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The Swine Flu Program was the Government's first attempt at immunization of the entire U.S. population and was based primarily on scientific judgments that a pandemic could occur at any time. No swine flu outbreak occurred during the 1976-77 flu season. If recent experience shows that considerable money can be saved and if the Department of Health, Education, and Welfare (HEW) intends to continue rigorously testing and approving every vaccine lot, then total Federal assumption of the liability coverage for vaccine production should be considered. Congress should establish a national liability policy before another immunization program is needed. HEW should continue its own potency tests on all lots of flu vaccine until manufacturers' test results can be relied on and should test vaccine intended for trial use as it would be tested for public use. The duration of protection provided by the vaccine is uncertain. In any future programs, State and local agencies will need better guidance and assistance from HEW in managing projects and will, in turn, have to make firm commitments to HEW. Expenditures for the Swine Flu Program reported by the Center for Disease Control were about \$103 million. Total costs have not yet been accurately determined but may far exceed the \$135 million appropriated. (SW)

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STATEMENT OF
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BEFORE
SUBCOMMITTEE ON HEALTH
AND THE ENVIRONMENT
COMMITTEE ON INTERSTATE
AND FOREIGN COMMERCE
ON
THE SWINE FLU PROGRAM

Mr. Chairman and Members of the Subcommittee, I am pleased to appear here today to discuss our report to the Congress (HRD-77-115, dated June 27, 1977) on our review of the swine flu program.

This program was an unprecedented venture in preventive medicine. It was the Government's first attempt at immunization of the entire U.S. population. Faced with the possibility of an epidemic that could cost many lives and billions of dollars and offered a chance to prevent it, the Department of Health, Education, and Welfare (HEW) planned, and the Congress approved, the \$135 million swine flu program.

We monitored program events as they occurred between August 1976 and March 1977 at the Center for Disease

Control (CDC) in Atlanta; the Bureau of Biologics, Food and Drug Administration; and the National Institute of Allergy and Infectious Diseases, National Institutes of Health in Bethesda, Maryland. We also monitored program implementation at five immunization projects, and visited 26 mass immunization clinics within these project areas.

Our report discusses considerations for future programs with respect to program justification and cost, Federal liability implications, vaccine production and testing, and program planning and implementation. I will briefly summarize each of these areas.

PROGRAM JUSTIFICATION

The decision to vaccinate everyone in the United States was based primarily on scientific judgments that a swine flu pandemic could occur at any time, regardless of whether outbreaks, in addition to the one at Fort Dix, were detected in the interim. Underlying this decision were several assumptions, including (1) vaccine manufacturers could produce enough acceptable vaccine and (2) the public and private health care system could deliver the vaccine promptly to the entire population. Criticism of this decision was also based on judgments and assumptions.

Many of the limited facts available were used to both support and condemn the program. The validity of either

position could be tested only over time. Even though the decision was a gamble, HEW officials said that gambling with money would be better than doing nothing and gambling with lives. In a sense, HEW lost its gamble with money. No swine flu outbreak occurred during the 1976-77 flu season.

For any future immunization effort as large or concentrated as the swine flu program, the many preventive health care questions that arose would likely have to be broadly considered again by all parties involved. The solutions devised for the swine flu program were not intended as a pattern for future efforts.

In any event, when decisions must be based on very limited scientific data, HEW should establish key points at which the program should be formally reevaluated.

LIABILITY CONTINUES
TO BE A PROBLEM

Although effective in getting the swine flu program started, we found that the legislation designed to solve program liability problems

- may result in profit to the insurance companies of nearly the entire \$8.65 million premium paid by vaccine manufacturers for liability insurance;
- leaves unresolved insurance company concerns about nonmeritorious claim risks; and
- may result in indeterminable costs to the Government for litigation, awards, and settlements

because of potential weaknesses in the form and procedures used to obtain "informed consent" from persons immunized.

In regard to future mass immunization programs, insurance executives stated that the Government should be responsible for both the liability and the costs of litigation, since the Government controls all key program aspects.

HEW's Assistant Secretary for Health stated that a national policy concerning compensation will have to be developed for any future mass immunization program. So that resolution of the liability issue does not delay or adversely affect public acceptance of future programs, we recommend that the Congress establish a national liability policy before another mass immunization program is needed.

We believe two alternatives should be considered in developing the most efficient and effective way to deal with vaccine liability. First, if experience gained from the swine flu program shows that considerable money can be saved and if HEW intends to continue rigorously testing and approving every vaccine lot, then total Federal assumption of the liability coverage for vaccine production should be considered. Second, the insurance industry could make manufacturers' premiums adjustable retrospectively based on claims experience.

The swine flu program was the first time that the Federal Government assumed responsibility and liability for informed consent. To evaluate the effect of its role will take years. HEW should monitor this process as it occurs for possible future program applications.

VACCINE TESTING MORE EXTENSIVE
THAN IN 1975

All vaccine which was released for use in the swine flu program that we reviewed ultimately met Food and Drug Administration potency and safety standards. Almost 30 percent of the vaccine was considered subpotent, and the agency did not permit its release to the public until the minimum potency requirement was met.

Tests showed that some of the trial vaccine did not meet specified potency levels, and trial participants were not given the same protection as the general public. The potency test does not accurately indicate the protection provided by the vaccine.

Because of the deficient potency test and the continual differences in manufacturer and Food and Drug Administration test results, we believe that the agency should continue its own potency tests on all lots of flu vaccine until manufacturers' test results can be relied on. In addition, the agency should speed up its work to

--identify and resolve potency test variances with
the manufacturers and

--develop and put into practice an improved method to measure potency and relate it to the level of protection provided by the vaccine.

To improve the accuracy of trial data and the protection of trial participants, the agency should test flu vaccine intended for trial use as it would be tested for public use.

POTENTIAL PROTECTION PROVIDED
BY SWINE FLU VACCINE

HEW officials estimated, based on past experience and trials, that the swine flu vaccine would adequately protect 70 to 90 percent of those vaccinated. However, protection is difficult to estimate based solely on previous experience.

Further, estimating protection based on trial results was complicated by problems in getting adequate antibody responses in younger people and by the inactivity of one vaccine component.

The duration of protection provided by the vaccine is uncertain.

NOT ENOUGH VACCINE PRODUCED
OR PRODUCED IN TIME

HEW estimated in late March 1976 that manufacturers could produce and deliver 200 million doses of vaccine by the end of November. Primarily because of unresolved liability questions, the first delivery was delayed--from July to October.

Vaccine available then could immunize only about 12 percent of the population. Although three of the four manufacturers said they continued to produce at full capacity during the delay and the fourth had met its original estimate, vaccine production fell short of the original estimates by about 43 million doses and required over 2 months longer to produce.

To assure that vaccine is delivered on schedule in any future programs, HEW must determine in a timely fashion how the vaccine will be formulated and packaged and what the delivery specifications will be. If manufacturers still cannot produce enough vaccine in time to meet the needs, alternative methods should be sought.

STATE READINESS AND IMPLEMENTATION

Each swine flu grant project offered immunization to anyone medically able to take the vaccine. However, because the epidemic never materialized and demand for vaccine was less than expected, the Nation's system for mass immunization was not fully tested. Some problems in planning and implementing swine flu immunizations at the local level should be considered for any future mass immunization programs.

State and local immunization projects were not ready to begin the program in July as planned. They were limited by

- less than full commitment by some project directors,
- complex, incomplete, and late vaccine recommendations,
- limited quantities and delayed delivery of vaccine,
- less-than-expected participation by private doctors, volunteers, and others,
- weaknesses in project operations, and
- lack of State liability insurance.

Project readiness and implementation were limited by biological and liability problems beyond the projects' control. Consequently, we could not determine whether State or local projects could be ready for future mass immunization programs.

In addition, State and local agencies will need better guidance and assistance from HEW in managing projects and will in turn have to make consistent firm commitments to HEW if any future mass immunization program is to succeed. The Secretary, HEW, should request the Department of Defense to revise its policy so that both military personnel and equipment can be quickly mobilized and effectively used in civilian immunization projects.

We also recommend that the Congress consider the effect which inadequate liability protection might have on State participation in future immunization programs. The Federal

Government could (1) assume total liability for the program, (2) assume no liability for program participants, or (3) assume limited liability similar to that provided under the swine flu program.

PROGRAM COSTS

Total costs for the swine flu program cannot yet be accurately determined. In some instances, accounting data is too limited to identify precise costs; and, in others, not all costs have been incurred or determined.

Total program costs include:

- Expenditures from funds appropriated for the program.
- Expenditures from other Federal funding sources.
- Expenditures from State and local funds to supplement the Federal grants.
- Lost opportunity costs to other health programs.
- Costs incurred for health care and lost earnings by individuals who have adverse reactions to the vaccine.

Expenditures from the \$135 million appropriated for the swine flu program were reported by CDC to be about \$103 million through September 9, 1977. Costs yet to be determined include:

- The final cost of the vaccine and vaccine storage.

Contracts for purchasing vaccine were not signed until last month. One is still unsigned. Final vaccine costs will not be known until HEW Audit Agency completes its evaluation of costs included in each final contract.

--Department of Justice costs of litigation and Federal funds for settlements and awards for claims over \$2,500 which are not recoverable from third parties. (HEW will pay settlements of \$2,500 or less from the \$135 million appropriated.) The total dollar amount of claims and suits filed as of September 8, 1977, exceeded \$1.5 billion.

The Center for Disease Control is estimating costs for which limited accounting data is available. Not all of the estimates are complete. These costs include:

- Personnel costs of full-time HEW employees detailed from other programs. (Estimated at \$0.5 million.)
- State and local program costs in addition to those funded by the Federal grants. (Estimated at \$24 million.)
- Lost opportunity costs to other programs. (No estimate yet.)
- Costs incurred for health care and lost earnings by individuals because of immunization reactions. (No estimate yet.)

Although precise costs cannot yet be determined, total costs of the program may far exceed the \$135 million appropriated.

Mr. Chairman, this concludes our statement. We shall be happy to answer any questions that you or other Members of the Subcommittee might have.