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THE WHITE HOUSE

ACTION

WASHINGTON

Last Day: August 23

August 11, 1976

MEMORANDUM FOR THE PRESIDENT
FROM: JIM CANNON 
SUBJECT: S. 3735 - National Swine Flu Immunization Program of 1976

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 _____ 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



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 HEW to move as expeditiously as possible to insure that we keep our original commitment of making this vaccine available to all Americans.



Meeting folder

THE WHITE HOUSE

WASHINGTON

SIGNING CEREMONY
NATIONAL SWINE FLU IMMUNIZATION PROGRAM
of 1976
(S. 3735)

Thursday, August 12, 1976
12:00 p.m. (10 minutes)
The Cabinet Room

From: Jim Cannon



I. PURPOSE

To sign into law 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.

II. BACKGROUND, PARTICIPANTS, PRESS PLAN

A. Background: On March 24, 1976, you announced plans for a National Influenza Immunization Program to inoculate Americans against a swine-type influenza virus. You requested the Congress to act on a supplemental appropriation request of \$135 million for this program which you signed into law on April 15.

Although significant progress was made toward our goal of making this vaccine available to all Americans, a serious threat developed when it became evident that liability insurance for those involved in the program would not be available through normal channels.

This legislation removes that obstacle by permitting the Federal government to make available necessary liability protection for those manufacturing, distributing, and administering the vaccine. In addition, a claims procedure is established for those few persons who might be injured as a result of receiving inoculations.



B. Participants: Selected Congressional and HEW guests (list attached).

C. Press Plan: Full press opportunity, photo and statement.

III. TALKING POINTS

Talking points to be provided by Bob Orben.



PARTICIPANTS

Secretary David Mathews

Under Secretary Marjorie Lynch

Dr. Delano Meriwether
Program Director for National
Influenza Immunization
Program
Department of Health, Education
and Welfare

Gene Haislip
Director, Office of
Health Legislation
Department of Health, Education
and Welfare

Dr. Theodore Cooper
Assistant Secretary for Health
Department of Health, Education
and Welfare

William H. Taft, IV
General Counsel
Department of Health, Education
and Welfare

Bernard Feiner
Assistant General Counsel
Department of Health, Education
and Welfare

John C. Kruse
Chief, Torts Section
Civil Division
Department of Justice

Dr. James Dickson
Deputy Assistant Secretary
for Health
Department of Health, Education
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Eli Bernzweiz
Special Assistant to the Administrator
Federal Insurance Administration
Department of Housing and Urban Development



Howard Clark
Special Assistant to the Administrator
Federal Insurance Administration
Department of Housing and Urban Development

Congressman Tim L. Carter

Jay Cutler
Administrative Assistant
Senator Javits' Office

Wendy Wertheimer
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James Stuber
Legislative Assistant
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Francis dePeyster
Office of Congressman Carter

Lee Hyde
Staff Member
Committee on Interstate and
Foreign Commerce