

88/12/76

APPROVED

AUG 12 1976

*Signed in Ceremony -
Cabinet Room - 12:00 Noon.
Statement + Remarks issued
8/12/76*

THE WHITE HOUSE
WASHINGTON
August 11, 1976

ACTION

Last Day: August 23

MEMORANDUM FOR THE PRESIDENT

FROM: JIM CANNON *JC*

SUBJECT: S. 3735 - National Swine Flu Immunization Program of 1976

*Archive
8/12/76*

Attached for your consideration is S. 3735, sponsored by Senator Kennedy.

The enrolled bill authorizes the Secretary of Health, Education and Welfare to carry out a national swine flu immunization program until August 1, 1977, and provides legal protection for agencies, organizations and individuals who manufacture, distribute, and administer swine flu vaccine against liability for other than their own negligence to persons alleging personal injury or death arising out of the administration of the vaccine.

Additional information is provided in OMB's enrolled bill report at Tab A.

OMB, Max Friedersdorf, Counsel's Office (Lazarus) and I recommend approval of the enrolled bill and the proposed signing statement which has been cleared by the White House Editorial Office (Smith).

RECOMMENDATION

That you sign S. 3735 at Tab B.

That you approve the signing statement at Tab C.

Approve *JC* Disapprove _____





EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

AUG 11 1976

MEMORANDUM FOR THE PRESIDENT

Subject: Enrolled Bill S. 3735 - National Swine Flu
Immunization Program of 1976
Sponsors - Sen. Kennedy (D) Massachusetts and
6 others

Last Day for Action

August 23, 1976.

Purpose

Authorizes the Secretary of Health, Education, and Welfare (HEW) to carry out a national swine flu immunization program until August 1, 1977, and provides legal protection for agencies, organizations, and individuals who manufacture, distribute, and administer swine flu vaccine against liability for other than their own negligence to persons alleging personal injury or death arising out of the administration of the vaccine.

Agency Recommendations

Office of Management and Budget	Approval (Signing statement attached)
Department of Health, Education, and Welfare	Approval
Department of Justice	No objection
Department of Housing and Urban Development	Approval (informally)

Discussion

S. 3735 is the result of extended negotiations between the Administration and the House and Senate Health Committees to obtain legislation that would enable the Government to provide a comprehensive program of swine flu immunization to protect the American public during the next flu season. You previously recommended funding for this program, and the Congress responded to your request by appropriating



\$135 million on April 15, 1976 in P.L. 94-266.

The enrolled bill responds to the concern of the vaccine manufacturers that they might be held liable for negligence or failures in those aspects of the immunization program over which they had no control. This concern stemmed from the trend in court decisions to hold manufacturers of some drugs and vaccines liable to users of the products under principles of strict product liability. Moreover, the insurance carriers refused to provide liability insurance because of the magnitude of the program and the uncertainties regarding the risk involved.

S. 3735 has the following three major features.

Program authorization - The enrolled bill would authorize HEW to conduct activities necessary to carry out the national swine flu immunization program until August 1, 1977. These activities include development, preparation, procurement and distribution of safe and effective vaccine, as well as related personnel training and research activities.

The bill would require HEW to develop, in consultation with the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and to implement a written informed consent form and procedures for assuring that the risks and benefits from the swine flu vaccine are fully explained to each person receiving the vaccine -- including information necessary to advise them with respect to their rights and remedies.

The bill would provide that any contract for procurement by the United States of swine flu vaccine shall be subject to renegotiation to eliminate any profit realized from such procurement. A "reasonable" profit -- to be determined by the Secretary of HEW -- would be allowed, however, with respect to influenza A/Victoria/75 vaccine, which would be administered with the swine flu vaccine to high risk groups.

HEW would be required to submit quarterly reports to the Congress on the administration of the swine flu program. The bill states that no funds are authorized to be appropriated for the swine flu activities specifically enumerated in the bill in addition to the funds already appropriated by P.L. 94-266, except for grants to the States to assist in meeting their costs related to the swine flu program.



The authorized activities summarized above are unnecessary, since HEW already has the statutory authority to conduct the program, and the activities have been underway for some time.

Protection against liability - S. 3735 would establish a procedure under which all claims for injury from inoculation with the swine flu vaccine would be asserted directly against the United States. The filing of claims and actions under the Federal Tort Claims Act would be the exclusive remedy for all eligible claimants. Since the United States is responsible only for negligence under that Act, the enrolled bill would make an exception for this program and permit a claimant to recover under any principle of strict liability in tort or breach of warranty which is applicable in the jurisdiction in which the act or omission is alleged to have occurred.

The bill would not absolve participants in the program -- drug manufacturers, public and private agencies, medical and paramedical personnel, and the government -- from negligence. In those instances in which payment is made by the Government to a claimant, either by court judgment or administrative settlement, the Government could bring an action to recover any damages awarded which are caused by the negligence of any of the other participants in the program.

The protection provided to all participants in the program would be available to public and private agencies and medical and paramedical personnel only if they administer the vaccine without charge and comply with the consent form and procedures requirements. Provisions are included in the bill for the removal to Federal court of suits filed in State court against participants in the program, and for the substitution of the United States as the sole defendant.

Within one year after enactment of the enrolled bill, and semiannually thereafter, the Secretary of HEW would be required to submit a report to the Congress on the conduct of settlement and litigation activities provided for in the bill.

Study of liability - The enrolled bill would require a study to be conducted or provided for by HEW 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 liability for such injuries in the future. The Secretary would be required to report to the Congress within one year the findings of the study and any appropriate recommendations for legislation.

In a letter to Chairman Rodino of the House Judiciary Committee on an earlier House version of this legislation, Secretary Mathews stated that it reflected the following four principles:

"1. The public's legal remedies for genuine injuries should not be circumscribed and an efficient method of pursuing them should be assured.

2. All program participants, including the Government, should be responsible for their own negligence.

3. No program participant or other person should make a windfall profit from this public health program.

4. No solution to the difficulties which have developed in this Government-sponsored and administered universal immunization program should be established as a precedent for other programs of smaller scope in which the Government plays a different and significantly smaller role."

With respect to the fourth principle, it should be noted that the "findings" section of S. 3735 refers to the "unique role" of the United States in the initiation, planning, and administration of the swine flu program. The bill as enrolled, however, also finds that the procedure instituted for handling claims in this case is necessary "until Congress develops a permanent approach for handling claims arising under programs of the Public Health Service Act." This latter finding, plus the requirement for a study by the Secretary mentioned above, suggests the possibility that S. 3735 may become a precedent for other programs.

The Department of Justice also sent a letter to Chairman Rodino on August 9 favoring enactment of the earlier House version of this legislation. Justice now states in the attached views letter that the additional requirement included in the enrolled bill that program participants comply with the informed consent form and procedure requirements is troublesome and will likely lead to considerable litigation. Justice believes it would



have been preferable if this program could have been accomplished with the normal insurance coverage usually provided to vaccine manufacturers. The Department notes, however, that extensive efforts to obtain such coverage were unavailing and the desirability of conducting the program was such that the legislation was deemed necessary. Justice concludes that the enrolled bill is technically and administratively acceptable, "in consideration of the strong policy reasons requiring the emergency enactment of the legislation."

In view of the general consensus that liability protection legislation is essential to resolve the impasse in the swine flu immunization program, and since the enrolled bill was worked out in lengthy discussions between the various concerned groups, your approval of S. 3735 is recommended. A draft signing statement is attached for your consideration.

James M. Frey
Assistant Director for
Legislative Reference

Enclosures



S. 3735



Swine The Bill Dept.
to A. Linder 9/15 (10:20)

STATEMENT BY THE PRESIDENT

I have today signed S. 3735, the "National Swine Flu Immunization Program of 1976."

I am gratified that the Congress has responded to this potential public health emergency by providing, as I requested, the assurances necessary to make possible the protection of all Americans against this threat.

S. 3735 will permit the Federal Government to assure appropriate liability protection for those manufacturing, distributing and administering the vaccine and provides a claims procedure for persons who might be injured. Extraordinary Federal measures are required to implement a program of this magnitude and I am sure that I speak for all Americans in expressing appreciation for this Congressional action.

Scientific and medical evidence continues to support the need for a national influenza immunization program. We have developed a safe and effective vaccine with a very low risk of adverse reactions. What we must do now is make it available as soon and efficiently as possible.

I strongly reaffirm my commitment to this program and I have directed the Secretary of Health, Education, and Welfare to move as expeditiously as possible to insure that we keep our original commitment of making this vaccine available to all Americans.



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OFFICE OF MANAGEMENT AND BUDGET

Date: 8-12-76

TO : *Bob Linder*

FROM: James M. Frey
Assistant Director for
Legislative Reference

*Attached is the official
HEW view's letter on the
same for enrolled bill,
S. 3735.*



T



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

AUG 11 1976

The Honorable James T. Lynn
Director, Office of Management
and Budget
Washington, D. C. 20503



Dear Mr. Lynn:

This is in response to your request for a report on S. 3735, an enrolled bill "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."

In summary, we strongly recommend that the President sign the enrolled bill, as its enactment is necessary to carry out the national program of immunization against swine influenza.

The bill would provide that the United States be substituted as the defendant in suits based on claims for personal injury or death resulting from swine influenza vaccine brought against vaccine manufacturers or other participants in the swine influenza immunization program. The United States, in turn, would have the right to recover for its losses in such a suit from a program participant whose negligence caused the injury or death. The provisions of the bill are summarized in more detail at Tab A.

From the outset of the swine influenza immunization program, the vaccine manufacturers have expressed their concern that they might be held liable for negligence or failures in those aspects of the immunization program over which they had no control. Their concerns stemmed from the trend in court decisions to hold manufacturers of some drugs and vaccines liable to users of the products under principles of strict products liability. Two Federal courts of appeals have held

manufacturers of polio vaccine liable, even in the absence of negligence, for failure to see to it that warnings of the hazards of the vaccine were communicated to the recipients of the vaccine.

In the case of the swine influenza vaccine, the manufacturers were understandably concerned that they would not be able to discharge their obligations to see to it that whatever warning might be appropriate reached the consumer, since the Government would be purchasing the entire output of the vaccine and would be responsible for its distribution to State health agencies, which in turn would arrange for the inoculation of the population. Additionally, in this emergency immunization program, the Government would be assuming functions normally undertaken by the manufacturers, i.e., establishing the specifications for the vaccine, investigating and determining the benefits and risks from its use, developing a statement of such benefits and risks, and seeing to it that the statement was communicated to the persons inoculated with the vaccine.

After carrying out extensive efforts to solve the liability problem of the manufacturers through (1) contract provisions without legislation, (2) proposed legislation indemnifying the manufacturers for losses for other than their own negligence, and (3) attempts to persuade the insurance companies to grant liability coverage to the manufacturers, a new legislative approach was developed through the joint efforts of the Congress, the Administration, and other interested parties.

The enrolled bill, reflecting this approach, embodies three principles:

1. The public's legal remedies for genuine injuries should not be circumscribed and an efficient method of pursuing them should be assured.



2. All program participants, including the Government, should be responsible for their own negligence.

3. No program participant or other person should make a windfall profit from this public health program.

The enrolled bill, by substituting the United States for program participants sued for death or personal injury resulting from swine influenza vaccine, protects not only non-negligent manufacturers, who up to now have been unable to obtain insurance, but also other participants in the program who have been finding difficulties in obtaining insurance. Additionally, except for insurance needed to protect participants against indemnification claims by the Government in those instances in which the participant may be negligent, no other insurance is necessary. This should materially reduce the cost of the vaccine to the Government since its price will reflect the cost of insurance. Windfall profits to insurance companies from excessively high premiums for risks the Government believes to be relatively minor would also be averted.

It is imperative that the President act expeditiously in relation to the enrolled bill. If the enrolled bill is signed, it will be possible to resume production with minimal delays, purchase the vaccine now already manufactured, and begin the distribution of the vaccine to make it available to the public by mid to late September. The vaccine produces effective immunity in most cases within two to three weeks of injection. It would be possible for the entire population who wished to be vaccinated to develop immunity by mid-December. The peak flu season is typically in January and February.

We strongly recommend that the President sign the enrolled bill.

Sincerely,


Secretary

Enclosure



SUMMARY OF THE PROVISIONS OF S. 3735

The bill would provide a redundant authority for carrying out the national swine influenza immunization program, and would require the Secretary to make quarterly reports on the administration of the program.

Each contract for the procurement of the swine influenza vaccine from a manufacturer would be subject to renegotiation to eliminate any profit realized from such procurement, except that with respect to vaccine against the strain of virus, known as influenza A/Victoria/75 (to be mixed with the swine influenza vaccine), a reasonable profit would be permitted. Any insurance premium included in the contract price and which was refunded to the manufacturer under any retrospective experience-rating plan or similar plan would be returned to the United States.

The enrolled bill would establish, as the exclusive remedy for persons alleging injury, a procedure consistent with that now provided for negligence claims against the United States under which all claims in connection with the program would have to be asserted directly against the United States. The enrolled bill would make the United States liable with respect to claims for personal injury or death arising out of the manufacture, distribution or administration of the vaccine in the same manner and to the same extent as the United States is now liable for claims based on the negligence of its own agents, except that the liability would be based on any theory of liability, and not solely negligence, that would govern an action against a program participant under the law of the place where the act or omission occurred, and the normal exceptions to the liability of the United States Government based on the due care or discretionary judgment of a Federal employee would not be available to the United States in defense of a claim against a program participant. Program participants would include the vaccine manufacturers and distributors, public and private agencies or organizations that participated in the program without charge for the vaccine or its administration and in compliance with the



informed consent form and procedures established for the program, and medical personnel who participated without charge for the vaccine or its administration and in compliance with the informed consent form and procedures established for the program.

The Attorney General would be required to defend any civil action or proceeding based on personal injury or death resulting from the administration of swine influenza vaccine brought against any employee of the United States or any program participant. Any person against whom the action or proceeding was brought would be required to deliver all relevant papers to the United States for its use in defending the action. A claim brought in a State court would be removed to the United States district court for that area. Program participants would be required to cooperate with the United States in the defense of claims, and, if they failed to do so, their protection under the enrolled bill would be revoked and suits against them permitted in the usual manner.

If payment were made by the United States to any claimant under the authority of the enrolled bill, the United States would have a right to recover for any portion of the payment attributable to negligent conduct on the part of any program participant in carrying out any obligation or responsibility in connection with the program or to the failure of any program participant to carry out any contract obligation or responsibility.

Within one year of the date of enactment of the enrolled bill and semi-annually thereafter, the Secretary would report to Congress on the conduct of the litigation and settlement activities under the bill.

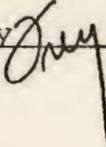
The Secretary would further be required to conduct a study of the scope and extent of liability for personal injuries arising out of immunization programs and alternative means of providing protection against that liability and compensation for those injuries. The Secretary would have to report on the study within a year after the date of enactment to the Congress with recommendations for legislation as the Secretary deemed appropriate.



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
ROUTE SLIP

DATE 8-11-76

TO: Bob Linder

FROM: Jim Frey 

REMARKS:

I should note that the HEW views letter attached is the Advance Copy. We have confirmed with HEW that this is their official recommendation.



OMB FORM 38
REV SEPT 70

To: J. Casanova
8-11-76
6:00 PM



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

AUG 11 1976

MEMORANDUM FOR THE PRESIDENT

Subject: Enrolled Bill S. 3735 - National Swine Flu
Immunization Program of 1976
Sponsors - Sen. Kennedy (D) Massachusetts and
6 others

Last Day for Action

August 23, 1976.

Purpose

Authorizes the Secretary of Health, Education, and Welfare (HEW) to carry out a national swine flu immunization program until August 1, 1977, and provides legal protection for agencies, organizations, and individuals who manufacture, distribute, and administer swine flu vaccine against liability for other than their own negligence to persons alleging personal injury or death arising out of the administration of the vaccine.

Agency Recommendations

Office of Management and Budget	Approval (Signing statement attached)
Department of Health, Education, and Welfare	Approval
Department of Justice	No objection
Department of Housing and Urban Development	Approval (informally)

Discussion

S. 3735 is the result of extended negotiations between the Administration and the House and Senate Health Committees to obtain legislation that would enable the Government to provide a comprehensive program of swine flu immunization to protect the American public during the next flu season. You previously recommended funding for this program, and the Congress responded to your request by appropriating



\$135 million on April 15, 1976 in P.L. 94-266.

The enrolled bill responds to the concern of the vaccine manufacturers that they might be held liable for negligence or failures in those aspects of the immunization program over which they had no control. This concern stemmed from the trend in court decisions to hold manufacturers of some drugs and vaccines liable to users of the products under principles of strict product liability. Moreover, the insurance carriers refused to provide liability insurance because of the magnitude of the program and the uncertainties regarding the risk involved.

S. 3735 has the following three major features.

Program authorization - The enrolled bill would authorize HEW to conduct activities necessary to carry out the national swine flu immunization program until August 1, 1977. These activities include development, preparation, procurement and distribution of safe and effective vaccine, as well as related personnel training and research activities.

The bill would require HEW to develop, in consultation with the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and to implement a written informed consent form and procedures for assuring that the risks and benefits from the swine flu vaccine are fully explained to each person receiving the vaccine -- including information necessary to advise them with respect to their rights and remedies.

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The authorized activities summarized above are unnecessary, since HEW already has the statutory authority to conduct the program, and the activities have been underway for some time.

Protection against liability - S. 3735 would establish a procedure under which all claims for injury from inoculation with the swine flu vaccine would be asserted directly against the United States. The filing of claims and actions under the Federal Tort Claims Act would be the exclusive remedy for all eligible claimants. Since the United States is responsible only for negligence under that Act, the enrolled bill would make an exception for this program and permit a claimant to recover under any principle of strict liability in tort or breach of warranty which is applicable in the jurisdiction in which the act or omission is alleged to have occurred.

The bill would not absolve participants in the program -- drug manufacturers, public and private agencies, medical and paramedical personnel, and the government -- from negligence. In those instances in which payment is made by the Government to a claimant, either by court judgment or administrative settlement, the Government could bring an action to recover any damages awarded which are caused by the negligence of any of the other participants in the program.

The protection provided to all participants in the program would be available to public and private agencies and medical and paramedical personnel only if they administer the vaccine without charge and comply with the consent form and procedures requirements. Provisions are included in the bill for the removal to Federal court of suits filed in State court against participants in the program, and for the substitution of the United States as the sole defendant.

Within one year after enactment of the enrolled bill, and semiannually thereafter, the Secretary of HEW would be required to submit a report to the Congress on the conduct of settlement and litigation activities provided for in the bill.

Study of liability - The enrolled bill would require a study to be conducted or provided for by HEW 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 liability for such injuries in the future. The Secretary would be required to report to the Congress within one year the findings of the study and any appropriate recommendations for legislation.

In a letter to Chairman Rodino of the House Judiciary Committee on an earlier House version of this legislation, Secretary Mathews stated that it reflected the following four principles:

"1. The public's legal remedies for genuine injuries should not be circumscribed and an efficient method of pursuing them should be assured.

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With respect to the fourth principle, it should be noted that the "findings" section of S. 3735 refers to the "unique role" of the United States in the initiation, planning, and administration of the swine flu program. The bill as enrolled, however, also finds that the procedure instituted for handling claims in this case is necessary "until Congress develops a permanent approach for handling claims arising under programs of the Public Health Service Act." This latter finding, plus the requirement for a study by the Secretary mentioned above, suggests the possibility that S. 3735 may become a precedent for other programs.

The Department of Justice also sent a letter to Chairman Rodino on August 9 favoring enactment of the earlier House version of this legislation. Justice now states in the attached views letter that the additional requirement included in the enrolled bill that program participants comply with the informed consent form and procedure requirements is troublesome and will likely lead to considerable litigation. Justice believes it would



have been preferable if this program could have been accomplished with the normal insurance coverage usually provided to vaccine manufacturers. The Department notes, however, that extensive efforts to obtain such coverage were unavailing and the desirability of conducting the program was such that the legislation was deemed necessary. Justice concludes that the enrolled bill is technically and administratively acceptable, "in consideration of the strong policy reasons requiring the emergency enactment of the legislation."

In view of the general consensus that liability protection legislation is essential to resolve the impasse in the swine flu immunization program, and since the enrolled bill was worked out in lengthy discussions between the various concerned groups, your approval of S. 3735 is recommended. A draft signing statement is attached for your consideration.

James M. Frey
Assistant Director for
Legislative Reference

Enclosures



~~TO THE SENATE:~~

I have today signed S. 3735, the "National Swine Flu Immunization Program of 1976."

I am gratified that the Congress has responded to this potential swine flu emergency by providing necessary protection for all those participants whose cooperation will be essential to assure that every American has the opportunity to obtain the desired protection. This unique threat requires extraordinary Federal measures to assure that we can avoid a catastrophe similar to that which occurred in 1918-1919. I am sure that I speak for all Americans in expressing this appreciation.

Secretary Mathews has recently consulted with the scientific and medical community on the need to continue this national program. The community has reaffirmed the desirability of the program. I urge all Americans to avail themselves of the opportunity to secure protection against swine flu.



THE WHITE HOUSE

ACTION MEMORANDUM

WASHINGTON

LOG NO.:

Date: August 11

Time: 600pm

FOR ACTION: Spencer Johnson
 Max Friedersdorf
 Ken Lazarus
 Robert Hartmann

cc (for information): Jack Marsh
 Jim Cavanaugh
 Ed Schmults

FROM THE STAFF SECRETARY

DUE: Date: August 11

Time: asap

SUBJECT:

S. 3735-National Swine Flu Immunization
 Program of 1976

ACTION REQUESTED:

 For Necessary Action For Your Recommendations Prepare Agenda and Brief Draft Reply For Your Comments Draft Remarks

REMARKS:

please return to judy johnston, ground floor west wing

PLEASE ATTACH THIS COPY TO MATERIAL SUBMITTED.

If you have any questions or if you anticipate a delay in submitting the required material, please telephone the Staff Secretary immediately.

K. R. COLE, JR.
 For the President

I have today signed S. 3735, the "National Swine Flu Immunization Program of 1976."

O.K. Mart.

I am gratified that the Congress has responded to this potential public health emergency by providing, as I requested the necessary assurances to those program participants whose cooperation is essential to protect all Americans against this threat.

S. 3735 will permit the Federal Government to assure appropriate liability protection for those manufacturing and distributing and administering the vaccine as well as a claims procedure for persons who might be injured, as a result of receiving the vaccine. Extraordinary Federal measures are required to implement a program of this magnitude and I am sure that I speak for all Americans in expressing appreciation for this Congressional action.

Scientific and medical evidence continues to support the need for a national influenza immunization program. We have developed a safe and effective vaccine with a very low risk of untoward reactions. What we must do now is make it available as soon and efficiently as possible.

I strongly reaffirm my commitment to this program and I have directed the Secretary of HEW to move as expeditiously as possible to insure that we keep our original commitment of making this vaccine available to all Americans.



OR on edp
D. Smith
8/11/76



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

ADVANCE COPY

The Honorable James T. Lynn
Director, Office of Management
and Budget
Washington, D. C. 20503

Dear Mr. Lynn:

This is in response to your request for a report on S. 3735, an enrolled bill "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."

In summary, we strongly recommend that the President sign the enrolled bill, as its enactment is necessary to carry out the national program of immunization against swine influenza.

The bill would provide that the United States be substituted as the defendant in suits based on claims for personal injury or death resulting from swine influenza vaccine brought against vaccine manufacturers or other participants in the swine influenza immunization program. The United States, in turn, would have the right to recover for its losses in such a suit from a program participant whose negligence caused the injury or death. The provisions of the bill are summarized in more detail at Tab A.

From the outset of the swine influenza immunization program, the vaccine manufacturers have expressed their concern that they might be held liable for negligence or failures in those aspects of the immunization program over which they had no control. Their concerns stemmed from the trend in court decisions to hold manufacturers of some drugs and vaccines liable to users of the products under principles of strict products liability. Two Federal courts of appeals have held



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In the case of the swine influenza vaccine, the manufacturers were understandably concerned that they would not be able to discharge their obligations to see to it that whatever warning might be appropriate reached the consumer, since the Government would be purchasing the entire output of the vaccine and would be responsible for its distribution to State health agencies, which in turn would arrange for the inoculation of the population. Additionally, in this emergency immunization program, the Government would be assuming functions normally undertaken by the manufacturers, i.e., establishing the specifications for the vaccine, investigating and determining the benefits and risks from its use, developing a statement of such benefits and risks, and seeing to it that the statement was communicated to the persons inoculated with the vaccine.

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Sincerely,

Secretary

Enclosure



SUMMARY OF THE PROVISIONS OF S. 3735

The bill would provide a redundant authority for carrying out the national swine influenza immunization program, and would require the Secretary to make quarterly reports on the administration of the program.

Each contract for the procurement of the swine influenza vaccine from a manufacturer would be subject to renegotiation to eliminate any profit realized from such procurement, except that with respect to vaccine against the strain of virus, known as influenza A/Victoria/75 (to be mixed with the swine influenza vaccine), a reasonable profit would be permitted. Any insurance premium included in the contract price and which was refunded to the manufacturer under any retrospective experience-rating plan or similar plan would be returned to the United States.

The enrolled bill would establish, as the exclusive remedy for persons alleging injury, a procedure consistent with that now provided for negligence claims against the United States under which all claims in connection with the program would have to be asserted directly against the United States. The enrolled bill would make the United States liable with respect to claims for personal injury or death arising out of the manufacture, distribution or administration of the vaccine in the same manner and to the same extent as the United States is now liable for claims based on the negligence of its own agents, except that the liability would be based on any theory of liability, and not solely negligence, that would govern an action against a program participant under the law of the place where the act or omission occurred, and the normal exceptions to the liability of the United States Government based on the due care or discretionary judgment of a Federal employee would not be available to the United States in defense of a claim against a program participant. Program participants would include the vaccine manufacturers and distributors, public and private agencies or organizations that participated in the program without charge for the vaccine or its administration and in compliance with the



informed consent form and procedures established for the program, and medical personnel who participated without charge for the vaccine or its administration and in compliance with the informed consent form and procedures established for the program.

The Attorney General would be required to defend any civil action or proceeding based on personal injury or death resulting from the administration of swine influenza vaccine brought against any employee of the United States or any program participant. Any person against whom the action or proceeding was brought would be required to deliver all relevant papers to the United States for its use in defending the action. A claim brought in a State court would be removed to the United States district court for that area. Program participants would be required to cooperate with the United States in the defense of claims, and, if they failed to do so, their protection under the enrolled bill would be revoked and suits against them permitted in the usual manner.

If payment were made by the United States to any claimant under the authority of the enrolled bill, the United States would have a right to recover for any portion of the payment attributable to negligent conduct on the part of any program participant in carrying out any obligation or responsibility in connection with the program or to the failure of any program participant to carry out any contract obligation or responsibility.

Within one year of the date of enactment of the enrolled bill and semi-annually thereafter, the Secretary would report to Congress on the conduct of the litigation and settlement activities under the bill.

The Secretary would further be required to conduct a study of the scope and extent of liability for personal injuries arising out of immunization programs and alternative means of providing protection against that liability and compensation for those injuries. The Secretary would have to report on the study within a year after the date of enactment to the Congress with recommendations for legislation as the Secretary deemed appropriate.



Department of Justice
Washington, D.C. 20530

August 11, 1976

Honorable James T. Lynn
Director, Office of Management
and Budget
Washington, D. C. 20503



Dear Mr. Lynn:

In compliance with your request, I have examined S. 3735, a Bill "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".

This Bill was passed by both Houses of Congress on August 10, 1976 to make it possible to conduct a national immunization program at the time deemed most advantageous by the physicians. It was recommended by its advocates as necessary emergency legislation.

Prior legislation authorized the Department of Health, Education and Welfare to develop and purchase the vaccine. This emergency legislation was deemed necessary because the vaccine manufacturers were unwilling to contract to sell the vaccine to the government for use in the national program for the reason that they could not obtain insurance coverage. It would have been preferable if this program could have been accomplished with the normal insurance coverage as is usually provided to vaccine manufacturers. However, extensive efforts to obtain such coverage were unavailing and the desirability of conducting the program was such that the legislation was deemed necessary.

As a substitute to the unavailable insurance, the Bill provides that in most contemplated situations the exclusive remedy for personal injury or death resulting from inoculation with the swine flu vaccine shall be against the United States under the Federal Tort Claims Act, 28 U.S.C. §§ 1346(b), 2671-2680. The Bill defines "program participant" to include manufacturers and distributors of the vaccine and agencies, organizations and individuals that provide or administer the inoculations

RECEIVED

under the program without charge and in compliance with an informed consent form and procedure to be prescribed. The Bill in effect abolishes any cause of action against any such program participant and substitutes therefor a cause of action against the United States.

The Federal Tort Claims Act is expanded in that a suit based upon the act of a program participant may be based upon theories of strict liability in tort or breach of warranty. Under existing law suits under the Federal Tort Claims Act may only be based upon negligence.

The Bill provides that the Attorney General shall certify that an action is one that arises out of the administration of vaccine under the swine flu program. Upon such certification the suit shall be removed to federal court if it was originally filed in a state court and regardless of where the suit was initially filed the United States shall be substituted as the defendant. The suit shall then proceed in accordance with the provisions governing Federal Tort Claims Act suits.

This Bill is patterned after previous legislation that has abolished suits against different classes of federal employees and provided that the exclusive remedy shall be against the United States under the Federal Tort Claims Act. The first such statute covered suits against government employees based upon their operation of automobiles. 28 U.S.C. § 2679(b)-(e). A statute with almost identical language immunized medical and paramedical employees of the Veterans Administration. 38 U.S.C. § 4116. Later, a very similar statute provided immunity to the medical and paramedical employees of the Public Health Service. 42 U.S.C. § 233(c). Within the last few weeks another similar statute extended this type of immunity to the medical and paramedical employees of the State Department. P.L. 94-350, signed July 12, 1976. This Bill will be interpreted based upon the legislative and court decision precedent developed from those statutes, although this Bill is novel in that it abolishes causes of actions against private individuals and organizations while the prior legislation applied only to federal employees.

The Bill also provides that a program participant shall cooperate with the United States in processing or defending against any claim or lawsuit which is based upon the acts or omissions of such a program participant. Upon a finding by the court that such a program participant has failed to cooperate



the status of a program participant is revoked by the court and such a former participant is then exposed to any and all liability that it would have had without this Bill.

The Bill also creates a right of the United States against any program participant to recover the portion of any damages the United States has paid based upon the failure of a 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 any negligent conduct on the part of any program participant in carrying out any obligation in connection with the swine flu program". The effect of the Bill is that program participants will not be subjected to any expense to defend meritless lawsuits, but they will be liable to the United States for amounts paid for personal injuries or deaths caused by the negligence of such program participants.

As originally developed and discussed in the House Interstate and Foreign Commerce Committee the Bill was technically and administratively sound. Because of the need to pass the legislation on an emergency basis prior to the recess some provisions were amended very hurriedly and with minimal consideration. The most troublesome provision is in Section (k) (2)(B) where the definition of a program participant was made subject to the additional requirement that to fit the definition an organization or an individual must have complied "with the informed consent form and procedures requirements prescribed". This additional provision will very likely lead to a considerable amount of litigation and will also leave in doubt the status of many agencies, organizations and individuals until a court ultimately determines any and all questions relating to compliance with the informed consent provisions. However, in consideration of the strong policy reasons requiring the emergency enactment of the legislation, the Bill is technically and administratively acceptable.

The Department of Justice has no objection to Executive approval of this Bill.

Sincerely,



MICHAEL M. UHLMANN
Assistant Attorney General



I have today signed S. 3735, the "National Swine Flu Immunization Program of 1976."

I am gratified that the Congress has responded to this potential public health emergency by providing, as I requested, the ~~necessary~~ ^{necessary to make possible} assurances to those ~~program participants~~ whose cooperation ~~is essential~~ ^{the protection of} to protect all Americans against this threat.

S. 3735 will permit the Federal Government to assure appropriate liability protection for those manufacturing, ~~and~~ ^{and provides} distributing and administering the vaccine ~~as well as~~ a claims procedure for persons who might be injured, ~~as a result of receiving the vaccine.~~ Extraordinary Federal measures are required to implement a program of this magnitude and I am sure that I speak for all Americans in expressing appreciation for this Congressional action.

Scientific and medical evidence continues to support the need for a national influenza immunization program. We have developed a safe and effective vaccine with a very low risk ^{→ what we must do now is} ~~of untoward reactions.~~ ^{make it available as soon and efficiently as possible} ~~of untoward reactions.~~ ^{reverse reactions.}

I strongly reaffirm my commitment to this program and I have directed the Secretary of HEW to move as expeditiously as possible to insure that we keep our original commitment of making this vaccine available to all Americans.



*OK on edit
D. Smith
8/11/76*

I have today signed S. 3735, the "National Swine Flu Immunization Program of 1976."

I am gratified that the Congress has responded to this potential public health emergency by providing, as I requested the necessary assurances to those program participants whose cooperation is essential to protect all Americans against this threat.

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EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
ROUTE SLIP

DATE 8-11-76

TO: Bob Linder

FROM: Jim Frey *Jim Frey*

REMARKS:

I should note that the HEW views letter attached is the Advance Copy. We have confirmed with HEW that this is their official recommendation.



OMB FORM 38
REV SEPT 70



Ninety-fourth Congress of the United States of America

AT THE SECOND SESSION

*Begun and held at the City of Washington on Monday, the nineteenth day of January,
one thousand nine hundred and seventy-six*

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 consultation shall be completed within two weeks after enactment of this Act, or by September 1, 1976, whichever is sooner. Such procedures shall include the information necessary to advise individuals with respect to their rights and remedies arising out of the administration of such vaccine.

"(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 profit realized from such procurement (except that with respect to vaccine against the strain of influenza virus known as influenza A/Victoria/75 profit shall be allowed but limited 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 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.

“(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, 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 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 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.

“(2)(A) The United States shall be liable with respect to claims submitted after September 30, 1976 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) 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 or two years from the date the claim arose, whichever is later, 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



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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.

“(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 raise 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 (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



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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.

“(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, notwithstanding any provision of State law, the right to recover for that portion of the damages so awarded or paid, as well as any costs of litigation, 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 any negligent conduct on the part of any program participant in carrying out any obligation 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—

“(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 the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands; and

“(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.”



S. 3735—6

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.

Speaker of the House of Representatives.

*Vice President of the United States and
President of the Senate.*

ENLARGED FOR RELEASE UNTIL 12:00 NOON (EDT),

Thursday, August 12, 1976

Office of the White House Press Secretary

THE WHITE HOUSE

STATEMENT BY THE PRESIDENT

I have today signed S. 3735, the "National Swine Flu Immunization Program of 1976."

I am gratified that the Congress has responded to this potential public health emergency by providing, as I requested, the assurances necessary to make possible the protection of all Americans against this threat.

S. 3735 will permit the Federal Government to assure appropriate liability protection for those manufacturing, distributing and administering the vaccine and provides a claims procedure for persons who might be injured. Extraordinary Federal measures are required to implement a program of this magnitude and I am sure that I speak for all Americans in expressing appreciation for this Congressional action.

Scientific and medical evidence continues to support the need for a national influenza immunization program. We have developed a safe and effective vaccine with a very low risk of adverse reactions. What we must do now is make it available as soon and efficiently as possible.

I strongly reaffirm my commitment to this program and I have directed the Secretary of Health, Education, and Welfare to move as expeditiously as possible to insure that we keep our original commitment of making this vaccine available to all Americans.

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OFFICE OF THE WHITE HOUSE PRESS SECRETARY

THE WHITE HOUSE

REMARKS OF THE PRESIDENT
UPON SIGNING S. 3735
THE NATIONAL SWINE FLU
IMMUNIZATION PROGRAM OF 1976

THE CABINET ROOM

12:12 P.M. EDT

Secretary Mathews, Congressman Carter, Dr. Cooper, distinguished members of the medical profession, ladies and gentlemen:

I am deeply appreciative that the Congress, as one of their final actions before the scheduled recess, sent to me for signature the National Swine Flu Immunization Program of 1976. I would like to express my deep appreciation to the bipartisan leadership of both the House and the Senate and responsible leaders in the committees that had jurisdiction for their cooperation in making certain that this legislation got to the White House in time for us to carry forth this program.

This program will permit the Federal Government to assure appropriate liability protection for those who manufacture, distribute and administer this life-saving vaccine. The program also provides a claims procedure for those who might be injured. Scientific and medical evidence continues to support the need for a swine flu inoculation program. A vaccine has been developed that is both safe and effective, with a very low risk of adverse reactions.

I have directed the Secretary of Health, Education and Welfare to move as quickly as possible to make this vaccine available to all Americans. I strongly reaffirm my commitment to this program, which will afford millions of Americans protection against an outbreak of swine flu this winter.

I say again, I am grateful that the Congress did take this action so this program could continue.

END (AT 12:14 P.M. EDT)

