine Flu Influenza Immunization Program Legislation

The bill would amend the Public Health Service Act to establish a mechanism to handle claims and if necessary, compensate persons injured as a result of inoculation with vaccine under the Swine Flu National Influenza Immunization Program. It 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 judgment.

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.

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

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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THE WHITE HOUSE

WASHINGTON

August 5, 1976

MEMORANDUM FOR: JOE JENCKS
BILL KENDALL
✓ CHARLIE LEPPERT
TOM LOEFFLER
PAT RAWLINS

FROM: JIM CAVANAUGH

SUBJECT: Swine Flu Vaccination Program

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AUGUST 4, 1976

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more

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Sincerely,

GERALD R. FORD

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