

RELEASED



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COMPTROLLER GENERAL OF THE UNITED STATES
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FEBRUARY 6, 1979

AD 00190

The Honorable John D. Dingell
Chairman, Subcommittee on Energy
and Power
Committee on Interstate and Foreign
Commerce
House of Representatives

HSE 02303

The Honorable Bob Eckhardt
Chairman, Subcommittee on Oversight
and Investigations
Committee on Interstate and Foreign
Commerce
House of Representatives

HSE 02305

On August 22, 1978, former Chairman John E. Moss of the Subcommittee on Oversight and Investigations and Chairman John D. Dingell of the Subcommittee on Energy and Power, House Committee on Interstate and Foreign Commerce, jointly requested that we undertake an updated audit of selected aspects of the swine flu program. Specifically, they asked that we obtain information on

- the amount each vaccine manufacturer received, including profit;
- the amount the Federal Government paid in procuring vaccine, including the status of agreements with each vaccine manufacturer;
- the amount the Federal Government paid for insuring the vaccine;
- the amount the Department of Health, Education, and Welfare (HEW) paid for program administration; and
- the amount the Federal Government has paid for claims and the number of claims pending.

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Many of these cost elements are still unresolved, primarily because (1) vaccine prices have not been finally negotiated, (2) the Government has not completed processing most of the claims it has received, (3) the Government is still receiving claims for adverse vaccine reactions, and (4) HEW is still incurring costs for research studies of children vaccinated during the program. According to HEW's swine flu vaccine contracting officer, vaccine price negotiations could take several more months. The Department of Justice attorney in charge of swine flu litigation said that processing claims will probably take several years.] However, because you expressed an immediate need for information on the swine flu program, this letter describes the status of program costs as of September 30, 1978, and claim processing as of December 15, 1978.

STATUS OF PROGRAM COSTS

Appropriated funds

On April 12, 1976, the House and the Senate passed a joint resolution (Public Law 94-266) providing over \$135 million for the swine flu program. The President approved the resolution on April 15, 1976. The following table shows HEW's charges against the appropriation as of September 30, 1978. The figures shown are unaudited as supplied by agency officials.

<u>Activity by agency</u>	<u>Obligations</u>	<u>Disbursements</u>	<u>Budgeted</u>
Center for Disease Control:			
Vaccine procurement	\$ 67,390,906	\$54,318,076	\$ -
Project grants	25,889,527	19,769,893	-
Direct operations	<u>2,464,627</u>	<u>2,405,798</u>	<u>-</u>
	95,745,060	76,493,767	127,851,000
Food and Drug Administration:			
Vaccine licensing and monitoring	<u>a/3,213,000</u>	1,720,881	<u>a/3,213,000</u>
National Institute of Allergy and Infectious Diseases:			
Research	<u>4,000,000</u>	<u>2,741,638</u>	<u>4,000,000</u>
Total	<u>\$102,958,060</u>	<u>\$80,956,286</u>	<u>b/\$135,064,000</u>

a/About \$1 million of the Food and Drug Administration budget is being used to fund ongoing research on vaccinated children by the National Institute of Allergy and Infectious Diseases.

b/Of these funds \$12 million was reprogrammed for other uses as mandated by Public Law 95-26, approved May 4, 1977.

The amount disbursed for vaccine procurement was paid to the vaccine manufacturers based on an estimated price for each dose shipped and includes swine flu liability insurance costs, some of which may be returned to the Government. 1/ Merck, Sharp, and Dohme has received \$15,665,309; Merrell-National Laboratories, \$16,710,523; Parke, Davis, and Company, \$12,711,398; and Wyeth Laboratories, \$9,071,324.

1/Parke, Davis, and Company has not received \$2.5 million for self-insurance which HEW withheld pending final contract signing.

Other costs

HEW incurred costs related to the swine flu program in addition to those charged to the \$135 million appropriation. These costs include program overhead in the Offices of the Secretary, Assistant Secretary for Health, and General Counsel, and the costs of Center for Disease Control personnel and resources temporarily diverted to swine flu from other programs. HEW did not maintain complete records allowing these costs for the swine flu program to be distinguished from those that should apply to other programs. However, a compilation of cost estimates provided by Center for Disease Control officials indicates that the Center's portion alone is nearly \$1 million.

Also, the Department of Justice is incurring costs for processing and defending claims against the Government resulting from the swine flu program. Since over 85 percent of these claims are still in process, the Department's costs are not final.

STATUS OF CLAIMS AGAINST
THE GOVERNMENT

As of December 15, 1978, the Federal Government had paid 11 swine-flu-related claims totaling about \$36,600. The following table shows the status of all other swine flu claims filed as of December 15, 1978.

<u>Claim status</u>	<u>Number of claims</u>	<u>Total amount claimed</u> (millions)
Pending	2,959	\$3,035.9
Denied	326	72.9
Withdrawn	<u>44</u>	<u>50.8</u>
Total	<u>a/3,329</u>	<u>\$3,159.6</u>

a/Of these claims 250 stipulate no amount.

VACCINE PROCUREMENT AND
LIABILITY COSTS

The following sections describe the status of vaccine procurement and liability costs in more detail. We have summarized information where the status remains unchanged from our previous reports to you about the program--"The Swine Flu Program: An Unprecedented Venture in Preventive Medicine" (HRD-77-115, June 27, 1977) and a letter concerning the adequacy of HEW's audit of vaccine manufacturing costs (HRD-78-163, Sept. 19, 1978).

Vaccine prices to be negotiated

The final amount to be received for vaccine by each manufacturer and the breakdown of that amount are still uncertain. For production expenses, the manufacturers have submitted cost claims (excluding liability insurance premiums) of about \$39.4 million and have been paid about \$39.7 million. Two of the four manufacturers claimed profit on the Victoria portion of the bivalent vaccine totaling about \$700,000 or about 4.4 percent of their production costs. Final prices will be negotiated by the HEW contracting officer.

Since our September 19 letter to you, the contracting officer has begun negotiations with Merrell-National Laboratories. According to the contracting officer, negotiations with Merck, Sharp, and Dohme and Wyeth Laboratories should begin soon. He said the negotiation process could take several months for each manufacturer because the HEW contract auditors recommended major cost disallowances on each contract.

The fourth manufacturer, Parke, Davis, and Company, has yet to sign a final contract. HEW has nearly completed its audit of the manufacturer's costs and we are monitoring this process. The Armed Services Board of Contract Appeals has made no final decision on the Shope vaccine dispute which is delaying the final contract. As we have previously reported, the Shope strain flu vaccine was mistakenly produced for the swine flu program. HEW would not approve the use of this vaccine during the program or pay for its production costs under the swine flu vaccine contract.

Federal liability cost to
be determined

The final total Federal liability costs are unknown because most swine flu claims against the Government are still pending. As explained in chapter 3 of our June 1977 report to the Congress, under the National Swine Flu Immunization Program of 1976 (Public Law 94-380), all claims for injury or death resulting from the program must be filed against the Federal Government and decided through procedures of the Federal Tort Claims Act (28 U.S.C. 2671 et seq.), as amended for purposes of the swine flu program. The Government's liability costs will include all costs to defend and settle these claims.

The Department of Justice incurs most of the Government's cost to defend the claims. However, Justice Department costs are not accumulated by specific type of claim, such as swine flu; therefore, swine flu costs must be reconstructed using basic Department records. The Department reported to HEW that processing and defending swine flu claims cost about \$170,000 through fiscal year 1977. We did not ask the Department to update these figures because most claims are still in process and costs are still being incurred.

The Government may also recover some liability costs from the vaccine manufacturers. According to the National Swine Flu Immunization Program of 1976, the Government can recover some or all of its costs to defend and settle claims from program participants if negligent conduct or failure to carry out a contractual obligation or responsibility is found.

To protect themselves against potential Government recovery suits, the manufacturers obtained a total of \$230 million of liability insurance. The first \$10 million is self-insured by the manufacturers. The other \$220 million was purchased from insurance companies for an \$8.7 million premium. Because this was considered a vaccine production cost, the Government funded both the self-insurance and the premium, or a total of \$18.7 million. The \$10 million self-insurance is to be used first to satisfy claims. When the self-insurance has been exhausted, the insurance purchased from the insurance companies will be used. Any remaining portion of the self-insurance is to be returned to the Government with interest.

The manufacturers' final liability costs and the amounts that may be recovered by the Government are unknown, because

none of the claims has reached a point where manufacturer negligence has been shown. Thus, the Government has yet to sue for negligence in the manufacture of swine flu vaccine.

We welcome the opportunity to discuss the details of the above matters with you or your staffs.

As arranged with your offices, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from its issue date. At that time we will send copies to the Secretary of Health, Education, and Welfare; the Director, Office of Management and Budget; and the Director, Center for Disease Control. Copies will be available to other parties who request them.



Comptroller General
of the United States