

114395  
~~15882~~  
**RESTRICTED** Not to be distributed outside the General  
Accounting Office except on the basis of specific approval  
by the Office of Congressional Relations.

**GAO**

United States General Accounting Office  
Washington, DC 20548

Human Resources  
Division

**RELEASED**

B-199297

JANUARY 14, 1981

The Honorable John A. Durkin  
United States Senate

Dear Senator Durkin:

Subject: Processing of Claims Resulting from the  
Swine Flu Program (HRD-81-33)

In your October 10, 1979, letter you asked us to review the (1) timeliness of the Department of Justice in processing swine flu claims and lawsuits and (2) adequacy of staffing and resources available to the Department of Justice to handle swine flu claims.

On July 22, 1980, we briefed your office on the results of our work. This letter summarizes the information provided during the briefing. A more detailed discussion of our findings is contained in enclosures I and II.

SCOPE OF REVIEW

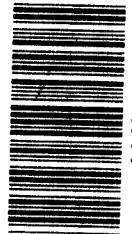
We reviewed the general method for claims processing filed against the Federal Government (title 28 U.S.C. and part 14 of title 28 of the CFR). We also reviewed the specific method established to process claims resulting from the swine flu program--Public Law 94-380 (the National Swine Flu Immunization Program of 1976, amending section 317 of the Public Health Service Act, 42 U.S.C. 247b). We reviewed the procedures established by the Departments of Justice and Health and Human Services (HHS) 1/ to process swine flu claims, determined from claim files the length of elapsed time to decide claims, and compiled descriptive data on the claims, such as the status of claims and the number of claims filed according to the nature of the alleged

1/On May 4, 1980, a separate Department of Education commenced operating. Before that date, activities discussed in this report were the responsibility of the Department of Health, Education, and Welfare.



(102052)

514262



114395

injury. We found that no criteria exist to objectively assess the timeliness of swine flu claims processing. However, we identified some claims processing procedures which took a long time.

We obtained limited information on the processing of lawsuits resulting from the swine flu program. This included determining Justice's role in swine flu litigation and gathering descriptive data similar to that compiled for claims. We were unable to determine with any confidence the average time it took to process lawsuits and whether they were being handled in a timely manner because no judgments had been entered as of December 31, 1979 (the date we used as a cutoff point to determine the time to process claims), and no criteria existed to assess the timeliness of the processes. Furthermore, lawsuit litigation is under the control of the courts and their calendars.

To determine claims processing time, we sampled 722 swine flu claims filed as of December 31, 1979, and statistically determined the average amount of time it took to process them. A discussion of the methodology we used in selecting our sample and projecting the results is contained in enclosure III.

Our review was made at the headquarters' offices of Justice and HHS located in Washington, D.C., and at the offices of the Public Health Service located in Rockville, Maryland. We held discussions with officials of these organizations, and we also interviewed officials and medical consultants of the Armed Forces Institute of Pathology (AFIP) and a medical consultant retained by Justice to review swine flu claims for medical validity.

We gave a draft of this report to Justice and the Public Health Service for comment. The Public Health Service offered no comments, and Justice's comments are included in enclosure V. We met with Justice officials and discussed their comments on the draft report. Their comments have been included, where appropriate, in this report.

FEDERAL GOVERNMENT ASSUMED RESPONSIBILITY  
FOR INJURIES RESULTING FROM THE SWINE FLU  
PROGRAM

In April 1976, the President approved Public Law 94-266 which provided over \$135 million to establish a nationwide flu immunization program, popularly referred to as the swine flu program. The lack of available liability coverage for several program participants including vaccine manufacturers and some States became an issue that threatened the successful implementation of the program.

To resolve the liability problem, the Congress, in August 1976, enacted Public Law 94-380. Under this act, the Federal Government assumed liability for personal injuries or death resulting from the swine flu vaccine. The act provides that claims and lawsuits for injury or death resulting from the swine flu 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.).

THE SWINE FLU PROGRAM RESULTED  
IN MANY CLAIMS AND LAWSUITS  
AGAINST THE FEDERAL GOVERNMENT

Before the swine flu program there were comparatively few vaccine-related claims made against the Government. Since 1963, Public Health Service records showed that only 27 non-swine flu claims were filed. However, as of December 31, 1979, we found that 3,839 claims and 988 lawsuits had been filed against the Government alleging injury, death, or other damage resulting from the 45 million swine flu immunizations given under the program.

At the time of our fieldwork, neither Justice nor HHS maintained statistics on the status of swine flu claims and lawsuits or on the nature of injuries alleged by individuals. After we completed our fieldwork, Justice developed a computer capability which provides such information. We used our sample of 722 swine flu claims to determine the status of claims. The sample results and our projections to the universe of 3,839 claims are shown in the table on the next page.

| <u>Claim status</u>                    | <u>Actual results<br/>from sample</u> | <u>Projected<br/>results</u> |
|--|---------------------------------------|------------------------------|
| Settled (awarded)                      | 107                                   | <u>a/107</u>                 |
| Denied                                 | 224                                   | 1,359                        |
| Closed (note b)                        | 53                                    | 322                          |
| Pending results of lawsuit<br>(note c) | 188                                   | 1,141                        |
| Pending action by Justice              | <u>150</u>                            | <u>910</u>                   |
| Total                                  | <u>722</u>                            | <u>3,839</u>                 |

a/Actual and projected results are the same because we included in our sample all of the 107 claims that had been settled as of December 31, 1979.

b/A claim may be closed if it is withdrawn by the claimant, abandoned by the claimant, or lacked the essential elements to be classified as a claim.

c/Includes claims for which lawsuits were filed before an administrative decision was made on the claims and claims that were closed or previously denied.

A Justice official told us that as of October 2, 1980, 3,965 claims and 1,384 lawsuits had been filed. Of the 3,965 claims filed, the Justice official said 316 claims had been settled for about \$12.3 million, 2,666 claims had been denied, 151 claims had been closed, 694 claims had become lawsuits before an administrative decision was made on the claims, and 138 claims were pending action by Justice. Of the 1,384 lawsuits filed, 1/ judgments or settlements were made on 98

1/The number of claims that had become lawsuits (694) and the total lawsuits filed (1,384) are not compatible because the latter figure includes lawsuits filed before a claim was decided and lawsuits filed on claims that were denied.

cases for about \$8.3 million, 1/ 129 cases were dismissed by the courts, and 1,157 cases were pending.

#### CLAIMS PROCESSING

Under the procedures of the Federal Tort Claims Act, a claim for injury or death caused by the activities of a Federal agency must be presented to the appropriate Federal agency for resolution, in this case HHS. In an effort to process the large number of anticipated swine flu claims efficiently, HHS and Justice, in the autumn of 1976, agreed that Justice would perform all necessary factfinding and legal analyses pursuant to claims processing. In performing its duties Justice made recommendations to HHS on the action to take on claims, while HHS retained authority for determining final action to be taken on claims. According to HHS officials, it has never overruled a Justice recommendation on the action to take on a claim.

Having assumed the responsibility for most of the work involved in claims processing, Justice established procedures to carry out this task. Justice had little guidance from either legislation or analogous programs in establishing its procedures. The chart on page 7 of enclosure I shows the procedures that were in effect as of March 1980 to process claims.

#### FEDERAL SYSTEM FOR CLAIMS PROCESSING TAKES AN AVERAGE OF ABOUT 1 YEAR

Our review indicated that it took, on the average, about 403 calendar days from the date that a claim was received by the Public Health Service to the date that Justice made a

---

1/According to Justice, as of October 2, 1980, Federal payments for swine flu claims (\$12.3 million) and lawsuits (\$0.9 million) amounted to about \$13.2 million. Although Justice records show that \$8.3 million was paid as a result of lawsuits, \$7.4 million was applicable to settlements that were originally filed as claims, but were later entered as lawsuits before Justice reached an administrative decision as to the merits of the claims. In the final analysis, this \$7.4 million represented settlements made after lawsuits were filed, but before entry of any judgments.

recommendation to HHS on the action to take on a claim. <sup>1/</sup> However, claims processing time varied according to whether claims were settled, denied, or closed. Settled claims took an average of 611 days to process; denied claims took an average of 338 days; and closed claims took 217 days to process. The overall processing time for claims which had been decided (settled, denied, or closed) took an average of 343 days.

There are no legal or self-imposed criteria by Justice or analogous claim situations that would enable us to objectively assess the efficiency with which Justice processed claims. However, we did identify three parts of the claims process which slowed claims processing time--the failure or tardiness of claimants to respond to Justice's requests for information, the lack of an adequate system to follow up on requests for information, and the lack of adequate staffing arrangements for performing medical review of claims.

Failure or tardiness of many claimants to respond to Justice's requests for information

Under the procedures established to implement the Federal Tort Claims Act, claimants may be required to submit additional information to support a claim, such as doctors' reports or medical bills. Justice officials claimed that the lack of timely responses by claimants or their representatives to their requests for information took a large amount of overall processing time. Some claimants did not respond to requests for information or did so only after repeated requests by Justice. For example, of the 3,839 claims filed at the time of our review, Justice sent letters to about 3,000 claimants requesting additional information to process the claims. About 1,400 of these requests required additional followup action by Justice.

---

<sup>1/</sup>Justice's recommendation to HHS was not the final action on claims. Additional action was taken by HHS to inform claimants of the decision on their claims, such as forwarding of notification letters and vouchers for payment. Overall, we did not find that these actions took a long time.

Justice lacked a formal system for following up on information requests

Justice adopted a followup policy on its requests for information from claimants, but it did not establish formal procedures which specified when followup should occur. We found that large amounts of time elapsed before Justice followed up on its information requests. In some cases, more than 6 months elapsed before Justice initiated followup action.

Justice officials told us that their first priority was to process claims which contained necessary information, and they did not establish formal followup procedures because there was no requirement for followup.

Lack of adequate staffing arrangements for medical review of claims

As of December 31, 1979, Justice had 13 full-time and 4 part-time professional staff, plus 3 full-time and 9 part-time support staff assigned to process swine flu claims and lawsuits.

Although Justice claimed that it had adequate resources to process swine flu claims, we found that, in addition to not using available staff for followup activities which delayed claims processing, Justice did not make adequate staffing arrangements for medical review of claims. This further delayed claims processing and resulted in a backlog of claims.

Justice employed no physicians to review the medical merits of claims. Justice had no legal requirement to make such a review, but planned for it as an appropriate step in representing the interests of the Federal Government and claimants. Instead of employing physicians, Justice arranged for staff from the Armed Forces Institute of Pathology and a medical consultant contracted by Justice to review claims. Mainly, only one or two physicians actually reviewed claims at any one time, and they did so on a part-time basis which resulted in a backlog of claims. To reduce the backlog, in November 1978 Justice eliminated medical review for claims

believed not to be related to the swine flu vaccine. <sup>1/</sup> By September 1979, Justice had eliminated medical review, except for unusual claims. In total, Justice sent about 1,700 claims to its consulting physicians for medical review; only about half of the claims actually went through the entire medical review process. We examined 162 of these claims and found that medical review took an average of 158 days. In terms of total processing time, we found that claims subjected to medical review took an average of 594 days to process, while claims not subjected to medical review averaged 337 days.

Justice officials believed medical review was handled efficiently. They said that when they found that medical review caused delays in claims processing they changed the process to try to speed it up rather than adding more staff to perform medical review of swine flu claims. Justice's director of the Torts Branch said that Justice's staff had developed sufficient knowledge about the effects of the swine flu vaccine to process claims without medical review. This resulted in Justice recommending that HHS deny claims alleging adverse effects that were on Justice's list of injuries which were believed unrelated to the swine flu vaccine. As Justice's staff gained experience in claims processing, the director said that they were able to identify the adverse effects, in most cases, that could have resulted from the swine flu vaccine, without medical review, and Justice forwarded these claims to HHS recommending that they be settled.

JUSTICE'S COMMENTS  
AND OUR EVALUATION

In a November 21, 1980, letter, Justice's Assistant Attorney General, Civil Division, said that the unprecedented

---

<sup>1/</sup>A list of injuries thought not to be related to swine flu vaccine was developed by Justice with the advice of consulting physicians, whom Justice said were the most eminent and qualified experts in the Nation. According to Justice officials, the list was developed to limit the need for medical review of individual claims by establishing objective criteria that allowed Justice staff to dispose of claims, without medical review. Among other things, the list included: any illnesses or injuries in which the onset of symptoms occurred 6 months or more after the vaccine was received (later revised to 4 months), muscular dystrophy, and acute myocardial infarction.



nature of the swine flu program and the number of claims it generated created novel and complex problems never before encountered under the procedures established for handling claims under the Federal Tort Claims Act. Furthermore, she said that while it took time to evolve an innovative approach to handling these claims, the process in effect at the time of our review was an excellent means of resolving voluminous administrative claims. The Assistant Attorney General also said that, in similar circumstances, future programs will benefit from the innovations that Justice implemented in considering swine flu claims.

Regarding followup activities, the Assistant Attorney General said that (1) given limited resources, Justice preferred to pay attention to claims that were actively pursued by claimants rather than to divert substantial resources to claimants who were not actively pursuing claims and (2) Justice's followup procedures became more vigorous and improved over time, especially after the surge in the number of claims filed in the latter part of 1978 abated. Justice officials told us that, in the summer of 1979, Justice began to improve its followup actions and a staff member was given responsibility for assuring that followup letters were sent to claimants promptly.

Our review of Justice's claims processing procedures, as of March 1980, showed that Justice's actions to improve its followup procedures had little impact on the manner in which followup activities were performed. The timing of these activities was determined by the Justice staff member assigned to process a claim, with no specific time frames established by Justice as to when these activities should begin. We found that sometimes more than 6 months elapsed before Justice followed up on information requests. In its comments, Justice said that instead of establishing specific time frames for followup, Justice's staff judgmentally determines the time to begin followup on a case-by-case basis depending on the amount and type of data needed by Justice.

Since we found that followup activities took a large amount of the overall time to process claims, it seems to us that Justice's actions could have been more effective if specific time frames for beginning followup were established. Also, additional staff resources were available to Justice, but were not used (see p. 13 of enc. II). We believe that delegating responsibility for followup to these resources,

especially during the surge of 1978 when many claims were being received, along with establishing specific time frames as to when followup should be performed would have reduced the time to obtain data necessary for claims processing.

Regarding Justice's handling of medical review of claims, the Assistant Attorney General said that she considers Justice's efforts to reduce the need for medical review to be worthy of emulation in future programs. In commenting on the number of physicians assigned by AFIP to perform medical reviews of swine flu claims, the Assistant Attorney General stated that Justice officials met with AFIP officials in late 1977 and were assured that AFIP would devote its resources to reviewing claims. However, Justice did not have a formal agreement with AFIP governing the number of claims to be reviewed or the amount of staff or time AFIP was to devote to this activity (see pp. 13 and 14 of enc. II). Furthermore, while AFIP said it would review as many claims as possible, it agreed to do so as long as this activity did not adversely affect its regular duties and workload. At any one time, AFIP had only one physician assigned to review about 1,350 claims, and always on a part-time basis. Given the fact that some claims took up to 10 hours to review, we believe this staffing arrangement contributed to the backlog of claims awaiting medical review.


The Assistant Attorney General also said that based on Justice's experience, the individual medical review of swine flu claims (which she stated our report assumes) is unnecessary and delays resolution of claims. Our report does not state that all claims should have been subjected to medical review. We believe, however, that Justice should have added more physicians early in the program to review claims, when Justice believed a medical review of each claim was necessary. In our opinion this would have significantly decreased the backlog of cases awaiting medical review. Secondly, the addition of more physicians to review claims would have expedited Justice's efforts to develop a knowledge base regarding acceptable and unacceptable adverse reactions from the swine flu vaccine. We believe that if Justice had taken these actions overall processing time for swine flu claims could have been reduced.

In summary, we believe that Justice's efforts to develop procedures to process the unprecedented number of claims that resulted from the swine flu program were reasonable, since it had little guidance from either legislation or similar programs. However, before Justice's procedures are used as a model for any similar undertaking by the Federal Government, we believe that, to timely resolve any claims that might result, the matters discussed above should be considered and steps taken to prevent their recurrence. Specifically, we believe that if a federally sponsored mass immunization program is again undertaken in which the Federal Government assumes liability for adverse vaccine reactions, sufficient staff should be provided for followup activities, as well as specific time frames established for beginning such actions. Furthermore, we believe that if medical reviews of claims are deemed desirable, a sufficient number of physicians should be provided for such reviews.)

- - - -

If you have any questions about the enclosed information, we would be pleased to discuss it with you. As agreed with your office, we will not release this report for 30 days unless you approve its release or make its contents public. At that time we will send copies to other interested parties and make copies available to others upon request.

Sincerely yours,

  
Gregory J. Ahart  
Director

Enclosures - 5

## C o n t e n t s

| ENCLOSURE |  | <u>Page</u> |
|-----------|--|-------------|
| I         | PROCESSING OF SWINE FLU CLAIMS TAKES<br>ABOUT 1 YEAR TO COMPLETE                               | 1           |
|           | Background   | 1           |
|           | Justice's system for handling swine<br>flu claims  | 6           |
|           | Claims processing takes an average<br>of about 1 year  | 6           |
| II        | STAFFING ARRANGEMENTS FOR MEDICAL<br>REVIEW OF SWINE FLU CLAIMS                                | 12          |
|           | Justice staff assigned to process<br>swine flu claims and lawsuits                             | 12          |
|           | Justice did not make adequate<br>arrangements for staff to<br>perform medical review of claims | 13          |
| III       | METHODOLOGY USED IN REVIEWING SWINE FLU<br>CLAIMS  | 18          |
|           | Sampling procedures  | 18          |
|           | Data analysis  | 18          |
| IV        | Letter, dated October 10, 1979, from<br>Senator John A. Durkin                                 | 20          |
| V         | Comments, dated November 21, 1980, from<br>the Department of Justice                           | 22          |

### ABBREVIATIONS

|      |   |
|------|---|
| AFIP | Armed Forces Institute of Pathology     |
| GAO  | General Accounting Office               |
| GBS  | Guillain-Barre Syndrome                 |
| HHS  | Department of Health and Human Services |
| PHS  | Public Health Service                   |

PROCESSING OF SWINE FLU CLAIMSTAKES ABOUT 1 YEAR TO COMPLETEBACKGROUND

Liability became an issue in implementing the swine flu program because several participants, including vaccine manufacturers and some States, could not obtain total liability coverage for the program. The manufacturers threatened to halt swine flu vaccine production and to withhold vaccine already produced if their liability concerns were not resolved. In several States lack of liability insurance could have inhibited program implementation.

In August 1976, the Congress addressed these concerns by enacting Public Law 94-380, the National Swine Flu Immunization Program of 1976 (42 U.S.C. 247b). Under this act, the Federal Government assumed liability for personal injuries or death resulting from the manufacture, distribution, or administration of the swine flu vaccine. The act provided that claims 1/ and lawsuits 2/ resulting from the swine flu 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.). The Government has the right to recover costs of defending and settling such claims if negligent conduct or failure to carry out any contractual obligation or responsibility by program participants is found. As a result of the act, the manufacturers agreed to continue producing and distributing the vaccine.

The program's objective was to make flu vaccine available to any person for whom it was not inadvisable. However, due to an unexpected outbreak of Guillain-Barre Syndrome (GBS), a rare and sometimes fatal neurological disease potentially related to the vaccine, the program was stopped in December 1976. About 45 million immunizations (22 percent of the population) were given.

---

1/A claim is a complaint for redress made to an executive agency concerning alleged injuries incurred as a result of the action(s) of that agency. The complaint is processed through an executive agency's internal processes.

2/A lawsuit involves a court proceeding aimed at enforcing a right or gaining payment for a wrong.

As the administrative agency with responsibility for implementing the swine flu program, the Department of Health and Human Services (HHS) has the responsibility for processing all claims against the Government resulting from the program. The Department of Justice, as counsel for the Federal Government, handles lawsuits brought against the Government. However, in order to expedite the processing of the many swine flu claims expected, an agreement was entered into by HHS and Justice in the fall of 1976 transferring the responsibility for factfinding and legal analyses of swine flu claims to Justice. In performing its duties, Justice made recommendations to HHS on the action to take on claims while HHS retained authority for determining final action. HHS officials stated that it has never overruled a Justice recommendation on a swine flu claim.

Under the provisions of the swine flu program, 3,839 claims and 988 lawsuits were filed against the Federal Government by December 31, 1979. The claims filed as of this date, excluding 158 for which we were unable to determine the claim amount, totaled about \$2.65 billion. Lawsuits filed as of the same date, excluding 98 for which we were unable to determine damages sought, totaled about \$1.1 billion. We determined the number of claims and lawsuits by nature of alleged injuries and their status from our sample of claims and lawsuits, which we projected to the entire population. Table I provides a breakdown of these claims and lawsuits by the nature of their alleged injury, and table II shows their status as of December 31, 1979.

Table I

Number of Claims and Lawsuits  
by Nature of Alleged Injury  
as of December 31, 1979 (note a)

| <u>Alleged<br/>injury</u>           | <u>Claims</u>  | <u>Lawsuits</u> |
|-------------------------------------|----------------|-----------------|
| GBS                                 | 1,261          | 597             |
| Personal injury<br>(other than GBS) | 1,958          | 266             |
| Death                               | 386            | 94              |
| Lost wages                          | 30             | 0               |
| Others (property<br>loss, unknown)  | <u>203</u>     | <u>31</u>       |
| Total                               | <u>b/3,838</u> | <u>988</u>      |

a/Figures in this table are based upon populationwide projections calculated from the weighting of our sample data (see pp. 18 and 19).

b/Column does not total to actual number of claims filed (3,839) due to rounding error in projecting the population.

Table IIStatus of Claims and Lawsuits  
as of December 31, 1979 (note a)

| <u>Claims</u>              |                | <u>Lawsuits</u> |                 |
|----------------------------|----------------|-----------------|-----------------|
| <u>Status</u>              | <u>Number</u>  | <u>Status</u>   | <u>Number</u>   |
| Settled (awarded)          | 107            | Settled         | 0               |
| Denied                     | 1,359          | Dismissed       | 98              |
| Closed (note b)            | 322            | Pending         | 879             |
| Pending results of lawsuit | <u>c/1,141</u> | On appeal       | 8               |
| Denied                     |                | Unknown         | <u>4</u>        |
| previously                 | 431            | Total           | <u>c/,d/989</u> |
| Closed                     |                |                 |                 |
| previously                 | 36             |                 |                 |
| Never                      |                |                 |                 |
| decided                    | 674            |                 |                 |
| Pending action by Justice  | <u>910</u>     |                 |                 |
| Total                      | <u>3,839</u>   |                 |                 |

a/See note a, table I.

b/A claim may be closed if it is withdrawn by the claimant, abandoned by the claimant, or lacked the essential elements to be classified as a claim.

c/Number of claims pending results of lawsuit and total number of lawsuits filed are not compatible due to sampling error.

d/Column does not total to actual number of lawsuits filed (988) due to rounding error in projecting the population.



A Justice official told us that as of October 2, 1980, 3,965 claims and 1,384 lawsuits had been filed. Of the 3,965 claims filed, the Justice official said 316 claims had been settled for about \$12.3 million, 2,666 claims had been denied, 151 claims had been closed, 138 claims were still pending action by Justice, and 694 claims had become lawsuits before an administrative decision was made on the claims. Of the 1,384 lawsuits filed, 1/ judgments or settlements had been made on 98 cases for about \$8.3 million, 2/ 129 cases had been dismissed by the courts, and 1,157 cases were still pending, according to the Justice official.

Our review indicated that it takes, on the average, 403 calendar days from the date that the Public Health Service (PHS) receives a claim to the date when Justice makes a recommendation to HHS on the action to take on a claim. Processing time can vary significantly according to the decision made on a claim. There are no legal or self-imposed criteria by Justice or analogous claim situations that would enable us to objectively assess the efficiency with which Justice processed claims. However, we identified three steps within Justice's processes--failure or tardiness of claimants to respond to Justice's requests for information, the lack of an adequate system to follow up on requests for information, and the lack of adequate staffing arrangements for medical review of claims--which seem to have significantly contributed to the lengthy claims processing time.

---

1/The number of claims that had become lawsuits (694) and the total lawsuits filed (1,384) are not compatible because the latter figure includes lawsuits filed before a claim was decided and lawsuits filed on claims that were denied.

2/According to Justice, as of October 2, 1980, Federal payments for swine flu claims (\$12.3 million) and lawsuits (\$0.9 million) amounted to about \$13.2 million. Although Justice records show that \$8.3 million was paid as a result of lawsuits, \$7.4 million was applicable to settlements that were originally filed as claims, but were later entered as lawsuits before Justice reached an administrative decision as to the merits of the claims. In the final analysis, this \$7.4 million represented settlements made after lawsuits were filed, but before entry of any judgments.

JUSTICE'S SYSTEM FOR HANDLING  
SWINE FLU CLAIMS

Justice had little guidance in developing its procedures for processing swine flu claims. Except for broad guidelines set forth in the Federal Tort Claims Act and the Code of Federal Regulations (28 CFR 14), there were no specific procedures in legislation which Justice could follow, and no other programs analogous to the swine flu program which Justice could use to develop a model for handling the voluminous claims. Our review showed that Justice's assistant chief, Torts Section, Civil Division, developed procedures as claims began to be filed. The procedures were revised as the claims workload increased. At the time of our review, the administrative procedures for processing swine flu claims had not been documented. The flow chart on the following page depicts the procedures for claims processing, as of March 1980.

CLAIMS PROCESSING TAKES AN  
AVERAGE OF ABOUT 1 YEAR

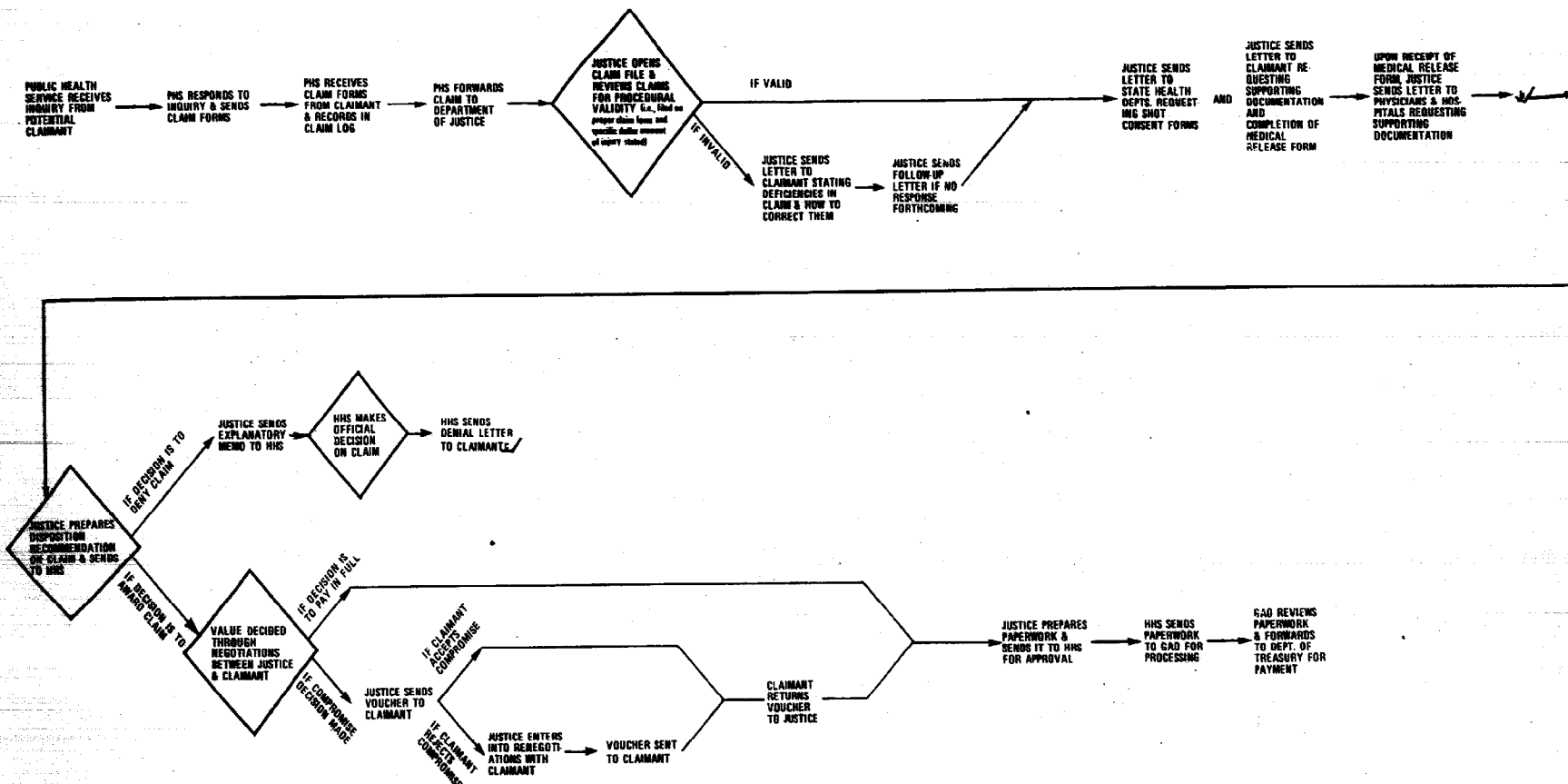
Our review of the swine flu claims process showed that on the average 403 calendar days elapsed from the date that PHS received a claim to the date that Justice recommended final action to HHS. <sup>1/</sup> Settled claims took an average of 611 days to process, claims that were denied took an average of 338 days to process, and closed claims took 217 days to process. The overall processing time for claims which had been decided (settled, denied, or closed) took an average of 343 days.

We found no legal or self-imposed criteria by Justice or analogous claim situations against which to assess the efficiency of the Federal system for processing swine flu claims. The Federal Tort Claims Act requires a claimant to present a claim to the Federal agency involved, in this case HHS, before seeking judicial relief in the courts. A claimant may file a lawsuit only when the Federal agency involved has denied the claim. The act provides that failure of an agency to make final disposition of a claim within 6 months after it is filed, shall at the option of the claimant,

---

<sup>1/</sup>On claims awarded in part, we dated final disposition action by Justice as the date on which the claimant signed a voucher accepting the negotiated settlement amount as full payment for a claim.

**PROCESSING STEPS FOR SWINE FLU CLAIMS  
MADE AGAINST THE FEDERAL GOVERNMENT  
AS OF MARCH 1980**



**LEGEND**  
 ◊ DECISION POINT

✓ HHS HAS STATED THAT SOME CLAIMS MAY NOT HAVE LITERALLY FOLLOWED THIS PROCESS. SOMETIMES ACTIONS WHICH WERE NOT A PART OF THE USUAL CLAIM OF ACTIVITY, SUCH AS OBTAINING A PHYSICAL EXAMINATION OF A CLAIMANT, WERE REQUIRED.

✓ IN NOVEMBER 1979, MEDICAL REVIEW WAS ELIMINATED FOR CLAIMS BELIEVED NOT TO BE RELATED TO THE SWINE FLU VACCINE. BY SEPTEMBER 1979, MEDICAL REVIEW WAS TERMINATED EXCEPT FOR UNUSUAL CLAIMS. CLAIMS THAT DID UNDERGO MEDICAL REVIEW WOULD HAVE BEEN SENT BY JUSTICE TO CONSULTING PHYSICIANS AT THIS POINT IN THE PROCESS.

✓ CLAIMANTS MAY REQUEST RECONSIDERATION OF THEIR CLAIMS UP TO 6 MONTHS AFTER DENIAL.

be deemed a final denial of the claim. A claimant may then file a lawsuit without waiting for a formal denial from the agency. However, the act did not establish this 6-month period as a legal requirement within which an agency must complete processing a claim. This 6-month period was created to establish a time frame whose expiration is considered the legal equivalent of administrative denial of a claim for vesting the courts with jurisdiction over the claim. It was enacted to protect claimants against agency inaction by allowing them further recourse if action on their claims took a long time.

Finally, the Congress established the 6-month time period on the premise that claims are filed randomly with relatively few claims arising from any one incident. There is no indication that the Congress would expect the same 6-month processing when, as in the situation arising from the swine flu program, thousands of claims were filed against the same agency over a relatively short period.

Although we could not assess the efficiency with which Justice processed claims, we did identify three parts of the claims process which slowed claims processing--the failure or tardiness of claimants to respond to Justice's requests for information needed to process claims, the lack of an adequate followup system, and the lack of adequate staffing arrangements for performing medical review. Since the problems encountered with the arrangements for performing medical review relate to the staff assigned to perform this function, this issue is discussed in enclosure II on staffing and resources.

Many claimants failed to respond  
or were late in responding to  
Justice's requests for information

Under the procedures established to implement the Federal Tort Claims Act, claimants may be required to submit additional information to support a claim, such as doctors' reports or medical bills. Justice officials claimed that the lack of timely responses by claimants or their representatives to its requests for information took a large amount of overall processing time. Some claimants did not respond at all to requests for information or did so only after repeated requests by Justice. For example, of the 3,839 claims filed at the time of our review, Justice sent letters to about 3,000 claimants requesting additional information to process the claims. About

1,400 of these 3,000 requests required additional followup action by Justice. At the time we completed our data collection efforts in February 1980, about 850 claimants (about 28 percent) had not responded to Justice's requests. Most of the 1,400 requests (about 95 percent) were made by February 1979. In addition, our sample showed that of the approximately 3,000 claimants Justice asked to submit additional information, Justice sent second requests to about 700 claimants and third requests to about 160 claimants. For those claimants who responded to Justice's initial requests for information, it took an average of 53 days for them to respond.

We believe that, if Justice had a better procedure for following up on its information requests, the processing time could have been reduced.

Justice lacked a formal system for following up on information requests

Although we found no legal or other criteria which required Justice to perform periodic followup on requests for information from parties involved in swine flu claims, Justice adopted a followup policy. Often Justice found that claims were not submitted in accordance with the requirements of part 14 of title 28 of the CFR which describes claim filing procedures. <sup>1/</sup> In these cases, Justice would send letters to claimants notifying them that their claim was invalid and explain how to submit a valid claim. If the claimant did not respond to Justice's initial letter, Justice would send a second letter and again explain how to correct the claim. Even when valid claims were submitted, additional information was generally required to support statements, dates, and figures submitted by claimants. If Justice did not receive a response to its initial request for additional information, Justice would send followup letters to claimants and again request the information. However, Justice had no formal procedures which specified when followup action should occur on its requests for information from claimants.

---

<sup>1/</sup>Part 14 of title 28 of the CFR requires that claims must be submitted on the proper claim form and request a specific dollar amount of compensation to be valid.

We found the largest amounts of processing time elapsed between Justice sending its initial requests for information and sending its followup requests. For example, if Justice received a submission which was procedurally invalid to begin processing a claim, and if the requested information was not received, we found that an average of 188 days elapsed before Justice sent a second letter requesting the information to be submitted. A similar situation occurred when the submission was classified as a claim, but additional information was needed before Justice could make a recommendation to HHS on disposition of the claim. After Justice sent a first letter, an average of 139 days elapsed before Justice sent a second letter requesting the additional information; and an average of 88 days if a third letter was needed.

Although the failure or tardiness of claimants to respond to Justice's requests for information contributed significantly to how long it took to process a claim, we believe that establishing formal procedures to request additional data for claims that were judged incomplete could have reduced processing time for such claims.

In discussing the need for a followup system with Justice officials they said that Justice's first priority was to process claims which contained necessary information and there was no followup requirement.

In commenting on our draft report, the Assistant Attorney General, Civil Division, said that (1) given limited resources, Justice preferred to pay attention to claims that were actively pursued by claimants rather than to divert substantial resources to claimants who were not actively pursuing claims and (2) Justice's followup procedures became more vigorous and improved over time, especially after the surge in the number of claims filed in the latter part of 1978 abated. Justice officials told us that in the summer of 1979, Justice began to improve its followup actions and a staff member was given responsibility for assuring that followup letters were sent to claimants promptly.

However, our review of Justice's claims processing procedures, as of March 1980, showed that Justice's actions to improve its followup procedures had little impact on the manner in which followup activities were performed. The timing of these activities was determined by the Justice staff member assigned to process a claim, with no specific time frames established by Justice as to when these activities should begin. We found that sometimes more than 6 months elapsed

before Justice followed up on information requests. In its comments, Justice said that instead of establishing specific time frames for followup, Justice's staff judgmentally determines the time to begin followup on a case-by-case basis depending on the amount and type of data needed by Justice.

Since we found that followup activities took a large amount of the overall time to process claims, it seems to us that Justice's actions could have been more effective if specific time frames for beginning followup were established. Also, additional staff resources were available to Justice, but were not used (see p. 13 of enc. II). We believe that delegating responsibility for followup to these resources, especially during the surge of 1978 when many claims were being received, along with establishing specific time frames as to when followup should be performed would have reduced the time to obtain data necessary for claims processing.

The Assistant Attorney General also said that part of the time it took to process claims resulted from the 6 to 8 weeks it took us to process a voucher for payment. However, our examination of 40 claims forwarded by Justice to us for processing from August to December 1979 showed that it took us an average of 17 days to process a voucher and forward it to the Department of the Treasury for payment.

STAFFING ARRANGEMENTS FOR MEDICAL REVIEW  
OF SWINE FLU CLAIMS

Initially, the Congressional Budget Office estimated that 17,200 claims might result from the swine flu program. This estimate was revised to 5,000 expected claims when the program was halted in December 1976. HHS and Justice officials decided that Justice was better equipped to handle the processing of these claims. According to HHS officials, HHS had only two or three attorneys available to handle swine flu claims, while Justice was able to assign considerably more staff. Also, by processing claims, Justice would develop the background information needed to represent the Federal Government in litigation which might result.

A Justice official claimed that adequate resources existed to process swine flu claims. However, as stated in enclosure I, Justice did not use its available staff to follow up on information requests which delayed claims processing. Also, Justice did not make adequate arrangements for a sufficient number of physicians to perform medical review of swine flu claims which further delayed claims processing and resulted in a backlog of claims.

JUSTICE STAFF ASSIGNED TO PROCESS  
SWINE FLU CLAIMS AND LAWSUITS

As of December 31, 1979, Justice had 13 full-time and 4 part-time professional staff, plus 3 full-time and 9 part-time support staff assigned to process swine flu claims and lawsuits.

--The director, Torts Branch, Civil Division, working part time on swine flu related matters.

--Ten attorneys working primarily full time on swine flu related matters.

--Three paralegals working full time on swine flu related matters.

--Three law clerks working part time on swine flu related matters.

--Three full time and nine part time support staff and additional support staff, as needed, to work on swine flu matters.



The director stated that the number of staff handling swine flu claims and lawsuits at Justice was adequate, and we found no instances where the director complained about a lack of staff or requests for additional staff were denied. Also, we did not find vacancies in the authorized staffing levels of the Torts Branch.

Based upon the Congressional Budget Office estimate that 5,000 claims might result from the swine flu program, Justice requested and received funds from the Congress in May 1977, for 28 additional positions to work on swine flu matters. In fiscal year 1979 House appropriations hearings, Justice officials stated that the need for all of these 28 positions for swine flu related work had not materialized and 10 of the additional staff were assigned to work on other torts cases.

We attempted to obtain funding information from Justice on the amounts authorized to process swine flu claims and lawsuits. Justice did not maintain this information, and the issue has not been addressed in appropriations hearings. Justice did not cite a lack of funds or any other resources as hindering its program.

JUSTICE DID NOT MAKE ADEQUATE  
ARRANGEMENTS FOR STAFF TO PERFORM  
MEDICAL REVIEW OF CLAIMS

In our opinion, Justice did not make adequate arrangements to have claims undergo review to determine their medical merits. When Justice began the claims process it was planned for all claims alleging injury to be submitted to consulting physicians for a review to determine their medical merits. Justice was not required to have claims medically reviewed, although it considered medical review to be an appropriate step in representing the interests of the Federal Government and claimants.

In approximately April 1977, Justice made arrangements with the Armed Forces Institute of Pathology (AFIP) 1/ to be the principal medical reviewer of swine flu claims. However,

---

1/AFIP is part of the Department of Defense. A part of its mission is to provide consultation services for the diagnosis of pathologic (diseased) tissues for Defense, other Federal agencies, and civilian pathologists.

Justice did not have a formal agreement with AFIP governing the number of claims to be reviewed, or the amount of staff or time AFIP was to contribute to this activity. AFIP agreed to review as many claims as possible, as long as this additional activity did not adversely affect its regular duties and workload. AFIP's Department of Legal Medicine, which performed the medical reviews, was not assigned any additional staff or resources. At any one time, AFIP had only one physician reviewing swine flu claims, and always on a part-time basis. 1/ AFIP physicians who reviewed swine flu claims estimate that it took between 2-1/2 and 10 hours to review each claim. Justice assigned 1,348 claims to AFIP for medical review, and in April 1980, when Justice told AFIP to stop medical review, AFIP had conducted about 539 reviews.

As the volume of claims increased, a backlog of claims awaiting medical review developed. In November 1978, Justice acted to speed up the medical review process. First, Justice entered into a contract with a physician employed by another Federal agency to supplement the AFIP staff performing medical reviews. The contract called for the physician to review 700 claims (on a part-time basis) by September 30, 1979. The physician estimated that he reviewed 200 to 300 claims and told us that it took him an average of 4 hours to review each claim. In addition, Justice employed two medical interns who reviewed about 50 claims and had about 35 claims that posed unusual problems reviewed by consulting experts and physicians. Secondly, at the same time, Justice decided to eliminate medical review for claims believed not to be related to the

---

1/Between the autumn of 1978 and June 1979, AFIP had a total of four medical students from the Centers for Disease Control (formerly the Center for Disease Control) performing preliminary reviews of swine flu claims. These preliminary reviews, in turn, had to be reviewed by an AFIP physician before being released.

vaccine. 1/ By September 1979, Justice eliminated medical review except for unusual cases because of the length of time it took.

Of the approximately 1,700 claims submitted by Justice to its consulting physicians for medical review, only about 874 medical reviews were actually performed. Of these 874 claims, we were able to obtain information on the time it took to complete medical review for only 162 claims (18.5 percent). Information in Justice's files on the other claims was insufficient to allow us to make projections on the time it took for medical review.

Our analysis of the 162 claims showed that it took an average of 158 days for physicians to complete medical review of a claim. We also found that claims undergoing medical review took an average of 594 days to process while those not undergoing medical review averaged 337 days. 2/ We were not able to statistically determine if the actions taken by Justice to expedite medical review succeeded in speeding up medical review and overall claims processing time because:

--The 1978 changes occurred too close together to be able to isolate their effects.

--Changes in the medical review process occurred at about the same time that changes in the claims

---

1/A list of injuries thought not to be related to swine flu vaccine was developed by Justice with the advice of consulting physicians whom Justice said were the most eminent and qualified experts in the Nation. According to Justice officials, the list was developed to limit the need for medical review of individual claims by establishing objective criteria that allowed Justice staff to dispose of claims, without medical review. Among other things, the list included: any illnesses or injuries in which the onset of symptoms occurred 6 months or more after the vaccine was received (later revised to 4 months), muscular dystrophy, and acute myocardial infarction.

2/The average time for medical review (158 days) and that of processing time without medical review (337 days) does not total average processing time (403 days) due to sampling error and differences in the percent of the sample for which we were able to make valid observations.

process were taking place which could have affected overall processing time. For example, Justice paralegals were assuming a large segment of the work on claims in 1978, and Justice staff had gained more experience in processing swine flu claims.

Justice officials told us that they believed the medical review was handled efficiently. They said that when they saw that the medical review was causing delays in claims processing they made changes in the review in an attempt to speed it up rather than adding more staff to perform medical review of swine flu claims. Justice's director of the Torts Branch said that Justice's staff had developed sufficient knowledge about the effects of the swine flu vaccine to process claims without medical review. This resulted in Justice recommending that HHS deny claims alleging adverse effects that were on Justice's list of injuries which were believed to be unrelated to the swine flu vaccine. As Justice's staff gained experience in claims processing, the director said they were able to identify the adverse effects, in most cases, that could have resulted from the swine flu vaccine, without medical review and Justice forwarded these claims to HHS recommending that they be settled.

In commenting on our draft report, the Assistant Attorney General said that she considers Justice's efforts to reduce the need for medical review of claims to be worthy of emulation in future programs. Regarding the number of physicians assigned to perform medical reviews of swine flu claims, the Assistant Attorney General stated that Justice officials met with AFIP officials in late 1977 and were assured that AFIP would devote its resources to reviewing claims. However, Justice did not have a formal agreement with AFIP governing the number of claims to be reviewed or the amount of staff or time AFIP was to devote to this activity (see pp. 13 and 14 of enc. II). Furthermore, while AFIP said it would review as many claims as possible, it agreed to do so only as long as this activity did not adversely affect its regular duties and workload. At any one time, AFIP had only one physician assigned to review about 1,350 claims, and always on a part-time basis. Given the fact that some claims took up to 10 hours to review, we believe this staffing arrangement contributed to the backlog of claims awaiting medical review.

The Assistant Attorney General also said that based on Justice's experience, the individual medical review of swine flu claims (which she stated our report assumes) is unnecessary and delays resolution of claims. Our report does not state that all claims should have been subjected to medical review. We believe, however, that Justice should have added more physicians early in the program to review claims, when Justice believed a medical review of each claim was necessary. In our opinion, this would have significantly decreased the backlog of cases awaiting medical review. Secondly, the addition of more physicians to review claims would have expedited Justice's efforts to develop a knowledge base regarding acceptable and unacceptable adverse reactions from the swine flu vaccine. We believe that, if Justice had taken these actions, overall processing time for swine flu claims could have been reduced.

In summary, we believe that Justice's efforts to develop procedures to process the unprecedented number of claims that resulted from the swine flu program were reasonable, since it had little guidance from either legislation or similar programs. However, before Justice's procedures are used as a model for any similar undertaking by the Federal Government, we believe that, to timely resolve any claims that might result, the matters discussed in this report should be considered and steps taken to prevent their recurrence. Specifically, we believe that if a federally sponsored mass immunization program is again undertaken in which the Federal Government assumes liability for adverse vaccine reactions, sufficient staff should be provided for followup activities, as well as specific time frames established for beginning such actions. Furthermore, we believe that, if medical reviews of claims are deemed desirable, a sufficient number of physicians should be provided for such reviews.

METHODOLOGYUSED IN REVIEWING SWINE FLU CLAIMSSAMPLING PROCEDURES

We sampled 722 of the 3,839 swine flu claims filed against the Federal Government as of December 31, 1979. Our sample included all of the 107 claims that had been settled as of that date. We also included 615 of the remaining 3,732 nonsettled claims 1/ to produce a sample that could be used at the 95 percent confidence level.

Using a systematic sampling technique, we drew our sample of nonsettled claims from a PHS list of assigned claim numbers arranged in ascending order. We selected the nonsettled claims beginning with the second claim number and examined each sixth claim thereafter.

We projected our data to the 3,839 claims in our universe by using a computer. We weighted the nonsettled claims in our sample by a factor of 6.07 2/ which was equal to their proportion of the claims population (3,732 divided by 615) and combined this weighted sample with the 107 settled claims to arrive at projected claims figures for the universe of 3,839 claims.

DATA ANALYSIS

Our computer analysis determined the elapsed number of calendar days between processing steps for each claim in our sample. We then computed the average number of elapsed calendar days between different processing steps for our various samples (settled claims, nonsettled claims, and all claims). Finally, we identified steps in the claims process that took a long time. We also developed descriptive information relating to the claims, such as categorizing claims by nature of alleged injury.

The table on the following page shows the average processing time and the sampling errors for our sample of claims.

---

1/We defined a nonsettled claim as one which has been denied, closed, or is still pending.

2/The actual factors were carried out to eight decimal places.

AVERAGE DAYS TO PROCESS A SWINE FLU CLAIMAS OF DECEMBER 31, 1979(95 PERCENT CONFIDENCE LEVEL)

| <u>Claim status</u>                    | <u>Total sample claims</u> | <u>Projected distribution of claims (note a)</u> | <u>Number of claims in sample with data to determine processing time</u> | <u>Projected number of claims in universe with data to determine processing time</u> | <u>Average processing time (days)</u> | <u>Sampling error</u> |
|--|----------------------------|--|--|--|---------------------------------------|-----------------------|
| Settled                                | 107                        | b/107  | 101  | 101  | 611                                   | + 0                   |
| Denied                                 | 224                        | 1,359  | 90   | 546  | 338                                   | + 3                   |
| Closed                                 | 53                         | 322  | 31   | 188  | 217                                   | + 5                   |
| Pending suit                           | 188                        | 1,141  | 25   | 152  | 203                                   | + 4                   |
| Pending action by Justice              | <u>150</u>                 | <u>910</u>                                       | <u>138</u>   | <u>837</u>   | 500                                   | + 2                   |
| Total                                  | <u>722</u>                 | <u>3,839</u>                                     | <u>385</u>   | <u>1,824</u>   | 403                                   | + 1                   |
| Overall-- (settled, denied, or closed) | 384                        | 1,788  | 222  | 835  | 343                                   | + 2                   |

a/Distribution based on weighted distribution of claims in sample.

b/For settled claims our sample was 100 percent of the settled claims and thus recognized as such in the distribution.

JOHN A. DURKIN  
NEW HAMPSHIRE

United States Senate  
WASHINGTON, D.C. 20510

October 10, 1979

Honorable Elmer B. Staats  
Comptroller General of the United States  
General Accounting Office  
441 G Street, NW  
Washington, DC 20548

Dear Mr. Staats:

Recent reports have come to my attention which raise serious questions about the efficacy and fairness of the Federal government's compensation program for victims of the 1976 Swine Flu Immunization Program.

In August 1976, Congress enacted the National Swine Flu Immunization Program (PL94-380) which established the government's liability for personal injuries or deaths resulting from the program. Under the program, the Justice Department assumed responsibility for processing claims against the Federal government.

In the intervening three years, nearly 4000 claims for damages totalling \$3.4 billion, have been filed with the government by individuals who received the swine flu vaccine. Over 700 of these claims have been filed by persons who developed Guillain-Barre Syndrome, a rare paralytic disease, after receiving the vaccination. Of the several thousand administrative claims and lawsuits which have been filed against the Federal government as a result of the swine flu program, only a handful have been settled.

The magnitude of the backlog and the fact that only a relatively small number of victims have received compensation raises serious questions as to whether the Department of Justice is handling the claims expeditiously and responsibly. These lengthy delays in settling the cases inflict even greater personal hardship on the victims and increase the difficulty of proving causal relationship between the vaccine and the injury, especially in the cases of Guillain-Barre.

In order to alleviate the backlog and to expedite settlement, Congress in 1977 provided supplemental appropriations at the request of the Department of Justice so that additional attorneys could be hired to handle swine flu claims. It is my understanding that these funds were never spent and that the tort section of the Justice Department's Civil Division assigned to handle the swine flu caseload remains seriously understaffed.



Honorable Elmer B. Staats  
Page 2  
October 10, 1979

Because I am concerned that the Justice Department's excessive backlog in claims will jeopardize fair settlement and create even greater burdens on victims seeking compensation, I hereby request the Government Accounting Office to conduct an immediate review of the Federal government's compensation program for victims of the swine flu vaccine concentrating on the following questions:

- 1) Are the staffing and resources made available to the Justice Department in connection with the swine flu immunization program sufficient to ensure proper handling of the enormous number of swine flu-related claims?
- 2) Are the claims pending before the Justice Department being processed and litigated in a timely and expeditious manner? If not, why not?
- 3) What, if any, recommendations can the GAO make for expediting and upgrading the Justice Department's procedure for processing and settling swine flu-related claims?
- 4) What, if any, legislative recommendations can the GAO make for facilitating prompt compensation of swine flu victims?

If you have any questions on this request, please do not hesitate to contact me, or have your staff contact Corey Peterson of my staff at 224-3524.

Sincerely,



Joseph A. Durkin  
United States Senator

JAD:cpp



U.S. Department of Justice  
Civil Division

Office of the Assistant Attorney General

Washington, D.C. 20530

NOV 21 1980

Mr. Gregory J. Ahart  
Director  
General Accounting Office  
441 G Street, N.W.  
Washington, D.C. 20548

Dear Mr. Ahart:

On Friday, November 14, 1980, your staff provided the Civil Division a copy of the draft letter to Senator Durkin regarding processing of claims resulting from the Swine Flu Program. At that time, we were advised that you intended to submit the final letter in the near future and that although you intended to have an oral discussion of the draft with Civil Division staff, your time constraints would not permit us to furnish written comments. In order to provide the Senator with as complete a record as possible and to correct certain errors and omissions in the draft, I am nonetheless submitting these written comments.

1. Settlement of Swine Flu Cases (p.6)

The draft states that "no cases had been settled as of December 1979." This is inaccurate. As of December 21, 1979, 26 suits had been settled. The confusion apparently results from the draft's characterization of settlements of lawsuits as "out-of-court claim settlements" when no final administrative resolution had been made of the claim. (See p.6 n.2) It is quite common to permit a claim to go to suit without taking final action on the claim, for many different reasons, including inability of the parties to agree on the amount of a compromise settlement. I know of no basis for the apparent suggestion in the report that a settlement of a suit out-of-court is the same as the settlement of the claim for statistical purposes, or as a matter of law or fact. The Federal Tort Claims Act requires that suits be considered separately from administrative claims whenever a suit is filed (see, e.g., 28 U.S.C. §§2677, 2678). It will be more accurate if your report deems a settlement of lawsuit to be a settlement of a lawsuit rather than a settlement of a claim.

2. Follow-up Procedures (pp. 8-9)

While you must make your own determination as to the amount of staff that, in your view, should be devoted to follow-up procedures, two matters deserve further attention. First, our follow-up procedures became more vigorous and improved over time, especially after the surge in number of claims in the latter part of 1978 abated. Second, it deserves to be emphasized that given limited resources, it seemed preferable to pay preferred attention to claims that were actively pursued by claimants rather than divert substantial resources away from those claimants to repeated follow-up efforts directed to those who were dilatory in pursuing their claims.

3. Medical Review (p.9)

Your draft states that you "noted that Justice's staffing arrangement for medical review created delays and resulted in a backlog of claims." p.9 I note that Civil Division representatives initially met with the Armed Forces Institute of Pathology in late 1977 and were assured that AFIP would devote its resources to processing of Swine Flu claims. When it became apparent that we were not obtaining a sufficient volume of medical review, we did take the further steps which your draft outlines. Your draft considerably understates the importance of the steps which the Civil Division took to eliminate the need for medical review. First and foremost, we obtained information and advice from the most eminent and qualified medical experts in the nation with the view to limiting the necessity for medical review of individual claims by establishing objective criteria that would permit our staff to dispose of the claims themselves. As your draft acknowledges, this effort led to a reduction of the number of claims that required medical review during the administrative process.

It is unclear whether your statement that "adequate arrangements including sufficient staff should be made for the medical review of claims which might result," App. II at 20, assumes that a medical review of each claim should be undertaken in future programs. Our experience suggests that individual review in such cases is unnecessary and delays resolution of claims. I therefore believe that the efforts that we made during 1978, 1979 and 1980 to reduce the need for individual medical review of claims is worthy of emulation in future programs and should be mentioned in your transmittal to Senator Durkin.

#### 4. Procedures for Handling Claims

Appendix I needs revision in certain respects. First, footnote one of the appendix states that "medical review was terminated in September 1979 except for unusual claims. Until this time, claims that were to undergo medical review would have been sent by Justice to consulting physicians at this point in the process." The first sentence of this footnote is accurate. However, the second sentence ignores the fact that long before September 1979, most claims were subject to procedures which permitted action without medical review. These procedures are set forth at page 19 of Appendix II to the draft. In addition, the chart is incomplete in that it does not take into account the possibility of action or activity in the claim's process which would not be part of the usual flow of activity, such as obtaining a physical examination of a claimant or special inquiries. Perhaps a footnote should be added to explain that there may be some claims that did not literally follow the usual process. Also, the chart suggests (footnote 3) that "[i]f claimant rejects the second offer, the claim is denied." This statement is inaccurate. We never have had a hard and fast rule on settlement offers. Depending on the circumstances, we might make one offer only or several.

#### 5. Closed Claims

Table 2 to Appendix I of the draft "defines" closed claims. That definition (footnote b) differs from our definition in that we do not deem a claim closed simply because it was filed beyond the expiration of the statute of limitations. We deny claims on that basis, instead.

#### 6. Payment

Your draft ends its consideration of claims with the transmittal to the General Accounting Office of Vouchers for Payment. It is our experience that the General Accounting Office requires six to eight weeks to process a voucher for payment, during the period covered by the report. Since a claimant does not actually receive compensation until the Treasury check is received, I believe that your draft should comment on and consider any means of expediting the General Accounting Office's and Treasury Department's processing of vouchers.

#### Conclusion

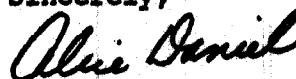
The unprecedented nature of the Swine Flu Program and the number of claims it generated created novel and complex problems never before encountered under the procedures

ENCLOSURE V

ENCLOSURE V

established for handling claims under the FTCA. I recognize that it took the Civil Division a period of time to evolve an innovative approach to handling these claims. I believe however, that the process in effect at the close of your period of study is an excellent means of resolving high volume administrative claims, in similar circumstances, so that future programs will benefit from the innovations that we implemented during the course of consideration of Swine Flu claims.

Sincerely,



ALICE DANIEL  
Assistant Attorney General