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COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-164031(5)

The Honorable Paul G. Rogers
Chairman, Subcommittee on Health
and the Environment
Committee on Interstate and
Foreign Commerce
House of Representatives

MAR 8 1977

Dear Mr. Chairman:

This is in response to your letter of January 24, 1977, requesting current information concerning several issues related to the swine flu program. The issues were raised by Congressmen Harry A. Waxman and Andrew Maguire in a letter to you dated January 5, 1977. Your office also forwarded to us for comment a second letter to you from the Congressmen dated February 4, 1977, which contained some additional issues. We have discussed all of these issues with your staff and those of Congressmen John E. Moss, Waxman, and Maguire during several briefings since December 1976. The most recent briefing to your staff occurred on February 11, 1977. We plan to address most of the issues in detail in our report to the Congress on our review.

The Center for Disease Control has responded to you concerning most of the issues contained in Congressmen Waxman's and Maguire's second letter. (See enclosure.) Where appropriate, we refer to the Center's response and give supplemental information. Our current knowledge on each issue is summarized below by issue statement. When similar issues were included in both letters, we combined the issue statements and our response.

ISSUES

That the cost of the program may significantly exceed the $135 million appropriated primarily because of the salary costs of the Federal and State personnel who participated in the program.

That as a result of the cost overrun, there have been diversions of funds from veneral disease control and school immunization programs and other public health programs in many areas.

What effect has the swine flu program had on other vaccination efforts?

Of the $135 million appropriated for the swine flu program, the Department of Health, Education, and Welfare (HEW) 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 by the Center for the purchase of vaccine was based on an estimated 200 million doses to be purchase 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 the expected 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. We do not expect charges to the appropriation to exceed $135 million. The total charges to the appropriation will be unknown, however, until after the program is terminated.

In discussing total program costs with your staff we also considered costs in addition to those paid from the $135 million. In some cases accounting data is too limited to identify the precise amounts involved, and in others, the actual costs are indeterminable.

Examples of these costs are as follows:

--Personnel costs of full-time HEW employees detailed from other programs.

--Department of Justice costs of litigation and Federal funds for settlements and awards not recoverable from third parties for claims over $2,500. (HEW will pay claims awarded for $2,500 or less from the $135 million appropriated.)

--Funds expended from State and local revenues in addition to the Federal funds, such as

a. direct appropriations (Pennsylvania, for example, 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

--The value of lost worktime by individuals

because of immunization reactions.

We do not expect to be able to measure the adverse effects of diversions of resources from other public health programs. A statistical analysis showing either decreases in the number of people vaccinated or the number of people diverted from other health programs does not necessarily mean an adverse impact. Determining the actual impact would require analysis over time of the effects on outcomes, such as disease incidence trends. The diversions of effort from other health programs were anticipated from the beginning of the swine flu program and were not the result of any cost overruns.

That there are still no contracts with the manufacturers of the vaccine. It is our understanding that among other issues in dispute, one of the drug producers is insisting that the Government pay for six million doses of vaccine which was produced by mistake.

Have contracts between the drug manufacturers and the Federal Government been altered since the swine flu program was suspended?

Congress intended for HEW to oversee vaccine production on the basis of signed contracts with the drug industry. These contracts were to establish a nonprofit price for swine flu vaccine and a specified profit margin for A/Victoria. We have received information that the contracts have never been signed. Current Government policy with respect to vaccine contracts should be reviewed.

As of February 14, 1977, none of the vaccine manufacturers had signed final contracts. The Center's explanation concerning the status of contracts and the reasons for delay in signing the final contracts are accurate according to our information. In addition, the Center's contract officer told us that the Center can make an unilateral determination of the price it will pay for Parke-Davis vaccine. Parke-Davis then has the option to agree to this price and sign the contract or refuse to sign and make a claim against the Federal Government for the disputed amount.

Due to limited knowledge concerning duration of conferred immunity, it remains unknown whether those who have been innoculated against swine flu will be protected for the entire 1977-78 season.

We have no problem with the Center's response concerning duration of conferred immunity. However, duration of immunity conferred by this year's vaccine may lose importance if the swine virus changes substantially or if the Fort Dix swine flu outbreak turns out to be an isolated occurrence. If a swine flu outbreak occurs but with a substantially changed virus, a new vaccine will be needed. If there is no further occurrence of swine flu, the duration of immunity to it will be irrelevant.

That when HEW recommended in the fall that all children be immunized, the agency knew there would not be sufficient vaccine to protect all of them.

The Center's response to this issue appears accurate and adequate based on our current knowledge.

> That because the drug companies were able, under the swine flu legislation, to make a profit on bivalent (swine flu/ A/Victoria) vaccine, but not on monovalent swine, a disincentive against the production of monovalent A/Victoria was provided. Indeed, the manufacturers recalled all monovalent A/Victoria and combined it with swine flu, with the result that virtually no monovalent A/Victoria has been available to the public for the past several months.

The Center's response to this issue is accurate, but the issue is incorrectly phrased. There was no disincentive to produce monovalent A/Victoria. As the Center reported, bulk stores of A/Victoria vaccine already existed in quantities adequate to provide vaccination to members of the "high risk" groups when the legislation was being considered. The disincentive, if any, would have been against the production of monovalent swine flu (A/New Jersey) vaccine.

Three of the four manufacturers produced a total of about 15 million fewer doses of A/New Jersey vaccine then their original production estimates, which were stated in June 1976, even though additional time (from December 31, 1976, to January 15, 1977) was given for production. One manufacturer produced about 18 million more doses than originally estimated.

We have not discussed with the manufacturers the reasons for these production variances. One reason given for reduced production by one manufacturer during testimony before your subcommittee was that the vaccine yield per egg was less than anticipated. Also, production of 6 million doses of a related swine influenza vaccine not used in the program (Shope vaccine) could have reduced the capacity of Parke-Davis to produce A/New Jersey vaccine.

> Serious concerns persist surrounding the adequacy of the forms and statutory requirements for informed consent of the public.

By assuming responsibility for the informed consent statement and process, the Federal Government may be liable for individual vaccine reactions even without occurrence of defective vaccine or negligence in its administration. Several concerns about the consent form's content regarding risks to pregnant women were expressed in testimony before your Subcommittee. We noted additional concerns about (1) the lack of a specific statement on the risk of neurologic disorders which the Advisory Committee on Immunization Practices included in its recommendation (manufacturers recognized the risk to the extent of including the statement with literature included with the vaccine when it was packaged for distribution) and (2) the lack of a warning on the probability of getting swine flu after receiving the shot. In addition, the Center's and the States' capabilities to monitor the adequacy of the informed consent process in every case are questionable.

The statistics cited by the Center from the national sample indicate that while the informed consent process may have been imperfect, a vast majority of the people vaccinated were provided with the consent form. However, these statistics do not necessarily depict success in the informed consent process. If claims for damages occur concerning informed consent, the extent of Federal liability will depend on the number of claims filed, the extent of damages claimed, and interpretation of the adequacy of the informed consent process in each individual case through Federal tort claims procedures (as provided for by Public Law 94-380) and any subsequent litigation. As of February 14, 1977, claims against the Federal Government for damages from the swine flu program totaled over $32 million.

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The Center was not asked to respond to the issues discussed below.

That although, as of February 1, 70 claims have been filed by people who believe they were injured by the vaccine, including 4 lawsuits seeking $19 million in damages in Oklahoma, the Justice Department presently has only 1 attorney assigned to swine flu litigation.

Until February 1977, the Department had only one attorney assigned to swine flu litigation. During February 1977 two additional attorneys have been detailed to the program for 3 months with the option of remaining. The Department's supplemental appropriation submitted to the Office of Management and Budget on October 5, 1976, requested $1.7 million for 28 attorneys and 23 support personnel. On January 28, 1977, the Office approved and forwarded to Congress an appropriation request for $1.2 million, reducing the total number of positions to 28. The Department of Justice estimates that 19 of the 28 will be attorneys. This appropriation request has not been approved by the Congress.

What are the implications of the prevalence of the Guillain-Barre syndrome among those receiving innoculations, the deaths which may be associated with the syndrome or deaths which otherwise may be associated with the program, and the suspension of the program for the liability precedents established in the swine flu legislation? What kind of liability coverage are manufacturers seeking, and the insurance companies offering, for new vaccines?

The extent of program participant liability for damages due to adverse reactions will be determined through Federal tort claims procedures (as provided for by Public Law 94-380) and any subsequent litigation. Whether program suspension will impact on the decisions in each case is uncertain.

Liability insurance industry executives have pointed out that, since the Federal Government will control all key aspects of any immunization program that is conducted as a matter of public policy, the Government should be responsible for both the liability and the costs of litigation. Because of the expense related to defending nonmeritorious claims, the insurers believe that the vaccine manufacturers will be uninsurable at an acceptable premium without some Federal Government assumption of liability. HEW has stated that a national policy concerning compensation will have to be developed for any future mass immunization programs. Other vaccines have been and probably will continue to be covered under the vaccine manufacturers' standard liability policies.

A review of the medical decisionmaking process which led to the swine flu program is needed. Specifically, should A/Victoria vaccine have been produced in a separate form? Was the possibility of the development of Guillain-Barre syndrome as a complication of immunization considered? When serious opposition to the nationwide program appeared in the fall, was the program adequately reviewed?

We will discuss the decisionmaking process leading to the initiation and continuation of the swine flu program in detail in our report. We will include the information considered to begin the program and the adequacy of ongoing program review.

The possibility of Guillain-Barre syndrome as a complication of immunity was not considered. According to the Center, the incidence of Guillain-Barre syndrome was infrequent. There was little or no evidence to link the syndrome to influenza vaccinations. The syndrome was not required to be reported to the Center prior to the swine flu program.

With regard to A/Victoria vaccine, it was produced in a separate form before production of A/New Jersey vaccine. As the Center reported, enough A/Victoria vaccine was already available to vaccinate members of the "high risk" groups. These groups would have been the only ones being vaccinated under normal circumstances. Mixing the two vaccines allowed these people to receive both in one innoculation. Even if A/Victoria vaccine had still been available in a monovalent form when the swine flu program was halted because of Guillain-Barre syndrome, A/Victoria vaccination would have been halted also. The syndrome was associated with all types of flu vaccines.

What course of action, if any, is appropriate for next year, and how can we avoid the mistakes and problems which continually plagued this year's program? How can we accurately assess the risk associated with administering, as well as not administering, flu vaccines?

The course of action appropriate for next year will depend on epidemiological evidence gathered through this flu season and into the summer. Many lessons applicable to future mass immunization programs can be learned from the swine flu program. The impact of problems relating to program elements such as informed consent, liability coverage, the decision review process, State readiness, and vaccine availability should be considered for future application. We will discuss each of these in detail in our report. Hopefully, the experience provided by the swine flu program will permit a more accurate assessment of the risks associated with administering or not administering flu vaccines in the future.

I trust that this information will be useful to you in assessing the costs and benefits of the swine flu program. Our report, now delayed until April, should provide more detailed information on many of these and other important program issues.

Sincerely yours,

R. F. Keller

ACTING Comptroller General
of the United States

Enclosure

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
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February 11, 1977

Honorable Paul G. Rogers
Chairman, Subcommittee on Health
and the Environment
Committee on Interstate and Foreign
Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Rogers:

As requested by Dr. Hyde of your staff, I am providing the following information relative to allegations forwarded to you by Congressmen Henry Waxman and Andrew Maguire in a letter dated February 4, 1977. The specific allegation is quoted, followed by our response. It is my understanding that the Department of Justice is providing information in response to allegation number 7.

1. "That the cost of the program may significantly exceed the $135 million appropriated primarily because of the salary costs of the Federal and State personnel who participated in the program."

   We do not expect the cost of the program to the Federal Government to exceed $135 million. In fact, because the production of influenza vaccine has been less than originally estimated, $35 million of the $100 million provided for this purpose remains uncommitted. While the final cost of influenza vaccine will be determined through negotiation when final deliveries are made, as required by P.L. 94-380, it is expected at this time that the final cost of vaccines will not exceed $64-67 million.

   Claims for vaccine associated injury which do not exceed $2,500 will be paid from the existing appropriation, but this is not expected to be large. Even if all claims of less than $2,500 which have been filed to date are found to be meritorious and are paid, the total cost would be about $33,000. Settlements exceeding $2,500 will be paid through normal tort claims procedures.

2. "That, as a result of the cost-overrun, there have been diversions of funds from venereal disease control and school immunization programs and other public health programs in many areas."

   As indicated above, there have been no cost overruns under the National Swine Flu Immunization Program of 1976. A variety of existing health personnel at the Federal, State, and local levels

have been used temporarily in the influenza program, but such diversions were anticipated from the beginning of the program. This will not result in cost overruns under the appropriation which was made to carry out the program, since there is no plan to charge the salaries of all of these people to influenza funds. A study of the actual cost of the program at the State and local level, as required by PL 94-380, is being carried out. Data from this study is expected to be available in April 1977.

3. "That there are still no contracts with the manufacturers of the vaccine. It is our understanding that among other issues in dispute, one of the drug producers is insisting that the Government pay for six million doses of Port Chalmers vaccine, which was produced by mistake."

Letter Contracts were signed with each vaccine manufacturer in September 1976. These contracts provide for deliveries of vaccine and payment on a provisional basis. This type of contract was used pending complete review of the manufacturers' accounting systems and cost estimates by the HEW Audit Agency, as required by PL 94-380. In addition, other provisions of the contracts had to be worked out between the manufacturer, HEW General Counsel and CDC. Signing of the definitized contract (replacing the letter contract), is now awaiting an interpretation from the Internal Revenue Service as to the taxability of the Self-Insurance-Retention Fund. The IRS ruling is expected shortly.

No manufacturer produced six million doses of Port Chalmers influenza vaccine by mistake. The Parke Davis Company did produce six million doses of swine influenza vaccine from a swine virus which is related to, but different from, the swine virus isolated during the Ft. Dix outbreak in early 1976. This vaccine was not used in the program. Finalization of the contract with Parke Davis is, therefore, also awaiting a ruling by our General Counsel on whether the cost of the production of these six million doses should and can be charged to the Government as part of the cost of developing and producing the A/New Jersey/76 (swine) vaccine which was used in the program.

4. "Due to limited knowledge concerning duration of conferred immunity, it remains unknown whether those who have been inoculated against swine flu will be protected for the entire 1977-78 season."

Some decline in antibody titers resulting from swine flu vaccination is expected, but is not expected to be large.

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Recent laboratory tests on sera drawn from volunteers 7 months after participation in the National Influenza Immunization Program vaccine trials in April 1976 have shown an anticipated slow decline in swine influenza virus antibody titers. A subsample of 30 individuals in the 25-34 year age group revealed that the percentage with titers of ≥ 40 ("equal to or greater than 40") decreased from 90 percent to 67 percent. Percentage of persons in the 35-51 age group with titers of ≥ 40 declined from 97 percent to 73 percent. Titers of ≥ 20 were virtually unchanged.

While many infections are thought to be prevented by a titer of at least 20, a titer of ≥ 40 is thought to represent a more acceptable degree of protection. Based on previous findings, swine antibody titers of vaccinated persons should level off after an initial decline. A larger study is planned later in the spring to determine the levels of antibody remaining in the volunteer population 1 year after immunization. Substantial antibody titers lasting for several years are anticipated.

5. "That when HEW recommended in the Fall that all children be immunized, the agency knew there would not be sufficient vaccine to protect all of them."

This statement is accurate. Final vaccine recommendations for children in normal health were not made until late November 1976. HEW knew that the monovalent split virus influenza A vaccine which was recommended for these children existed in supplies too limited to permit vaccination of all U.S. children. (There was, however, an adequate supply of the split-virus bivalent vaccine for children at "high risk.") HEW was confronted with the choice among four unattractive alternatives, i.e.: (a) reject the recommendation of the Advisory Committee on Immunization Practices for administration of vaccine to children. (b) Make vaccine available to children only through private channels. (c) Make vaccine available to children through all delivery systems on a first-come-first serve basis. (d) Request that each official health agency express its opinion as to preference for use of vaccine in its State.

The last option was chosen and implemented. However, the National Influenza Immunization Program was curtailed before initiation of vaccination programs for normally healthy children.

6. "That because the drug companies were able, under the swine flu legislation, to make a profit on bivalent (swine flu/A Victoria) vaccine, but not on monovalent swine, a disincentive against the production of monovalent A Victoria was provided. Indeed, the manufacturers recalled all monovalent A Victoria and combined it

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with swine flu, with the result that virtually no monovalent A Victoria had been available to the public for the past several months."

There is nothing to suggest that this interpretation is accurate. The original decision to devote the full production potential to the development of A/New Jersey vaccine was made by the Government in March 1976 with the following facts in mind: (a) All the United States population was viewed as vulnerable to A/New Jersey infection, therefore, every person needed the protection of a dose of A/New Jersey vaccine. (b) The only hope for producing an adequate number of doses (estimated 200 million) of A/New Jersey vaccine rested on full utilization of all available vaccine production potential. (c) Bulk stores of A/Victoria antigen already existed in quantities adequate to provide vaccination to members of the "high risk" group. (d) A/Victoria influenza had already infected about one-half of the United States population last winter, thus at least half of the population did not require the protection of A/Victoria vaccine. (e) There was no perceived need for a vaccine providing protection only against A/Victoria. (f) Since every individual needed protection against A/New Jersey, including all those individuals who would receive A/Victoria vaccine, it was logical to combine A/New Jersey and A/Victoria antigens in one vaccine requiring only one injection.

Only after this decision had been made and production of all A/Victoria vaccine had been completed was legislation enacted (PL 94-380) which limited profit to the A/Victoria component of the bivalent vaccine. There has never been any monovalent A/Victoria vaccine marketed in the United States.

8. "Serious concerns persist surrounding the adequacy of the forms and statutory requirements for informed consent of the public."

Project grant guidelines issued by the Center for Disease Control (CDC) required all States to provide each person requesting vaccination with a CDC approved statement of risks and benefits, and to obtain written documentation that such information was provided. The only exceptions were active duty military personnel, and persons seen by an individual physician who did not wish to be afforded the liability protection of PL 94-380.

Several methods of monitoring the implementation of informed consent procedures have been undertaken. Federal personnel at CDC and in the PHS Regional Offices have been instructed to make an on-site review of the implementation of these procedures as part of their regular technical assistance visits. Personnel of the Government Accounting Office have been most helpful in giving us and appropriate State officials feedback on their on-site reviews. All reports of irregularities

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from these and other sources have been investigated. In general, major problems have been discovered in very few situations, and have occurred in isolated clinics. State level commitment to and implementation of informed consent procedures have been uniformly good. The speed with which the program was developed, the many last minute changes in informed consent procedures, and the great diffusion of vaccination responsibility among virtually all health care providers in each State, have been primarily responsible for the few problems which have arisen.

In addition, CDC undertook an evaluation of the implementation of the procedures by questioning a national sample of persons who have been vaccinated. These data are useful in assessing the overall implementation of informed consent procedures, although they are based on individual recollections of what occurred and are subject to the normal limitations of national sampling procedures.

Of the people interviewed during early December, 32 percent said they had received a shot (up from 14 percent the month before). Of these, 89 percent said they were shown or given a form at the place where they were vaccinated telling about the benefits of the vaccine and about possible side effects or reactions to it (up from 86 percent a month before). It should be noted that physicians were required to use the form only if they sought the protection of PL 94-380. Ninety-three percent of those recalling a form said they understood all (79 percent) or most (an additional 14 percent) of the information on it.

Of the persons vaccinated, 16 percent said they didn't sign anything to receive the vaccine (up from 10 percent a month earlier). This percentage was highest, as expected, when the vaccination was provided in a doctor's office (39 percent) or in a hospital (33 percent). Of those who didn't sign anything, 11 percent said they had been asked to, but didn't.

These data suggest that the vast majority of persons vaccinated recalled informed consent procedures which were consistent with Federal guidelines. However, even allowing for faulty memories, the system was evidently not perfect.

Please let me know if you need additional information regarding any of these allegations, and I will provide it promptly.

Sincerely yours,

David Sencer

David J. Sencer, M.D.
Assistant Surgeon General
Director