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STATEMENT OF
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BEFORE THE
SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH
COMMITTEE ON LABOR AND HUMAN RESOURCES
UNITED STATES SENATE
ON THE
1978-79 FLU PROGRAM

SEN07102

Mr. Chairman and Members of the Subcommittee:

I am pleased to appear here today to discuss our review of the 1978-79 flu program. As requested by the Subcommittee, we examined the program's management and effectiveness and determined from available records the current status of liability claims against the Federal Government arising out of all Federal immunization programs, particularly the swine flu program.

We reviewed the activities of the Office of the Secretary, Center for Disease Control (CDC), and National Institutes of Health in the Department of Health, Education, and Welfare (HEW), and the activities of the Department of Justice. We also interviewed, by telephone, 12 State and 6 county health officials regarding their individual programs.

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BACKGROUND

On March 23, 1978, the President proposed to the Congress an ongoing Federal flu immunization program administered by HEW to supplement existing flu immunization activities and to begin during the 1978-79 flu season. Through this program, HEW planned to increase the number of high-risk individuals immunized from 20 to 40 percent of the total estimated 42 million high-risk population during 1978-79, and to about 60 percent by 1980. HEW's basic objective was to reduce excess mortality among the high-risk group. The proposed budget for the 1978-79 program was $15 million; immunizations were to begin in August and to be completed by late November.

However, congressional concerns were expressed about the need for a Federal flu program, liability, and HEW's ability to plan and implement a safe and effective program. Because funding was delayed, in July 1978, HEW revised the budget request to $8.2 million for a 1978-79 flu program. Congress funded the program at the requested level on August 25, 1978 (Public Law 95-355) and the President signed the legislation on September 8, 1978. Immunizations began in late October 1978 and HEW encouraged immunization projects to continue through January 1979.

PROGRAM RESULTS

The effectiveness of the 1978-79 flu program in preventing excess mortality among high-risk individuals is unknown. Its effectiveness in vaccinating the target population was minimal because of a variety of problems associated with the virus itself and with program management.

The Russian flu strain expected to be predominant during the 1978-79 flu season was not, and a slightly different strain called Brazil flu became predominant. The 1978-79 flu strains in total primarily attacked individuals under age 26. Only a small portion of those over age 65 and the chronically ill over age 26 were attacked. These latter two groups comprise the majority of the high-risk population. Those who were attacked, experienced a relatively mild illness. Therefore, this season's flu caused no measurable excess mortality. In In addition, although the Russian flu vaccine used during the program is expected to provide some protection against Brazilian flu, the level of protection provided is uncertain. Consequently, it is difficult to conclude that the vaccine was effective in preventing excess mortality.

As of February 28, 1979, immunization projects reported administering about 1 million of the 3.5 million doses of vaccine that HEW had planned to be administered under the

1978-79 flu program. Problems which contributed to the failure to administer the number of vaccinations planned include:

--uncertainties about the nature and behavior of flu viruses,

--incomplete predictions of vaccine acceptability,

--uncertain and late program funding,

--ignored program implementation schedules, and

--unresolved liability problems.

Solutions to these problems are needed before HEW can plan and implement an effective flu program.

Uncertainties about the nature and behavior of flu viruses

Flu is not as predictable and controllable through immunization as some other common diseases such as measles or polio. Unlike the more stable organisms which cause these common diseases, flu viruses constantly change and current scientific knowledge is inadequate to predict with certainty (1) the antigenic content of the coming year's flu virus, (2) the level and severity of the disease caused by the virus, and (3) the group of individuals most likely to be affected. As a result, HEW's predictions can and do create controversy about the need for and implementation of a flu program. For the 1978-79 flu program this controversy affected its acceptance by the public and health professionals.

Like the swine flu program, this year's flu program shows how risky predicting flu virus behavior can be. Not only did the predicted Russian flu not become predominant as expected, but also the predicted population group to be most seriously affected was attacked infrequently. HEW had predicted, based on past experience, that the 1978-79 flu would be most severe in the chronically ill and those over 65 years of age. However, the population attacked most frequently were people under 26 years of age, and the disease consequences were generally mild in those attacked. More scientific knowledge about the flu virus is needed to improve the reliability of predictions for each coming flu season. Such knowledge is also needed to facilitate planning for the best way to control excess flu mortality.

Incomplete predictions of vaccine acceptibility

Although the 1978-79 flu program was targeted at high-risk individuals, many of whom would normally be under the care of a private physician, the potential demand for vaccine by this group through public programs was never assessed. Several State officials said that the most significant factor regarding the program's failure to meet immunization goals was the lack of response by the high-risk group.

HEW assumed that high-risk people would desire vaccination based largely on (1) a CDC survey of the general

adult population completed in February 1978 which showed that about 50 percent would want to be immunized if a nationwide program were recommended, and (2) its success in motivating a large portion of the high-risk population to be vaccinated in the swine flu program. The CDC survey, however, did not specifically assess the attitudes of high-risk people. While they were probably included in the survey, their specific responses to the question on willingness to be immunized were not separately analyzed.

Uncertain and late program funding

Most flu program grantees attributed the small number of people vaccinated during the program to a number of factors affected by uncertain and late funding. These factors included key program components such as vaccine availability, project readiness to proceed, delivery schedules, and public information programs. Although HEW encouraged potential grantees to develop program plans and procedures in anticipation of funding legislation, some grantees which planned to participate cancelled their efforts because of late funding. According to CDC, flu immunizations should be completed by late November for optimal program effectiveness. The 1978-79 flu program was originally planned to meet this schedule. However, by the end of November, fewer than 600,000 doses had been administered.

According to an HEW official, using normal operating funds, HEW began planning for the flu program before it was funded, in anticipation that an appropriation would be forthcoming. He said that starting a flu program before the peak flu season would have been impossible had HEW waited to begin until funds were appropriated. Key activities carried out in advance of the appropriation included:

--Surveying immunization grantees to determine

(1) if they would participate in the proposed program and

(2) the extent of their participation based on various possible funding dates. Surveys were conducted on February 7 and 24, May 4, July 21 and August 17, 1978.

--Developing grant guidelines and furnishing them to immunization grantees by June 1, 1978.

--Obtaining comments and advice from advisory committees, States, and other organizations on the information form explaining the benefits and risks of vaccination.

--Developing vaccine contract proposals (RFPs) and furnishing them to vaccine manufacturers before June 1, 1978. The RFPs did not contain vaccine

potency specifications because these did not become available until July, 1978.

--Arranging for adequate vaccine production by the manufacturers.

--Conducting preliminary reviews of most grant applications. CDC encouraged grantees to submit applications early, and by the time the Congress appropriated funds for the program 37 applications had been received and reviewed. Eleven applications were received after the appropriation.

HEW was required by the legislation to obligate all funds for the 1978-79 flu program by September 30, 1978. By then HEW reported obligating $6.7 of the $8.2 million appropriated as follows:

--$5.1 million for grants to 48 immunization projects for vaccine procurement and program implementation,

--$0.5 million for CDC direct operations, and

--$1.1 million for NIH participation in vaccine clinical trials.

HEW officials said that the $1.5 million unobligated was returned to the Treasury.

Ideally, according to CDC and grantee schedules, funds should be available to grantees by mid-June or early July to allow enough lead time to prepare a program. However, 1978-79 flu program grantees could not make firm plans or

commitments until funds were appropriated in early September and grants were received at the end of September. Thus, although vaccine became available in early October, few projects scheduled active vaccination programs before November. In addition, some States reported that the delay in program implementation reduced the demand for vaccine by health professionals and the public and caused conflicts with ongoing children's immunization programs.

Ignored program implementation schedules

HEW continued efforts to get funding and to promote the flu program after a point in time when its potential effectiveness was severely limited. A reduced program to immunize about 40 percent of the original goal was utimately funded.

As recommended by our report on the swine flu program (The Swine Flu Program: An Unprecedented Venture in Preventive Medicine, HRD-77-115, June 27, 1977), CDC has established a timephased plan for dealing with pandemic influenza which includes specific decision points. CDC did not characterize the 1978-79 flu as a pandemic flu but did have decision points incorporated in its program plan. CDC and several States reported in May 1978 that if grant funds were unavailable by early summer, immunization projects might be unable to develop adequate programs. At that time, CDC reported that if grant funds were

not available by July 20, 1978, the advisability of proceeding with the program should be reconsidered.

On July 26, 1978, the Director, CDC, recommended to the Assistant Secretary for Health that the 1978-79 flu program be revised from an active vaccine administration program, and be limited to improving surveillance operations across the country and planning for administering vaccine the following year. However, the Secretary, HEW, chose to proceed with the program anyway because (1) it would provide vaccine for poor people in the high-risk groups who would otherwise be unable to obtain it, and (2) he saw it as an opportunity to establish an ongoing flu immunization program.

Unresolved liability problems

Liability problems which became an issue for public vaccination programs during the swine flu program, continued to plague the 1978-79 flu program. This was reported as a major factor in the States' inability to meet immunization targets, because some public health officials were reluctant to participate in the program.

Before the program was funded, a representative of the Association of State and Territorial Health Officers testified in April 1978, before the Health Subcommittee of the House Interstate and Foreign Commerce Committee,

that the liability issue was the main cause of State (or grantee) objection to the program. He said the program should not go forward until the liability issue had been solved. After the program had been implemented, several immunization project health officials told us that some public health officials in their projects either did not participate in the program or did so reluctantly because of concerns about liability.

Much of the liability problem for project participants seems to stem from concerns about the Guillain-Barre Syndrome and the numbers of claims arising from the swine flu program. Under the swine flu program, the Federal Government assumed all liability, but could seek recovery where negligence could be shown on the part of program participants. Responsibility for liability in the 1978-79 flu program is unclear where no negligence is involved. Project participants were responsible for their actions in administering the vaccine, and for informing vaccinees of the potential benefits and risks of vaccination.

STATUS OF LIABILITY CLAIMS

Since 1963, Public Health Service records show that 3,721 vaccine-related claims have been made against the Federal Government through the Public Health Service, of

which 3,694 are swine flu claims. The other 27 claims by type of vaccine are as follows:

Polio	19
Flu	3
Smallpox	3
Typhus/Typhoid	1
Measles	1

Disposition of claims

As of March 23, 1979, claims filed relating to the Swine Flu program totaled $3,351,065,780.

--No claims have been settled through the courts.

--20 claims have been settled out of court for a total of $117,483. 575 claims have been withdrawn or denied leaving 3,099 claims pending.

--1,045 claims totaling $952,549,318 relate to Guillain-Barre Syndrome.

Public Health Service records indicate that the Federal Government has paid only one non-swine flu vaccine claimant, who won a suit against the Government over paralysis sustained from live polio vaccine. The original claim against the Government was for $7,000,000. In 1975, the plaintiff was awarded $1,029,973 in damages and an additional $3,201 in allowable costs.

Presently, 10 non-swine flu claims are pending, totaling $44,050,000. The earliest pending claim was filed during fiscal year 1976.

The Federal Government's approach to vaccine-related suits

The Chief of the Torts Section, Civil Division of the Department of Justice, said that making public the approaches being taken by the Government to resolve swine flu claims might adversely affect the Government's negotiating position. For other vaccine-related claims, the Government is assuming no fault or obligation to compensate. When trying to settle claims out of court, the Torts Section Chief told us that the Department handles each case based on criteria relevant to that case. Some of the criteria used include: nature of adverse reaction, law of the relevant jurisdiction, prognosis, and health insurance coverage.

SUMMARY OF OBSERVATIONS

Existing knowledge about flu is inadequate to assure that an effective federally funded flu program can be planned and implemented. Each year HEW must decide based on uncertain information

--what the flu strain will be, the level and severity of disease it will cause, and the group of individuals most at risk,

--whether a program can be developed and funded for timely implementation, and

--if the public and health care providers will participate.

Planning a program around such uncertainty is a gamble at best. The program could result in decreased flu morbidity and mortality or it could be costly, ineffective, and detrimental to public confidence in the Federal Government's ability to provide leadership in preventive health care.

We recognize that HEW ~~may~~ needs to seek Congressional funding based on incomplete information about the nature and behavior of the expected flu. However, ~~based on our work, we believe that~~ the Secretary, HEW, should give greater consideration to ~~the following factors in determin~~ in determining the role of the Federal Government and the amount of funds which should be spent:

(1) The extent and severity of flu expected,

(2) the extent of demand measured in the target population, and

(3) the capability of existing public and private settings to meet that demand.

Also, the Secretary should establish a time-phased approach to the program similar to that already established for dealing with potential flu pandemics. This approach includes meaningful decision points but should also include cutoff

dates if unexpected problems occur which cannot be adequately resolved.

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Mr. Chairman, this concludes my statement. We shall be happy to answer any questions that you may have.