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[Answers to Questions Regarding Swine Flu Program]. HRD-77-52; B-164031(5). February 18, 1977. 3 pp.

Report to Rep. John B. Hoss, Chairman, House Committee on Interstate and Foreign Commerce; Oversight and Investigations Subcommittee; by Robert F. Keller, Acting Comptroller General.

Issue Area: Health Programs: Early Diagnosis and Disease Control (1201).

Contact: Human Resources Div.

Budget Function: Health: Health Care Services (551); Health: Prevention and Control of Health Problems (553).

Organization Concerned: Department of Health, Education, and Welfare; Center for Disease Control; Parke, Davis and Co.

Congressional Relevance: House Committee on Interstate and Foreign Commerce; Oversight and Investigations Subcommittee.

A previous GAO review of the swine flu program raised questions about total program cost, execution of contracts with vaccine manufacturers, and access to manufacturers' records by GAO. Findings/Conclusions: Of the \$135 million appropriated for the program, the Center for Disease Control set aside \$100 million for the purchase of vaccine, \$26 million for grants to States, and \$9 million for administrative and other expenses. Since vaccine production ceased as of January 15, 1977, the Center had obligated only about \$66 million for vaccine purchases as of February 15, 1977. Other funds set aside have been or will be expended. Some program costs were not paid for from the \$135 million appropriated. As of February 14, 1977, none of the vaccine manufacturers had signed final contracts. Contract signing has been delayed pending an Internal Revenue Service ruling on whether insurance funds which are reimbursable to the Government are taxable. Additional delays have resulted from a dispute between Parke, Davis and Company and the Center concerning the cost of a vaccine developed for another type of influenza. Some manufacturers have denied access to records by GAO as provided in contracts and this matter is under litigation. (HTW)

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COMPTROLLER GENERAL OF THE UNITED STATES

WASHINGTON, D.C. 20540



B-164931(5)

February 18, 1977

The Honorable John E. Moss
Chairman, Subcommittee on
Oversight and Investigation
Committee on Interstate and
Foreign Commerce
House of Representatives

Dear Mr. Chairman:

I received your letter of February 8, 1977, requesting immediate clarification of three issues raised subsequent to our briefing of your office on January 31, 1977, on the results of our review of the swine flu program. The issues concerned the total program cost, the execution of contracts with the vaccine manufacturers and access to manufacturers' records by the General Accounting Office. I believe the following response will clarify these issues. We plan to discuss the first two issues in greater detail when we report to the Congress on our review.

The first issue concerns the cost of the program. Of the \$135 million appropriated for the swine flu program, the Center for Disease Control set aside \$100 million for the purchase of vaccine, \$26 million for grants to States and \$9 million for its administrative and other expenses. The amount set aside for the purchase of vaccine was based on an estimated 200 million doses to be purchased at an average cost of \$0.50 a dose. Vaccine production ceased as of January 15, 1977. Only about 157 million doses were manufactured and it is expected that the unit cost per dose will be less than \$0.50. Therefore, as of February 15, 1977, the Center had obligated only about \$66 million for vaccine purchases. All of the funds set aside for grants to States and for administrative and other expenses have been or will be expended.

In our review of the swine flu program we have identified program costs which have not been paid for from the \$135 million appropriated. In some cases accounting data is too limited to identify the precise amounts involved and in others the actual costs are indeterminable.

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Examples of these costs are as follows:

- personnel costs of full-time Department of Health, Education, and Welfare (HEW) employees detailed from other programs,
- Department of Justice costs of litigation and settlement not recoverable from third parties for claims over \$2,500 (HEW will settle claims for \$2,500 or less),
- funds expended from State and local revenues in addition to the Federal grant funds, such as:
 - a. direct appropriations for program costs (e.g., Pennsylvania appropriated \$1.4 million and has expended over \$1 million),
 - b. personnel costs of full-time employees detailed from other programs, and
 - c. additional costs for swine flu liability insurance,
- lost opportunity costs to other programs, and
- lost work from reactions.

You also asked of the status of the contracts for the purchase of the vaccine. As of February 14, 1977, none of the vaccine manufacturers had signed final contracts. Interim letter contracts had been signed by all four manufacturers by September 22, 1976. Three of the four manufacturers and the Center have agreed to all cost elements of the final contracts. No elements may be added. Contract signing has been delayed since January 1977, pending an Internal Revenue Service ruling on whether to tax as income \$2.5 million included in each contract for self-insurance retention funds. These funds are reimbursable to the Government, plus interest, less the amount of claims expenses incurred by the manufacturers.

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In addition to this delay, Parke, Davis and Company and the Center are still in dispute concerning a \$1.2 million cost for Shope vaccine (a vaccine developed for another type of influenza) produced which could not be used in the program. The contract officer told us that the Center can make a unilateral determination of the price it will pay for Parke-Davis vaccine. Parke-Davis then has the option to either agree to this price and sign the contract or refuse to sign and make a claim against the Federal Government for the disputed amount.

Your third question concerned our access to the vaccine manufacturers' cost data. No action can be taken to ascertain the validity of drug company cost data until the vaccine contracts, which specify the cost elements for which the companies will be reimbursed, are signed. At that time, HEW is required to audit cost data validity. We plan to monitor its efforts to the extent considered necessary. Also, at the request of the Chairman, Subcommittee on Energy and Environment, House Committee on Small Business, we agreed to assign staff to assist the Subcommittee in its study of manufacturing costs and profits in the production of the swine flu vaccine.

The vaccine contracts contain standard clauses providing for access to vaccine manufacturers' records. Several manufacturers, including one which manufactured swine flu vaccine, have recently denied our access under these clauses in other contracts. This matter is presently being litigated in the courts.

I trust that this information will be useful to your continuing investigation of the swine flu program. Our report, now delayed until April, should provide more detailed information on some of these and other important program issues.

Sincerely yours,


ACTING Comptroller General
of the United States