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REVIEW AND EVALUATION OF THE SWINE FLU IMMUNIZATION PROGRAM

DOCUMENTS

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HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

OF THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE HOUSE OF REPRESENTATIVES

NINETY-FIFTH CONGRESS

FIRST SESSION

ON

THE EXPERIENCES OF THE PAST 18 MONTHS OF THE SWINE FLU PROGRAM

SEPTEMBER 16, 1977

Serial No. 95–50

Printed for the use of the
Committee on Interstate and Foreign Commerce

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Association of State and Territorial Health Officials (ASTHO), Douglas S. Lloyd, M.D.
Chubb & Son, Inc., Henry U. Harder, president.
General Accounting Office:
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- Oswald, Peter, Supervisory Auditor.

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United States Conference of City Health Officers, Richard M. Biery, M.D.

REVIEW AND EVALUATION OF THE SWINE FLU IMMUNIZATION PROGRAM

FRIDAY, SEPTEMBER 16, 1977

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The subcommittee met at 10 a.m., pursuant to notice, in room 2123, Rayburn House Office Building, Hon. Paul G. Rogers, chairman, presiding.

Mr. ROGERS. The subcommittee will come to order, please.

On March 24, 1976, the President announced a national program designed to offer immunization to every American citizen against a newly discovered influenza virus. This initiative came to be known as the swine flu program of 1976.

Congress responded. Under the general immunization authority of the Public Health Service Act, the Appropriations Committee took a bill to the House floor providing appropriations for the swine flu program on April 5, 1976. The funding bill passed the Senate on April 9 with amendments, and the House agreed to the Senate amendments on April 12. H.J. Res. 890 became Public Law 94-268 on April 15, 1976. This committee was advised by HEW that new legislative authority for the program was unnecessary, that HEW could implement the program by contracting with manufacturers. This proved not to be the case.

The subcommittee responded to the President's request and held our first legislative hearings on March 31, 1976. We developed legislation which, although not ultimately enacted, passed the House by voice vote on April 15. Subsequently, we held four additional hearings on the implementation of the program. We were concerned over program operations such as the lag in the production of sufficient quantities of vaccine, changes in instructions to State and local health departments, and the establishment of dosage schedules for children. The major problem which required this subcommittee's attention, however, was that of liability. The liability issue led to Public Law 94-380, the national swine flu immunization program of 1976, which was necessary to the eventual implementation of the program.

Once this major preventive medicine program was underway, however, it was plagued by continued problems, the most unfortunate being the complication of Guillain-Barre, which led to the decision to terminate the campaign on December 16, 1976.

At the request of this subcommittee, the General Accounting Office has conducted an extensive review of many aspects of the swine flu program. We are here today to receive that report, and to review with individuals who were involved with the swine flu program, the experiences of the past 18 months.

I would note that our purpose in conducting this hearing is to learn directly of those public policy questions which have arisen or have assumed greater importance as a result of the swine flu program, and to receive whatever constructive suggestions the invited witnesses, and the public at large, may care to offer as possible solutions to those questions.

We shall certainly explore, among other areas, questions related to the Government's decisionmaking process; liability issues—professional liability, product liability, and compensation for citizens who may have been injured as a result of immunization, vaccine production and testing, informed consent, program management, and cost calculations.

Because we have a large number of people wishing to be heard today, we have requested that all witnesses be as brief and concise in their oral testimony as possible. Full copies of prepared statements will, of course, be made a part of the record.

Our first witnesses will be from the General Accounting Office; however, before we hear from GAO, I think other members of the subcommittee may have opening comments. Dr. Carter.

Mr. CARTER. I do, Mr. Chairman, yes sir, I have. I am pleased to join you in holding oversight hearings on the national swine flu immunization program for 1976. It was indeed our Nation's first large-scale venture in preventive medicine and I believe it represents an important step toward a commitment to a preventive philosophy which we have talked about a great deal.

Since the swine flu program was a first step, we know that it had its shortcomings, but I hope today's hearing will not be wasted on trying to find scapegoats. Instead I invite the witnesses today to provide suggestions to help the committee address the many difficult policy and procedural questions which have arisen from the swine flu program.

We need to focus our attention on the future of our Nation's preventive goals and to consider what approach we should take for future immunization programs. Particularly, I hope we can focus on the following issues which should be of concern to all of us—the issue of liability, the issue of public and private roles in future immunization efforts, the issue of provider participation, the issue of Federal-State relations and future immunization efforts, the issue of vaccine research and development, and the issue of informed consent.

I look forward to hearing from the witnesses today on these and other matters.

Thank you, Mr. Chairman.

Mr. ROGERS. Thank you.

Mr. Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman.

There are some in the Federal Government who think we shouldn't be holding these hearings at all. They say this hearing will undermine people's confidence in government health pro-

grams. But I feel the American people are so much more intelligent and sensible than they are given credit for. They know the swine flu program was a blunder. That is not the issue. The issue is government credibility and government decisionmaking. The issue is why when a government program gets underway is there so much momentum that dissenting views are not listened to?

I respect the fact that those responsible for the swine flu program acted in good faith. I think they made the best judgments they could. What I am concerned about is that once decisions were made to immunize our population, a public relations campaign got underway which ended up deceiving our people and leaving in its wake public distrust.

The only way to restore public trust is to dig into this program and find out what went wrong. In April, Secretary Califano announced a national immunization program. We must learn from our mistakes in the past before we inaugurate a new immunization drive.

I think the swine flu program was the Federal Government's "Moby Dick." I think it was a great white whale that we pursued so doggedly that commonsense was lost sight of. The program was a terrible waste.

We thought it would cost $135 million, but it looks now like it will cost us well over $1 billion.

We thought a national immunization program would draw us all together in a national effort. This was to be a model for future immunization programs. Instead, we squandered the precious trust the public accords us.

Do you know what could be done with a $1 billion? We could provide all poor children with dental care. We could screen poor children for signs of mental retardation at an age when such a handicap is most easily treated. Can you conceive of how $1 billion could help programs for the handicapped of our Nation. Or how it could be used to modernize our veterans hospitals?

When I think what could be done with the funds we now must devote to cleaning up after the swine flu program I feel frustrated. With all our expertise, why didn't we know better?

I hope we can get answers to some of these questions in this hearing, and I want to thank the chairman for calling these hearings so that we can look into the issue of the swine flu immunization program.

Mr. ROGERS. Mr. Maquire, did you have a statement?

Mr. MAGUIRE. No, Mr. Chairman.

Mr. ROGERS. We are pleased to have as our first witnesses the representatives of the General Accounting Office, who conducted the study requested by the committee. The witnesses are Mr. Gregory J. Ahart, Director of the Human Resources Division, General Accounting Office, who is accompanied by Jesse Flowers, Michael Burnett, and Peter Oswald, supervisory auditors of the General Accounting Office.

We welcome all of you gentlemen here. Your statement will be made a part of the record in full at this point and you may proceed as desired.

STATEMENT OF GREGORY J. AHART, DIRECTOR, HUMAN RESOURCES DIVISION, GENERAL ACCOUNTING OFFICE; ACCOMPANIED BY MICHAEL BURNETT, JESSE FLOWERS, AND PETER OSWALD, SUPERVISORY AUDITORS, GAO

Mr. AHART. My statement is quite brief. I will try to make it as brief as possible.

Mr. ROGERS. You may proceed.

Mr. AHART. Thank you.

We are pleased to be here this morning to discuss our report on the swine flu program. This program as you mentioned is an unprecedented venture in preventive medicine. It was the Government's first attempt at immunization of the entire U.S. population.

We monitored program events as they occurred between August 1976 and March 1977 at the Center for Disease Control—CDC—in Atlanta; the Bureau of Biologics, Food and Drug Administration; and the National Institute of Allergy and Infectious Diseases, National Institutes of Health in Bethesda, Md. We also monitored program implementation at 5 immunization projects and visited 26 mass immunization clinics within these project areas.

Our report discusses considerations for future programs with respect to program justification and cost, Federal liability implications, vaccine production and testing, and program planning and implementation. I will try to summarize each of these areas and we will be happy to have a copy of the full report in the record.

Mr. ROGERS. We will put the report in the record as an appendix [see p. 501.]

Mr. AHART. I will briefly summarize these areas.

PROGRAM JUSTIFICATION

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

HEW officials said that gambling with money would be better than doing nothing and gambling with lives. In a sense, HEW lost its gamble with money. No swine flu outbreak occurred.

For any future immunization effort as large or concentrated as the swine flu program, the many preventive health care questions that arose would likely have to be broadly considered again by all parties involved.

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

LIABILITY CONTINUES TO BE A PROBLEM

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

May result in profit to the insurance companies of nearly the entire $8.65 million premium paid to vaccine manufacturers for liability insurance;

Leaves unresolved insurance company concerns about nonmeritorious claim risks; and

May result in indeterminable costs to the Government for litigation, awards, and settlements because of potential weaknesses in the form and procedures used to obtain informed consent from persons immunized.

So that resolution of the liability issue does not delay or adversely affect public acceptance of future programs, we recommend that the Congress establish a national liability policy before another mass immunization program is needed.

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

VACCINE TESTING MORE EXTENSIVE THAN IN 1975

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

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

Because of the deficient potency test and the continual differences in manufacturer and Food and Drug Administration test results, we believe that the agency should continue its own potency tests on all lots of flu vaccine until manufacturers' test results can be relied on. In addition, the agency should speed up its work to: Identify and resolve potency test variances with the manufacturers, and develop and put into practice an improved method to measure potency and relate it to the level of protection provided by the vaccine.

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

POTENTIAL PROTECTION PROVIDED BY SWINE FLU VACCINE

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

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

The duration of protection provided by the vaccine is uncertain.

NOT ENOUGH VACCINE PRODUCED OR PRODUCED IN TIME

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

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

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

STATE READINESS AND IMPLEMENTATION

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

State and local immunization projects were not ready to begin the program in July as planned. They were limited by: Less than full commitment by some project directors; complex, incomplete, and late vaccine recommendations; less than expected participation by private doctors, volunteers, and others; weaknesses in project operations; and lack of State liability insurance.

We could not determine whether State or local projects could be ready for future mass immunization programs.

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

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

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

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

Mr. ROGERS. $103?

Mr. AHART. Yes, sir, out of $135, Mr. Chairman.

Costs yet to be determined include: The final cost of the vaccine and vaccine storage; Department of Justice costs of litigation and Federal funds for settlements and awards for claims over $2,500 which are not recoverable from third parties. The total dollar amount of the claims and suits filed as of September 8, 1977, exceeded $1.5 billion.

The Center for Disease Control is estimating costs for which limited accounting data is available. Not all of the estimates are complete. These costs include: Personnel costs of full time HEW employees detailed from other programs—estimated at $0.5 million; State and local program costs in addition to those funded by the Federal grants—estimated at $24 million; lost opportunity costs to other programs—no estimate yet; costs incurred for health care and lost earnings by individuals because of immunization reactions—no estimate yet.

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

This briefly summarizes the main points in our report, Mr. Chairman, and we would be happy to answer any questions you may have.

[Mr. Ahart's prepared statement follows:]

STATEMENT OF GREGORY J. AHART, DIRECTOR, HUMAN RESOURCES DIVISION, UNITED STATES GENERAL ACCOUNTING OFFICE

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

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

We monitored program events as they occurred between August 1976 and March 1977 at the Center for Disease Control (CDC) in Atlanta; the Bureau of Biologics, Food and Drug Administration; and the National Institute of Allergy and Infectious Diseases, National Institutes of Health in Bethesda, Maryland. We also monitored program implementation at five immunization projects, and visited 26 mass immunization clinics within these project areas.

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

PROGRAM JUSTIFICATION

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

Many of the limited facts available were used to both support and condemn the program. The validity of either position could be tested only over time. Even though

the decision was a gamble, HEW officials said that gambling with money would be better than doing nothing and gambling with lives. In a sense, HEW lost its gamble with money. No swine flu outbreak occurred during the 1976–77 flu season.

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

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

LIABILITY CONTINUES TO BE A PROBLEM

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

May result in profit to the insurance companies of nearly the entire $8.65 million premium paid by vaccine manufacturers for liability insurance;

Leaves unresolved insurance company concerns about nonmeritorious claim risks; and

May result in indeterminable costs to the Government for litigation, awards, and settlements because of potential weaknesses in the form and procedures used to obtain "informed consent" from persons immunized.

In regard to future mass immunization programs, insurance executives stated that the Government should be responsible for both the liability and the costs of litigation, since the Government controls all key program aspects. HEW's Assistant Secretary for Health stated that a national policy concerning compensation will have to be developed for any future mass immunization program. So that resolution of the liability issue does not delay or adversely affect public acceptance of future programs, we recommend that the Congress establish a national liability policy before another mass immunization program is needed.

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

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

VACCINE TESTING MORE EXTENSIVE THAN IN 1975

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

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

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

Identify and resolve potency test variances with the manufacturers, and

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

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

POTENTIAL PROTECTION PROVIDED BY SWINE FLU VACCINE

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

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

The duration of protection provided by the vaccine is uncertain.

NOT ENOUGH VACCINE PRODUCED OR PRODUCED IN TIME

HEW estimated in late March 1976 that manufacturers could produce and deliver 200 million doses of vaccine by the end of November. Primarily because of unresolved liability questions, the first delivery was delayed—from July to October. Vaccine available then could immunize only about 12 percent of the population. Although three of the four manufacturers said they continued to produce at full capacity during the delay and the fourth had met its original estimate, vaccine production fell short of the original estimates by about 43 million doses and required over 2 months longer to produce.

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

STATE READINESS AND IMPLEMENTATION

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

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

Less than full commitment by some project directors;
Complex, incomplete, and late vaccine recommendations;
Limited quantities and delayed delivery of vaccine;
Less-then-expected participation by private doctors, volunteers, and others;
Weaknesses in project operations; and
Lack of State liability insurance.

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

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

We also recommend that the Congress consider the effect which inadequate liability protection might have on State participation in future immunization programs. The Federal Government could (1) assume total liability for the program, (2) assume no liability for program participants, or (3) assume limited liability similar to that provided under the swine flu program.

PROGRAM COSTS

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

Total program costs include:

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

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

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

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

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

Personnel costs of full-time HEW employees detailed from other programs. (Estimated at $0.5 million.)

State and local program costs in addition to those funded by the Federal grants. (Estimated at $24 million.)

Lost opportunity costs to other programs. (No estimate yet.)

Costs incurred for health care and lost earnings by individuals because of immunization reactions. (No estimate yet.)

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

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

Mr. ROGERS. Thank you very much, and the committee is grateful to the General Accounting Office for the report and the time spent on this problem in trying to help us.

Mr. Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman.

I would like to go into the whole question of costs with you, if I might.

You say in some instances the accounting data is too limited to identity precise costs. Why is accounting data too limited at this point for you to identify precise costs?

Mr. AHART. I think, Mr. Waxman, that what we are talking about there is where the State and local levels put people that ordinarily would work on other programs, into this program. I don't think their accounting systems are such that they kept account of all the time everybody might have spent on the program.

The same is true at the Federal level, although there has been an estimate of what time other HEW employees spent on the program. Their accounting system is not such that you could precisely keep the exact amount of time and related personnel costs associated with the program.

Mr. WAXMAN. You are able to determine the costs to the Government for the vaccine; is that correct?

Mr. AHART. That will be determined ultimately. Right now I understand the estimated cost of the vaccine is about $67 million.

Contracts with three of the manufacturers have been signed. Those contracts do lay out the cost elements for which the firms will be reimbursed. They will be subject to audit by HEW audit agency and a final cost determination made.

Mr. WAXMAN. Will they be subject to audit by GAO?

Mr. AHART. Presumably, if we have any problem with what the HEW audit agency does and feel there is a need for us to audit they would be subject to our audit as well.

Mr. WAXMAN. I find that a peculiar response. Doesn't GAO work for the Congress and isn't GAO going to be independent of the administration? Are you going to rely on the administration for the figures to determine whether it was an appropriate cost or not?

Mr. AHART. Obviously if you look at the Government as a whole we rely upon the executive branch agencies a great deal for the propriety and accuracy of costs. We are a relatively small organiza-

tion. We feel that it is a responsibility of the management of HEW in this case to make a proper cost determination. We would not spend our resources until we had some question as to the adequacy of their determination. We would not redo their work on a routine basis.

Mr. WAXMAN. So HEW promotes a program for swine flu vaccine, pays for the program costs, and would obviously be embarrassed if they weren't doing their job. GAO, which is an arm of the Congress, is to be an independent arm of the Congress so that we can check on the administration, relies on the administration's figure for the administration's program for us to know whether the administration is doing its job. I find that a frustrating answer that you are giving me.

Mr. AHART. I don't think it is quite as simple as the way you have related it. If you take a look at the organization of HEW you will find that the audit agency is established under the Office of the Inspector General, which is a statutory job. It is fully independent of the operating bureaus of the agency—CDC, and the Food and Drug Administration, and others—which are directly involved in the program. It is independent of the contracting authority. It is responsible to the Secretary. So there is a high degree of independence between that arm of HEW and the people who were in support of the program.

I would suspect that the HEW audit agency didn't have a particular point of view on whether we should or should not go forward with the swine flu program.

Mr. WAXMAN. In your report you indicate that there were no signed contracts with HEW and the vaccine manufacturers in the beginning. I gather there were no signed contracts for a long period of time; is that correct?

Mr. AHART. That is correct.

Mr. WAXMAN. Now, isn't it fair to assume that the fact that the contracts remained unsigned for so long would allow the vaccine manufacturers to elude a timely audit by either you or HEW auditors.

Mr. AHART. I don't think that would be the case. There were letter contracts, letters of intent, in effect, with the HEW. The final signing of the definitive contracts was held up, I understand, for two reasons. There was a question as to what the income tax treatment would be of the $2.5 million insurance fund which was provided each of the manufacturers under the contracts. That was finally resolved by Internal Revenue Service with a ruling last April which stated that it would not be taxable.

The other question was whether or not the standards of the Cost Accounting Standards Board would be applicable to the contracts as provided for in the letter contracts of September, or whether it would be waived by HEW in the circumstances.

They were finally waived last month at which time three of the contracts, final contracts, were signed.

Mr. WAXMAN. What was waived?

Mr. AHART. The cost accounting standards promulgated by the Cost Accounting Standards Board were waived in this case.

Mr. WAXMAN. What were those? What exactly did HEW decide to waive?

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Mr. AHART. Basically the Cost Accounting Standards Board is to promulgate standards for allocation of cost to Federal contracts and these are applicable to certain contractors depending on their level of business, size of the contract and other matters.

Mr. WAXMAN. Is that the process by which the Government decides what actual costs were to determine whether profits were the amount to be provided for pursuant to the contract?

Mr. AHART. In case of most contracting situations that would be true.

Mr. WAXMAN. How do we know what the actual costs of the vaccine were to the manufacturers?

Mr. AHART. This will be done when they submit their cost reports and HEW goes back and audits against the records of the firms as they maintain them and then a judgment will be made as to the allowability of the costs which are claimed.

Mr. WAXMAN. Is HEW going to rely on the statement of what the manufacturers say were those costs in determining what those costs were?

Mr. AHART. I think in the first instance the manufacturers must come forward with their statement of what costs are chargeable to the contracts.

Mr. WAXMAN. What is going to be done to look behind that to be sure that the statement that they make as to what their costs were are in fact correct?

Mr. AHART. The HEW Audit Agency wil go into the manufacturers records and verify the information provided in the cost reports submitted by the manufacturers, verify it to the original records maintained by the four manufacturing firms.

Mr. WAXMAN. Do you know whether HEW had done this yet?

Mr. AHART. I don't think they have gone into any of the firms yet. Let me ask my associates if they have knowledge where that stands?

Mr. WAXMAN. The contracts were only signed last month?

Mr. AHART. Three of the contracts were signed in August of 1977. We don't know if they are in there yet or not. Let me ask Mr. Burnett if he has current knowledge on that.

Mr. BURNETT. Yes sir; they have begun work in region 3 where two manufacturers are, I believe Wyeth and Merck. They have visited those manufacturing plants and they are in the process of putting together their report for those two.

They have not begun work, as I understand it, in region 5, which would include Parke-Davis and Merrill National.

Mr. WAXMAN. So we didn't have contracts until August of 1977 for any of the drug manufacturers; is that correct?

Mr. AHART. They did not have final signed contracts. They did have letter contracts, letters of intent which were issued sometime during 1976.

Mr. WAXMAN. Was there competitive bidding among the manufacturers of the flu vaccine before the contracts were let out?

Mr. AHART. There was not competitive bidding. In this case the contracts were on a cost basis. Competitive bidding is not feasible in that short a time frame. Also, in this case you only have six licensed manufacturers in the country to produce vaccine. You only had four currently in a position to produce and it was felt that

the capability of all four would be necessary to produce the desired 200 million doses of vaccine within a time frame that would make it useful should a pandemic occur in the fall of 1976.

Mr. WAXMAN. One thing the Congress felt very strongly about when we authorized that liability legislation was that the drug manufacturers were not to make a profit. This was a national emergency and we weren't going to allow profiteering at the expense of the American people during such a situation.

Can you tell us for certain that no profit was made?

Mr. AHART. We have not audited the contracts, Mr. Waxman. The way the contracts are written it is my understanding there will be no profit allowance on the swine flu portion of it. There will be an allowance of profit on the Victoria—A component of the bivalent vaccine and obviously I am not in a position to attest to whether there is or is not any profit on the portion of the bivalent vaccine that there should be no profit on.

Mr. WAXMAN. I find it very frustrating. You represent the Government Accounting Office, an arm of the U.S. Congress. We asked you to look into the question of how this program was being handled economically, what costs were going into it, whether the program was being carried out pursuant to the intent of Congress, and as I understand your testimony, you are going to rely on HEW to report on their own program, when they get around to it, and we don't even know to this point in September of 1977 whether profits were made or not.

I assume we don't even know the cost per vaccine for each individual patient; is that correct?

Mr. AHART. The estimated cost of the vaccine is somewhat less than HEW's original estimate of about 50 cents per dose. I think they are down in the range of about 30 cents per dose for the monovalent vaccine and in the range of 40 to 49 cents on the bivalent vaccine. The estimates are somewhat lower than the original estimate. I don't think it is unusual or unexpected that we would wait until the agency with the prime management responsibility made its determination before we decide whether or not there is a need for further effort. This is basically the agreement which we reached with this subcommittee quite a number of months ago, that we would rely basically on the HEW aduit agency and when they got through to make a judgment on whether there was a further need for audit and for the General Accounting Office to become involved in the audit portion of it.

Mr. WAXMAN. Can you tell us how much money the insurance companies will make as a result of the swine flu program?

Mr. AHART. The total premiums paid to insurance companies by the four manufacturers, and that they will be reimbursed under the contract for, was $8.65 million. It is our judgment, based on the liability protection provided by the Congress last year, that virtually all of that could be profit to the insurance companies.

Mr. WAXMAN. All of it could be profit for the insurance companies?

Mr. AHART. Yes; as stated in my statement.

Mr. WAXMAN. In other words, they were not giving anything in return for that money?

Mr. AHART. Well, it is hard to see where they are going to be reached under the liability provisions, because of the way Congress has set up the liability protection. The sole recourse is to the Government, then the Government must reach manufacturers and whatnot. If we reach manufacturers and recover more than the $2.5 million each—is that correct, Mr. Burnett? It is possible some of the $8.6 million may have to be paid back to the Government.

Mr. WAXMAN. How would that take place?

Mr. AHART. Well, basically it would occur when someone sues the Government or submits a claim to the Government, it is settled or the judgment is rendered in court that the Government has the liability under the statute, and then the Government in turn feels that the real culprit in the case was negligence on the part of the manufacturer and would go against the manufacturer for recovery and the manufacturer is found to be liable.

Mr. WAXMAN. I understand what you are saying. You are saying if under the remote possibility that we go back against the drug manufacturer and he is held liable, in spite of the liability section passed by the Congress, then that insurance, $8 million plus, will cover that possibility?

Mr. AHART. Yes, sir.

Mr. BURNETT. Only in excess of the $2.5 million which is self-insured by the manufacturers. That is the first layer that we get to.

Mr. WAXMAN. So I think it is fair to assume the drug manufacturers and insurance companies have ongoing relationships with each other of all of the products that they produce, isn't that correct?

Mr. AHART. I assume all drug manufacturing firms would have liability insurance on a continuing basis. I don't know in this case whether it was the same firms and same companies involved as in the ongoing thing. I would suspect they would turn to the regular insurance, yes.

Mr. WAXMAN. I am not saying this is the case. If a drug manufacturer in exchange for the $8 million which the taxpayers are paying for liability, which is very unlikely, in exchange for that $8 million gets a break on some other insurance coverage somewhere else, would HEW's accounting office or GAO's accounting office ever be able to tell us that information?

Mr. AHART. I suspect not. Under the hypothetical case that you are mentioning.

Mr. WAXMAN. Well, they came in together, the drug manufacturers and the insurance industry, and they cried to us that they would not go forward with the program to protect the American people from an epidemic, a pandemic, they said they couldn't do it, they wouldn't do it, unless we absolved them of liability. I am a bit frustrated because now we can never really seem to get somebody in Government who can dig into those records to find out once we gave them the money how much the program is going to cost for the vaccine and for the insurance coverage, not the liability that the Government is going to assume but for the program itself for the purpose of the vaccine.

Mr. AHART. What has been spent just for the vaccine?

Mr. WAXMAN. Yes.

Mr. AHART. Just for the vaccine I think the current estimate is $67 million. The original estimate was $100 million. The current estimate is $67 million.

Mr. WAXMAN. My time is up and I hope we will have another round because there are some questions that I feel very frustrated about.

I just want to make one last comment, Mr. Chairman. My frustration is that the GAO report doesn't seem to really be digging in and I guess my suspicion becomes even greater when I see the report of a program that I am so critical of, entitled "The Swine Flu Program, An Unprecedented Venture in Preventive Medicine." "Unprecedented" is a peculiarly favorable of describing what I consider a blunder on the part of the Congress of the United States.

Thank you, Mr. Chairman.

Mr. ROGERS. Perhaps General Accounting didn't want to characterize Congress' action that way, Mr. Waxman.

Mr. WAXMAN. Obviously they don't want to offend anybody, but that is not their job.

Mr. ROGERS. Dr. Carter.

Mr. CARTER. Thank you, Mr. Chairman.

Of course we were all involved in the swine flu legislation. It alarms us no end that we had over a 1,000 cases of Guillain-Barre syndrome following this program.

As a result of this we have suits pending against the Federal Government now of $1.5 billion.

I can't condemn an insurance company for not wanting to insure against claims which are in realm of $1.5 billion by paying premiums of $8.65 million. It doesn't seem to me to be logical, does it to you, Mr. Ahart?

Mr. AHART. Well, of course, the $8 million in premiums or $8.65 million was negotiated, I presume, with full understanding of the liability protection which was afforded by the act which was passed last summer. So certainly that premium does not equate with the total potential liability risk.

Mr. CARTER. What premium would equate with such a risk?

Mr. AHART. Well, I think the problem—I wouldn't want to speak for the insurance companies—I think the problem they had is they didn't have anyway, since this is the first time that the Government has ever undertaken a program to immunize everyone in the country—that they would have no experience upon which to base a premium which they felt would be reasonable in those kinds of circumstances.

Mr. CARTER. As an auditor and one familiar with the work of an actuary, would you consider taking out a policy for insuring against incidents that might happen as a result of immunizations from swine flu?

Mr. AHART. Well, I think as fas as I can go in answering that question, Dr. Carter, is that I can certainly understand the concerns which the insurance companies would have had at the time in being asked to insure the manufacturers against liability.

Mr. CARTER. Yes, sir.

What do you think about manufacturers in this case, do you blame them for not wanting to assume liability in these cases?

Mr. AHART. Well, I am not here to cast blame on manufacturers, insurance companies, or anyone else. In this crash program , the

companies were making judgments based on where they stood in the program and what they expected their possible risk might be. I certainly don't blame the manufacturers for being concerned about the fact that they would have potential liability by participating in the program and they couldn't get insurance companies to unsure them.

Mr. CARTER. I certainly feel that they did their best, although they did make some errors. One marketed about 6 million doses of the Shope vaccine, which was really not the true swine vaccine and was not used. And, with respect to the Guillain-Barre syndrome, we had almost as many cases from those who didn't take the vaccine as those who did.

As far as I can find out, no one has really found the cause this syndrome other than it seems to follow any type of injection, not just swine flu. I don't know the association. It may be a virus that has been undiscovered.

But 45 million people were immunized in quite a short period of time. Whether this was helpful or not we don't know, but we do know that the most emminent scientists in the United States were here advising us to embark on this program.

Of course, hindsight shows many, many things. Perhaps it was a mistake but our intention certainly was to protect the American public from what might have been a disaster.

Thank you, Mr. Chairman.

Mr. ROGERS. Mr. Maguire.

Mr. MAGUIRE. Thank you, Mr. Chairman.

Mr. Ahart, we were most careful in drafting this legislation to prevent a situation in which the manufacturers would reap untoward profits from this program. Today you are telling us that the insurance companies will receive $8.65 million in premium payment costs which will be passed on to the Federal Government and, therefore, to the American people, and that it is very likely that that will be sheer profit.

I recall that as we began this program, with all of the uncertainties that were associated with it, we had an expectation that the Congress was going to try to act responsibly in the face of the case that was being made by medical authorities and scientists and we anticipated that the manufacturers would also rise to the occasion by preparing and producing the vaccine on a very tight time schedule.

We then suddenly confronted a situation in which the insurance companies, in effect held us up for ransome. They said sorry, we won't do it without the insurance companies. It was impossible to proceed. So ultimately a very strange concoction, at least with respect to previous history, had to be devised, which is this liability arrangement which you have described and which we are all familiar with.

I am very concerned that the party which I felt acted least responsibly in the situation now appears on the verge of reaping enormous profits.

I would like to know, sir, your opinion of where the responsibility for this rather exceptional situation rests and what, if anything, can be done about it now. Is it the fault of the U.S. Congress for not drafting the legislation in a way that would have precluded this particular result?

Mr. AHART. No; I don't think it is the fault of the U.S. Congess or probably any other one party involved in this process. As you indicated, the action was taken at a time when there was strong support for the program. Something needed to be done if the program was going to go ahead.

The insurance companies were not in a position, I think, to make a very good judgment on what kind of a premium would be good if they were to assume their regular liability with respect to manufacturers. I don't think they were in a terribly good position to judge what might be the residual liability through the third party recovery mechanism of the law. I am not sure there is anybody you could point a finger at, Mr. Maguire, and say thery are to blame for it. It was something done in concert faced with a very difficult situation.

What we are suggesting in my statement and in our report is that the Congress, assuming the possibility of some future large immunization program, since it has a little bit more time to consider than they did last summer, sit down and think about and perhaps establish a policy for liability in future programs.

Mr. MAGUIRE. On page 4 of your statement you said the insurance industry could make manufacturers premium adjustable retrospectively based on claims experiences.

Mr. AHART. That is correct.

Mr. MAGUIRE. Do you believe that we could have done that last year?

Mr. AHART. I am not sure if it could have been done or not.

Mr. MAGUIRE. This is the point now. If we take that recommendation and say either we ought to do that in the future or we should have done that last year and the insurance companies come back and say I am sorry, we are not going to play ball on that basis, then where are we? Aren't we in exactly the same position?

Mr. AHART. I think you are if the insurance companies would not be agreeable to entering into that kind of arrangement.

Mr. MAGUIRE. You think they would not?

Mr. AHART. I don't know if they would or not.

Mr. MAGUIRE. Have you talked to them about that?

Mr. AHART. I don't know if my staff has or not. Mr. Burnett, have we talked to insurance companies about that?

Mr. BURNETT. No, we haven't.

Mr. MAGUIRE. Well, of course, it is a nice theory but if the insurance companies aren't buying, then we will continue to have a situation in which they will hold the American people up for ransom. I am going to have to say to the American people, gee, I am really sorry, the $8.65 million that the insurance companies got as pure profit is something we could't figure out any way to recover. Can't we prevent that from happening in the future, is that your best judgment?

Mr. AHART. We did lay out two alternatives. The one I mentioned. The other one is the full assumption of liability by the Federal Government and that obviously——

Mr. MAGUIRE. That is another alternative. I am pursuing the alternative that you have suggested here. My next question is this: is there any reason why we cannot now insist on this retrospective adjustment?

Mr. AHART. I don't think we have explored that. My judgment would be without knowing anything further about it that it is a contractual matter between the manufacturers and their insurance companies. I don't think those have any provision for recovery.

Mr. MAGUIRE. When were those contracts signed between the manufacturers and the insurance companies?

Mr. AHART. I assume they were signed shortly after the passage of the liability legislation last summer. I don't know if we have the exact date or not. Mr. Burnett?

Mr. BURNETT. We don't have the exact date but it would be sometime in September.

Mr. MAGUIRE. This particular point would not be subject to contract provisions that would be entered into between the Government and the manufacturers for the supply of vaccine, i.e., the contracts which were just completed last month?

Mr. AHART. That is right.

Mr. MAGUIRE. Mr. Chairman, I find this an astonishing situation. I don't think that Mr. Ahart has really given us much of an option here if in fact it depends on the cooperation of the insurance companies and if in fact they are unwilling to cooperate, but I will explore that point further when representatives of the companies appear.

Thank you, Mr. Chairman.

Mr. ROGERS. Well, I think it is a matter of fact that that issue was what brought about congressional action, because if the program was to proceed, the only way was to provide some method of handling the liability problem. As you recall, the manufacturers said they would not make or sell vaccine unless they were insured.

Mr. MAGUIRE. A perfectly understandable position, I might say.

Mr. ROGERS. It happened to be the situation; and I would agree.

Mr. MAGUIRE. Let me ask one more question.

Mr. ROGERS. Certainly.

Mr. MAGUIRE. If the insurance companies do not cooperate either retrospectively or in the future what happens? Under GAO's analysis, what happens to that free capital? Do they then invest in other things? Do they reduce premiums to all of their subscribers? What happens to the $8.65 million—or should happen to it, in your judgment?

Mr. AHART. If it is not required for——

Mr. MAGUIRE. It may be a payment of taxes in lieu of fair contractual arrangements or something.

Mr. AHART. If it should not be required as a result of this program to cover liability which the insurance companies are contractually bound to cover, I assume it would be considered as profit. If it is a profitmaking, stock insurance company, it might go out in dividends, depending on what the insurance commission in the particular State has to say about the rate structure and all that. Anything could happen. I wouldn't want to speculate as to where this $8.65 million which is now held by insurance companies will finally end up.

Mr. MAGUIRE. Thank you, Mr. Chairman.

Mr. WAXMAN. It is profit to the insurance companies of $8.65 million, yet Congress said there shall be no profit to be gained

through this swine flu program because it was a national emergency. Why can't we get that money back?

Mr. AHART. My recollection is Congress said there should be no profit gained by the manufacturers. These are not manufacturers, these are insurance companies.

Mr. WAXMAN. I see. I asked you earlier whether if some arrangement had been made between the insurance companies and manufacturers so the manufacturers can still get a benefit, whether if that took place we would even know about it, and your answer was we wouldn't.

Mr. AHART. I said the likelihood is we would not.

Mr. WAXMAN. You mentioned something was waived by HEW when they finally signed contracts. Is that a renegotiation so HEW can go back and get profits that were made by the manufacturers?

Mr. AHART. No; it has nothing to do with renegotiation. These are cost accounting standards promulgated by the Cost Accounting Standards Board. They are applicable under the law to defense contracts. They are applicable under the Federal Procurement Regulations to most civilian contracts, civil agency contracts. There is provision in the law for waiver. That provision was exercised by HEW recently, I think last month, so these contracts could be signed and the waiver was premised on the fact that drug companies traditionally, it is my understanding, do not allocate costs other than the manufacturing costs and perhaps some manufacturing overhead to individual products, individual product lines, and that they really would have no way under their accounting system to apply all of the standards which have been promulgated by the Cost Accounting Standards Board and that was the justification. HEW agreed with that justification and has waived the application of the standards.

Mr. WAXMAN. Are you satisfied that we are finding out whether the drug manufacturers have made a profit or not?

Mr. AHART. Well, I would only speculate at this point in time that the HEW audit agency will perform a competent audit of costs against the contractual provisions. If in our judgment or someone else's judgment they do not do an adequate job then we are in the wings and we will do whatever is necessary to satisfy ourselves that the contract was reasonably complied with.

Mr. WAXMAN. Isn't HEW very late in giving you and us a report on the costs for this vaccine?

Mr. AHART. Well, again, the contracts were not finalized until last month. From Mr. Burnett's statements earlier, I assume the auditors in some cases went in before the contracts were finally signed.

The general provision in law on contract settlement audits is that manufacturers must retain records for a period of 3 years after final payment. They are certainly within the general statutory timeframe and requirements for retention of audit records so the contracts can be audited.

Mr. WAXMAN. We have the situation where contracts were only recently signed, HEW was supposed to report back to Congress about the cost for the program and has not yet completed their report, and you tell me that you will only look into it when you have suspicion HEW is not doing its auditing job properly.

Don't you have enough reason now to be suspicious something is there for you to look into?

Mr. AHART. No; I think that we are perfectly willing to let the HEW audit agency do its work and then if we are not satisfied with its work, do whatever we feel is necessary. I feel very comfortable with that.

Mr. WAXMAN. When do you think we will get that report?

Mr. AHART. I think Mr. Burnett said they are writing the reports on two of the contract audits at the present time. They are going into the other two manufacturers to audit costs. I will ask him when we can expect the final audit report on each of the reports.

Mr. BURNETT. One of the HEW auditors in region 3 speculated the final package of all four audits would be completed by December.

Mr. WAXMAN. By December?

Mr. BURNETT. Yes, sir, that is strictly his best——

Mr. WAXMAN. How long will it take you to decide whether you are going to be satisfied with their work?

Mr. AHART. Mr. Burnett.

Mr. BURNETT. We would probably take 1 month beyond that.

Mr. WAXMAN. A month?

Mr. MAGUIRE. I do have one more question before this witness leaves.

Let's go back for a moment to the question of liability. Did you do any comparative analysis of that $8.65 million premium which was paid under these contracts and other kinds of insurance premiums by drug manufacturers to their insurance companies?

The reason I asked that is I wonder whether the dollar paid was more than or less than or about the same as the dollar paid in other kinds of instances?

Mr. BURNETT. We didn't do that and I don't think it is possible to do that because this is the first time that the insurance industry is insuring strictly manufacturers' negligence. Always before they covered the whole range of liability. The Government picked up most of that this time and are just talking about manufacturer's negligence that——

Mr. MAGUIRE. Precisely. Now, to the extent that the Government picked up the lion's share of the liability, would it not then follow that the premiums paid for the limited remaining elements of possible liability should be far, far less than the premiums paid in the other overall liability instance than you referred to, and is it in fact the case that those premiums are far less?

Mr. AHART. I think our only answer to that, Mr. Maguire, would be that they move from a situation where they were not willing to insure at all to a situation where they were willing to insure only the manufacturer's negligence. Presumably the premium that they would have charged for a situation in which they would not insure at all would be much larger than the $8.65 million. I don't think you can find a comparable kind of problem of insurance.

Mr. MAGUIRE. I think what you are saying is that the premiums that were paid for this very, very limited amount of liability may have been—I don't know this is the case, I am asking—far in excess of the kinds of premiums that are paid in other instances for total liability. Right or wrong?

Mr. AHART. No; I don't think I am saying that.

Mr. MAGUIRE. You don't think so? But you have no comparative data?

Mr. AHART. I don't know. As Mr. Burnett points out, I don't think that kind of comparison is really possible given the vagaries of this kind of program.

Mr. MAGUIRE. That is what we have been hearing for 1 solid year and it would seem to me GAO of the United States ought to be able to make some kind of projection or estimate that would give us some understanding of whether or not we are being victimized in this situation or whether we are paying reasonable fee. I don't see any data in the report, or in the statement, or in the answers to the questions that would give us any guidance on that matter. I am disappointed at that, Mr. Chairman.

In your judgment, Mr. Ahard, why did it take so long for HEW and the manufacturers to sign the contracts?

Mr. AHART. I pointed out, I believe, two reasons that held up the final signing of the contracts, the three that are already signed. One is still not signed. The first reason was the uncertainty as to the income tax treatment of the $2.5 million given each manufacturer as an insurance reserve, a self-insurance reserve. That was finally resolved in April and Internal Revenue Service ruled it would not be taxable.

The other one was the need felt by the manufacturers for waiver of the cost accounting standards, as we have already discussed. Those were finally waived in August and contracts were signed in three cases.

Mr. ROGERS. May I say, if the gentleman would permit, the Chair would like to question before we have to vote.

Mr. WAXMAN. On the last point——

Mr. ROGERS. All right.

Mr. WAXMAN. That provision that HEW waived just didn't make any sense in these circumstances because this isn't like a defense contract. Why did the manufacturers hold out at least from April to August of this year, and maybe one would assume all the way from the first time we had letters of intent, to August of this year, before they would sign contracts with the U.S. Government until that was waived?

Mr. AHART. Well, if they had signed it without it being waived then they would have been subject to the standards. Presumably, it took the contracting officer that length of time to make up his mind the waiver in the circumtances was justified.

Mr. WAXMAN. They didn't want to be held to some standards?

Mr. AHART. They didn't feel that it was possible for them to be held to these standards based on the way they keep their accounting records. It is not only applicable to defense contracts, the standards under the Federal procurement regulations are also applicable to most civilian agency contracts as well, including HEW, unless waived.

Mr. WAXMAN. The chairman has been very generous and I want to express my appreciation, but let me also say this in closing, Mr. Chairman, I consider that report an unprecedented venture in not giving Congress the information that we ought to have by an organization that works for the U.S. Congress. I just don't want

GAO, who works for us, to rely on HEW to accept their figures, if and when they ever get around to giving us those figures. I think we are entitled to know whether profiteering took place and whether we are all victims, as Mr. Maguire said, of a situation where the American people will never know the true facts. I hope this is not our last hearing and, certainly, as far as I am concerned, it is not the end of the responsibility for GAO. I expect to get a full report from them later on when they look into the HEW audit and I expect them to do the audit.

Mr. AHART. I don't think GAO is trying to shirk its responsibility in this at all. The agreement or the decision to await the HEW audit of the cost in the contract was a decision reached jointly with this subcommittee, with the subcommittee fully onboard, it is my understanding and ——

Mr. WAXMAN. Wait a second. This subcommittee agreed with you to allow you to go ahead and rely on HEW figures?

Mr. AHART. I think that is the case. Is this correct?

Mr. WAXMAN. Can you clarify to me, as a member of the subcommittee, how that decision was made and who made such a decision?

Mr. AHART. Generally we work with the staff of the committee. I am not sure whether the chairman or individual members were in on that decision or not.

Mr. WAXMAN. You work for the U.S. Congress.

Mr. AHART. That is correct.

Mr. WAXMAN. Congressmen, not staffs of the committee. I guess we will have to go into the situation whether our own staff is giving you such laxity in doing the job that the U.S. Congressmen, the Members elected by the people, asked you to do a job to let you off the hook in doing that job. We want that job done.

Mr. ROGERS. Let me say this. I don't think anybody is going to have laxity. HEW is doing an audit there; and it will be reviewed by GAO. I think GAO should give the agency the opportunity to do their audit first and then they should check it. HEW will be up next and we will question them on this matter.

I was concerned about your figure of $1.5 billion in claims. Does that include the one suit for $1 billion?

Mr. BURNETT. Yes; it does.

Mr. ROGERS. So $1 billion of the $1.5 billion is one suit, is that right?

Mr. BURNETT. That is correct.

Mr. ROGERS. Does it also include the claim for $200 million that has already been dismissed?

Mr. BURNETT. I don't believe so, no.

Mr. ROGERS. Pardon?

Mr. BURNETT. No.

Mr. ROGERS. You did not include the $200 million claim?

Mr. BURNETT. No.

Mr. ROGERS. I guess we can get from Justice what claims are included. I think that suit was for revocation of a driver's license 5 years prior to the swine flu injection. Well, anybody can make a claim, that was a $200 million claim that evidently has been dismissed. I think we need to begin to get some balance in what is happening.

The second bell has rung. The Chair does have some other questions, so we will be in recess for 10 minutes to allow Members to answer the call.

[Brief recess.]

Mr. ROGERS. The subcommittee will come to order, please.

I think I will continue with questions at this time. Members are on their way back.

One of the major frustrations of the committee and apparently to State and local health departments, and perhaps even manufacturers and insurers, was the undefined nature of the administrative organizational operation of the swine flu program. We were never sure with any certainty who was actually in charge. We got different answers at different times from different people, and I noticed you did not speak to the question of organization and administration in your report. I wonder if you could comment. Did you look at that?

Mr. AHART. We did not look at it specifically. We do understand perhaps earlier on in the program there may have been some confusion in the program on the part of people who were in charge at the Federal level. We didn't enter on the scene until August 1976. At that time, it is my understanding, it was pretty clearly established that Dr. Millar was calling the shots for the program and was in charge and we didn't really see any confusion on the——

Mr. ROGERS. Who was in charge?

Mr. AHART. I think Dr. Millar was pretty much recognized as being in charge of the program by the time we entered on the scene, so we didn't see this confusion that apparently may have prevailed earlier on in the program.

Mr. ROGERS. Yes; I think that was the crucial time, early on, and it would be helpful if you could look at that for us, to see what actually went on. There seemed to be great confusion, and I think we probably need to address that in any future program so that it is very clear who has the responsibility for the program and decisions to be made.

Now, let me ask you this: What about the Bureau of Biologics? I understand there were problems there. Did you find any?

Mr. AHART. Let me ask Mr. Oswald who was in on the origin of our work at the Bureau of Biologics to respond to that.

Mr. OSWALD. Mr. Rogers, in our review at the Bureau of Biologics we found that every lot of vaccine was rigorously tested for potency, for safety, and for several other contaminants that may cause problems with the vaccine. We found that about 15½ million doses of the 55 million doses that we reviewed were subpotent, but in every case the Bureau of Biologics required that the manufacturers increase the potency of those vaccines before they were released to the public.

The testing of clinical trial vaccine was somewhat different and there are different statutory requirements for such testing.

The clincial trial vaccine safety test was not performed on every lot of the vaccine before it was used in the trials. Thus, we feel that that did not afford the same protection to the public that was afforded with the vaccine that was routinely released to the public.

Also, the potency tests with vaccine used in the clinical trials showed that about 29 out of 34 lots of vaccine were less than the values that were desired. This was for three of the four manufacturers. The fourth manufacturer did meet all of the desired potency requirements.

The Bureau explained to us that they didn't require the manufacturers to upgrade the potency of these vaccines because it would have delayed the program approximately 1 month, and they also felt that the differences were not great enough to disrupt the recommendations that would be made based on those potency values.

Mr. ROGERS. What about the delay in establishing potency standards for the vaccine?

Mr. OSWALD. Excuse me?

Mr. ROGERS. In establishing the potency standards for the vaccine, were there any delays there?

Mr. OSWALD. The delay was really the result of problems in determining what potency was necessary in age groups under 25 to achieve an antibody response which was considered sufficient to protect recipients.

Because of some problems there, they decided that a second phase of clinical trials would be conducted. The second phase was essentially to determine what the dose must be for those under 25 and that delayed the vaccine recommendations.

Mr. ROGERS. What about delay in the consent form?

Mr. BURNETT. We didn't have so much problem with the delay in the consent form as with the content of the form. I don't know exactly what you are referring to when you say delay.

Mr. ROGERS. Wasn't it July before it was determined what should be included on the consent form?

Mr. BURNETT. It was delayed until about July, yes, but the vaccine recommendations were not available then anyway.

Mr. ROGERS. It is my understanding that the consent form had to be changed. Why shouldn't we have a procedure in place where we know what has to go into a consent form? It seems to me that was not well done, that we had forms already printed and then had to redo the forms?

Mr. BURNETT. They did not redo all those forms, no. They introduced a second page to the original form.

Mr. ROGERS. Just added another page?

Mr. BURNETT. That is correct. They did that after the legislation required them to go through the National Commission for the Protection of Human Subjects.

Mr. AHART. I think there was a delay in getting the final form put together. I think what Mr. Burnett is saying is that was not the controlling delay in the sense that it happened to delay the program because since the final vaccine recommendations were not available anyway, the program couldn't start. We did have as pointed out in my statement, quite a bit of problem with the content of the form itself even as supplemented after the review by the National Commission—in not laying out candidly all the risks which the people might be taking by allowing themselves to be injected.

Mr. ROGERS. Did you discuss this with the Bureau of Biologics, or with whom?

Mr. BURNETT. CDC is the one.

Mr. ROGERS. What about the manufacturers?

Mr. BURNETT. No; the manufacturers were not involved in putting together the infored consent form.

Mr. ROGERS. They were not, they had no input at all into what the——

Mr. BURNETT. I don't believe so.

Mr. ROGERS. As to what the consent form should have in it?

Mr. BURNETT. No. The Federal Government was responsible for that aspect of the program.

Mr. ROGERS. So as far as you know, there was no contact with the manufacturers on that?

Mr. BURNETT. As far as I know, no, there wasn't.

Mr. ROGERS. Did you question the manufacturer on that?

Mr. BURNETT. No.

Mr. ROGERS. Did you question the manufacturers on anything?

Mr. BURNETT. No, sir, we did not.

Mr. ROGERS. You mean you have not talked to the manufacturers at all?

Mr. BURNETT. No.

Mr. ROGERS. Why not?

Mr. AHART. Mr. Chairman, in the arrangements that we worked out with this subcommittee and the other subcommittees that signed the joint request to us, it was understood we would work with the Federal components that had responsibility for this program, we would not become involved directly in the manufacturers operations. The interest there was on the cost of the program, as opposed to the consent form or anything like that. We would leave the audit to HEW and then later go in, if necessary. In the context of those agreements there was really no need for us to talk to the manufacturers or get involved in their records or substantive discussions with them.

Mr. ROGERS. What about the delay in signing the contracts?

Mr. AHART. We have monitored the delay in the signing of the contracts. We have not directly involved ourselves in them. There were letter contracts that had been signed, last year, which would control the substance of the final contracts, subject to these things that needed to be ironed out.

Mr. ROGERS. As a matter of fact, isn't it true that one of the reasons the contracts hadn't been signed is that the cost figures had not been agreed upon?

Mr. AHART. My understanding is that the two principal things were the income tax status of the self-insurance funds which were provided under the contracts and the applicability of the cost accounting standards to those contracts. Those were the two factors that had the greatest impact on delay in the finalization.

With the exception of the Parke-Davis contract, which is still not signed, which is still open on the question of whether or not they will be reimbursed for the Shope vaccine which they manufactured, which, I think, amounts to $1.2 million. The contracting officer in this case has made a determination it will not be reim-

bursed. I think that determination went out last month and Parke-Davis has 30 days within which to respond to that proposal.

Mr. ROGERS. Well, in monitoring the contracts, it is my understanding you have not checked into costs.

Mr. AHART. That is correct, we have not.

Mr. ROGERS. Would it be a normal process to do so, though?

Mr. AHART. Our contract audit work is very selective. We obviously don't audit all contracts of the Federal Government. In this particular case, pursuant to the agreements we felt we had with this subcommittee and the others involved, we will await the HEW audit completion. We will take a look at what we feel the qualities of that audit are. If we feel it is necessary or someone feels it is necessary, then we would involve ourselves directly.

Mr. ROGERS. Now, I have some concern about that. Dr. Hyde, who was the staff man, is no longer with the subcommittee. I think it might be helpful if we could have a letter of understanding of what the GAO audit would be.

Mr. AHART. I am not sure we have that with us, I think——

Mr. ROGERS. No; I understand you may not have it.

Mr. AHART. I do think we have an exchange of letters with at least one or more of the subcommittees which lay out the substance of this understanding.

[See letter dated December 20, 1977, p. 28, this hearing.]

Mr. WAXMAN. Mr. Chairman, the subcommittee made a request to GAO for information about this program, but I also sent letters as a Member of Congress to GAO asking for an audit of the program. I was never informed by GAO that there was an understanding that you wouldn't do certain things and that understanding was with my own subcommittee.

Does GAO have an obligation to inform a Congressman that they are not going to pursue a matter even though a Congressman requested it?

Mr. AHART. Yes, we certainly do have that responsibility. I would be very much surprised if it hadn't been done in the case of your request. If it hasn't been done we certainly were deficient in that regard.

Our principal concern I think in this case had to be with the four subcommittees that jointly requested that we do the work and we worked out the basic relations with them. We did issue a separate report to you on the concerns you had over and above, perhaps to some extent duplicative of the subcommittee's interests. We issued that to you I think on June 27, the same date we issued our full report to the Congress in response to the requests of the subcommittees.

Mr. WAXMAN. I am being informed for the very first time you had an understanding with the subcommittee that I am a member of and I understood the chairman to ask you to furnish us a letter. Is your understanding all reduced to writing so it is very clear for a Congressman now to see what understanding his subcommittee had with GAO?

Mr. AHART. As I indicated to the chairman, I think there was an exchange of correspondence or letters back from us, which confirm the understandings we had reached. In negotiating the scope of our review with the people that we are speaking of, the four subcommittees, obviously we could not bring all four subcommittees into

the room and get them all to vote on that, but we did in our usual way deal with the principal staff members and reach agreements on what would or would not be done.

Mr. WAXMAN. So your understandings with the subcommittee are based on a written document exclusively or were there conversations?

Mr. AHART. There were conversations which in my recollection, and I could verify this, were reduced to a written document which we sent to the subcommittees so there would be no misunderstanding of the agreements reached.

Mr. WAXMAN. There were no copies ever sent to other Members of Congress who had made requests to GAO on their own behalf as Members of Congress.

Mr. AHART. I will be happy to check our records in your personal case, Mr. Waxman, to see what we did or did not tell you and what we did or did not send you and be glad to furnish to you copies of the correspondence with the subcommittee which lay out the charter, the scope we agreed upon with them.

Mr. WAXMAN. I can assure you when you send it to me, that will be the first time I will see them, and I also want to say for the record, what gives me additional reasons for concern was, that the staff person you were negotiating with, happened to be a very strong proponent of the swine flu program and the swine flu liability section of that program.

I feel a sense of frustration as a Member of Congress and a member of the subcommittee and as one of four interested enough to be here at a hearing on swine flu to have been treated the way I have been by the GAO.

I am also a member of the Government Operations which looks into the GAO for operation of Government and perhaps an inquiry into the GAO and swine flu ought to be required. I don't know where it ends, if I as a Member of Congress don't find out this information how are my constituents ever going to know? How are the American people going to know if we blunder with a program like this and can't explain what we did and why we did it and how we did it? Is there a cover up? I think that becomes a legitimate question.

Mr. AHART. Well, I can only assure you, Congressman Waxman, we tried to be as responsive to your interests and to the subcommittee's interests as we possibly could be. If we have failed to meet all of your interests, then I really can't——

The following letter with attachments was received for the record:]

98-930 O - 78 -- 3

UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

HUMAN RESOURCES
DIVISION

DEC 20 1977

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

Dear Mr. Chairman:

During hearings before your Subcommittee on September 16, 1977, you requested copies of all correspondence between our Office and the congressional committees requesting our study of the swine flu program. The specific correspondence requested concerned the scope of our study. Subsequent to those hearings, we met with your Subcommittee staff on September 21, 1977, to discuss the chronology of events and the content of discussions which led us to limit the scope of our evaluation of vaccine manufacturing costs. We also sent a letter to Congressman Waxman on September 21, 1977, concerning the same subject (see enclosure I).

In addition to the above actions, we sent for the hearings record, a copy of our February 18, 1977, letter to Congressman Moss (see enclosure II) which discussed reasons for the delayed study of vaccine manufacturing costs and our agreement with the requesting committees.

We trust that this information will assist the Subcommittee in finalizing its hearings of September 16, 1977, on the swine flu program.

Sincerely yours,

Morton C. Henig

Gregory J. Ahart
Director

Enclosures - 2

ENCLOSURE I

ENCLOSURE I

UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

SEP 21 1977

HUMAN RESOURCES DIVISION

B-164031(5)

The Honorable Henry A. Waxman
House of Representatives

Dear Mr. Waxman:

During the swine flu program hearings on September 16, 1977, you stated that you had not received responses to questions you had directed to us on several occasions.

As promised, we reviewed our files and found that on January 5 and February 4, 1977, you and Congressman Andrew Maguire wrote to Chairman Paul G. Rogers raising a number of issues regarding the swine flu program. Chairman Rogers, in turn, forwarded these letters to us and requested that we respond to him. In a March 8, 1977, letter to Chairman Rogers (see Enclosure I), we responded to all the questions raised in your two letters.

On February 24 and March 3, 1977, you corresponded directly to us requesting information concerning vaccines. We responded to you by letter dated June 27, 1977 (see Enclosure II).

You also questioned why we had not audited the drug companies' records to determine the actual costs to manufacture the monovalent and swine flu/A-Victoria vaccines. As I stated to you, we had agreed with Dr. Lee Hyde of the Subcommittee staff to assess the adequacy of the Department of Health, Education, and Welfare's efforts to assure that the drug companies were reimbursed for costs and profits permitted under the legislation authorizing the swine flu program. This agreement is the same as we had reached in earlier discussions with staff representing Chairmen Brooks, Dingell, Flowers, and Moss who jointly signed an August 30, 1976, letter asking us to review various aspects of the swi. flu program.

[Enclosures No. I and II to this letter not printed.]

B-164031(5)

Public Law 94-380 which authorized the swine flu program stipulates that contracts for procurement of the vaccine from a vaccine manufacturer shall be renegotiated to effect the elimination of manufacturer profit on monovalent vaccine and limit the manufacturer's profit on bivalent vaccine to an amount not exceeding a reasonable profit, pursuant to criteria determined by the Secretary of the Department of Health, Education, and Welfare.

As I stated in testimony, contracts for purchasing the vaccine were not signed until last month. One is still unsigned. The Department has initiated its efforts to audit the signed contracts and we plan to fulfill our agreement and evaluate the adequacy of the Department's efforts. We will provide you with the results of our assessment.

Sincerely yours,

Gregory J. Ahart

Gregory J. Ahart
Director

Enclosures - 2

ENCLOSURE II

ENCLOSURE II

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

B-164031(5)

February 18, 1977

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

Dear Mr. Chairman:

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

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

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

Examples of these costs are as follows:

--personnel costs of full-time Department of Health, Education, and Welfare (HEW) employees detailed from other programs,

--Department of Justice costs of litigation and settlement not recoverable from third parties for claims over $2,500 (HEW will settle claims for $2,500 or less),

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

a. direct appropriations for program costs (e.g., Pennsylvania appropriated $1.4 million and has expended over $1 million),

b. personnel costs of full-time employees detailed from other programs, and

c. additional costs for swine flu liability insurance,

--lost opportunity costs to other programs, and

--lost work from reactions.

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

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

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

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

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

Sincerely yours,

R.F. Keller

ACTING Comptroller General
of the United States

Mr. ROGERS. If I may continue my questioning.

You make certain recommendations. For instance, you say that to assure that vaccine is delivered on schedule in any future program, HEW must determine in a timely fashion how the vaccine will be formulated and packaged, and what the delivery specifications will be.

That was one of the biologic's problems I was talking about in getting everything set so we could move rapidly.

Now, you also state that if the manufacturers still cannot produce enough vaccine in time to meet the needs, alternative methods should be sought. By that do you mean that the Government should go in and produce vaccine?

Mr. AHART. Well, there are two possibilities there. We do have two firms other than these four which are licensed to manufacture vaccines that are not currently in production. Perhaps that would offer some capability.

There is always the option of going to Government operated production facilities, should that be considered necessary by the Congress or others.

Mr. ROGERS. But that is an alternative you feel should be considered?

Mr. AHART. We think it ought to be thought about if there are going to be any further programs of this nature where you are trying to immunize everyone in the country within a short period of time.

Mr. ROGERS. I noticed you also recommended that the Congress consider the effect which inadequate liability protection might have on State participation in future immunization programs.

You suggest that the Federal Government could, (1) assume total liability for the program, (2) assume liability for the participants or, (3) assume limited liability similar to that provided under the swine flu program.

As I recall, this problem came up because of a court suit, the Reyes case, where an eight-month-old child had been vaccinated and the court held that the child had not been given a proper warning by the nurse who had administered the vaccine. As a result the lawsuit held the manufacturer liable for not giving the warning.

Do you recall that as being approximately correct?

Mr. AHART. I am not personally familiar with that case.

Mr. OSWALD. That is correct.

Mr. ROGERS. I think that is correct.

Now, that was why the manufacturers said: "We will not do it without insurance." That is why insurance companies, as I understand it, said: "We won't insure on a mass scale unless the Government assumes the responsibility of warning."

I have seen statements which say that the money paid to the insurance companies will never be called upon to be paid out. What is the potential liability of the companies for the $8.65 million?

Mr. AHART. Well, as the legislation was worked out in the Congress, there was the decision made that the companies would at a minimum—and this is where it came out—be held liable for their own negligence in the matter. So this was a residual that is the only thing for which they could be held liable.

They felt they needed protection from insurance on that and got it.

Now, with the Government having undertaken the responsibility for informed consent and with the Government also having tested and approved each lot of vaccine that the manufacturers produced, before it was released to the public, it struck us at least that there is not too much potential to reach the manufacturers on a negligence charge under those kinds of circumstances.

Mr. ROGERS. You realize that it is not only a negligence charge which would be the basis for liability of the manufacturers? Are you under the impression it is only negligence?

Mr. AHART. Let me ask Mr. Burnett to comment. I thought that that is what the manufacturers residual liability was, the way the legislation was worked out; is that correct?

Mr. BURNETT. Yes, I believe so.

Mr. ROGERS. Only negligence, you feel?

Mr. BURNETT. Are you speaking of breach of warranty?

Mr. ROGERS. Sure.

Mr. BURNETT. Yes, as the second part.

I believe that comes down to negligence also.

Mr. ROGERS. Any obligation or responsibility in connection with the program includes all actions in connection with the manufacture and distribution of the vaccine other than the actions involving a duty specifically assumed by the United States under the program.

What are the duties specifically assumed by the United States; to warn?

Mr. AHART. To warn; yes.

Mr. ROGERS. What else?

Mr. AHART. Distribute the vaccine.

Mr. ROGERS. Well, the manufacturers also distributed the vaccine.

Mr. AHART. To whom? The manufacturers distributed the vaccine to HEW.

Mr. ROGERS. I understand. Also if a specific lot just happened to be bad.

Mr. BURNETT. Yes.

Mr. ROGERS. If there is anything wrong with a specific lot of vaccine that is the responsibility of the manufacturer?

Mr. BURNETT. Mitigated perhaps, and we don't have any feel for that, it will just be up to the courts to decide, but mitigated perhaps by the fact that the Bureau of Biologics tested every batch of the vaccine before it was released.

Mr. ROGERS. Well, I understand that.

But if it is the product liability there——

Mr. AHART. There would be product liability. Whether or not in a court case it would be found that that was attributable solely to the company's action and hold them solely accountable, we can't speculate on that.

Mr. ROGERS. As a matter of fact, then, we are not limited just to negligence in going against insurance companies for product liability.

Mr. BURNETT. Yes.

Mr. ROGERS. I think you ought to look at that again.

Now, what coverages are the manufacturers getting for the insurance premium? Is it $8 million, or is the total responsibility of the insurance company up to $25 million or more?

Mr. AHART. I think the total coverage for the $8.65 million is about $220 million.

Mr. ROGERS. So they have a potential liability still of $220 million?

Mr. AHART. That is correct.

Mr. ROGERS. Is that still subject to liability for all of the claims filed within the time period given by the statute of limitations?

Mr. AHART. It will be subject to, first of all, all the claims that are filed against the Government and then beyond that whatever portion of those claims the Government feels it could make a case of liability on the part of the manufacturer and go against the manufacturer for reimbursement?

Mr. ROGERS. Yes.

Mr. AHART. Then, if that should absorb the total $2.5 million of each firm's self-insurance fund, then as I understand it the insurance coverage provided by the insurance companies could be reached.

Mr. ROGERS. So, perhaps it is premature to say as yet that there will be no call on that fund; in fact there may be a call up to $220 million?

Mr. AHART. That is correct. I think we put it in our statement this way, and I will repeat it, "may result in profit of nearly the entire——"

Mr. ROGERS. I would agree.

Mr. AHART. There is that possibility.

Mr. ROGERS. But also there may be a liability up to as much as $220 million.

Mr. AHART. That is the total coverage, yes sir.

Mr. ROGERS. I would hope that the General Accounting Office would continue to monitor the program, and we will make an official request that this be done. I agree with the gentleman from California, that I think you should discuss the program with all participants. Did you have discussions with insurance companies at all?

Mr. AHART. Mr. Burnett.

Mr. BURNETT. Yes, with representatives of the insurance industry.

Mr. ROGERS. You have made inquiry of them?

Mr. BURNETT. Yes, sir.

Mr. ROGERS. Are there any participants you have not visited with?

Mr. BURNETT. Beyond the manufacturers? No, we have not talked to manufacturers.

Mr. ROGERS. The manufacturers were really the only ones you did not contact?

Mr. AHART. That is correct.

Mr. ROGERS. I would hope that you would do that in the followup audit.

Thank you so much for your presence here. We are grateful.

Mr. Walgren, did you have any questions?

Mr. WALGREN. I just wondered, I don't know whether these should be addressed to GAO, how much unused vaccine is presently existent and in whose hands?

Mr. AHART. Let me see if we have that information. Mr. Flowers, do we know how much vaccine is yet unused?

Mr. FLOWERS. They produced 157 million and have administered about 45 million, so out of the total 157 million produced——

Mr. BURNETT. About 110 million left, and as we understand it, there is some still with the States and HEW has possession of some.

Mr. WALGREN. So the States have some, HEW has some, and do the manufacturers still have any?

Mr. BURNETT. That, I couldn't tell you.

Mr. ROGERS. I expect HEW can probably get into this for us.

Mr. WALGREN. OK, thank you, I think they would probably know better.

Mr. ROGERS. Thank you for your presence today. You have been most helpful and we will formalize a request for continued investigations.

Thank you.

Our next witnesses will be the Department of Health, Education, and Welfare, Dr. J. Donald Millar, Director of the Bureau of State Services, Center for Disease Control, accompanied by Dr. Harry M. Meyer, Jr., Director of the Bureau of Biologics, Food, and Drug, and also by Dr. William Jordan, National Institute of Allergy and Infectious Diseases. We welcome you gentlemen to the committee.

Your statements will be made a part of the record in full. Before you begin, I might say that I wrote to the Secretary reminding him of the requirement for the liability alternative study which was due on August 12. We did get a response yesterday; a first draft of the report outlining some options with no recommended procedures or no formal cost recommendations. It is my understanding, from the letter, that costs studies are to be completed by October 15.

Dr. Millar.

STATEMENT OF J. DONALD MILLAR, M.D., DIRECTOR, BUREAU OF STATE SERVICES, CENTER FOR DISEASE CONTROL, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, ACCOMPANIED BY WINDELL BRADFORD, ADMINISTRATIVE ASSISTANT TO DR. MILLAR; HARRY M. MEYER, JR., M.D., DIRECTOR, BUREAU OF BIOLOGICS, FOOD AND DRUG ADMINISTRATION; AND WILLIAM JORDAN, M.D., NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Dr. MILLAR. Thank you, Mr. Chairman. I also have with me on my left, Mr. Windell Bradford of my administrative staff.

Mr. ROGERS. We welcome you.

Dr. MILLAR. I am grateful for this opportunity to appear before you to review our experiences in trying for the first time in history to prevent the widespread death and disability from a flu pandemic. I hope this review can be constructively used to address the obvious problems which confront any future attempt at a major national effort in preventive medicine.

Mr. Chairman, you have very aptly designated and described these problems and I won't repeat them. I think that our challenge is to address these problems and resolve them in advance, such that national health emergencies in the future can be met head on and in time.

Much attention has been given to the controversial aspects of the swine flu program and I would like at this point to cite some of what I believe to be the undersung positive accomplishments of the program.

The first is the immunity provided. Under the circumstances, a remarkably significant proportion of Americans were immunized. Among those designated as having a high risk of dying from flu, over 40 percent received the vaccine protecting against both swine flu and A-Victoria flu. That is more than twice the coverage level ever previously achieved among this most important group of individuals.

In the general population above the age of 18, 32 percent were immunized. This is several times higher than was accomplished in 1957 and 1968, the only previously attempts at immunization in the face of a pandemic.

You will recall that in both of those instances immunizations had hardly begun when the pandemic stormed across the country and those efforts had very little effect on the outcome.

A second very positive achievement is the remarkable performance of State and local health departments. Almost without exception, they proved capable of a rapid Herculean effort in response to national needs. It has been popular in recent years to impugn the ability of health departments to move rapidly and effectively. However, in spite of delays in the availability of vaccine, complicated immunization schedules, specific shortage of some types of vaccine, and continuous media emphasis on these and other problems, the health departments established programs which immunized more people in 2½ months than in any previous immunization program in this country's history.

Third, a major milestone was achieved by requiring the nationwide use of information-consent procedures. There seems now to be widespread acceptance of the notion that individuals presenting themselves or their children for immunization should understand both the risks and the benefits of the procedure.

Other positive aspects of the program include the manufacturers' record production of 150 million doses of flu vaccine. Prior to release of the vaccine, these were subjected to the largest field trials in the history of flu vaccines. A system was established for the first time to monitor illnesses following immunization. There was a five-fold increase in surveillance for influenza disease and the implementation of the program directly involved an impressively wide array of American institutions, public, private, and voluntary.

As the historical evidence emerges, I feel that the national influenza program will prove to have been an appropriate response to the facts at hand at the time the decisions were made, and in the words of the GAO report, "an unprecedented venture in preventive medicine."

There were numerous well-publicized legal, logistical and administrative problems in implementing the swine flu immunization program requiring special solutions.

Some problems were brought to this committee as they emerged. There are two developments which may be viewed as major negative outcomes of the program. Both have already been referred to.

The unexpected discovery of an apparent association between influenza immunization and the Guillain-Barre syndrome. This syndrome is an uncommon condition of unknown cause characterized by transient "ascending paralysis." Although the cause of the

snydrome has never been known, two-thirds of the persons with this condition report an illness or other health event in weeks preceding onset. At least 150 different such antecedent conditions have been listed.

For the first time we observed a small but finite statistical association between influenza immunization and this syndrome.

Following the report of five cases in two States, in November 1976, an intensive investigation was initiated. Neurologists in each of the 50 States were asked to identify all cases of the syndrome that they saw during the period October 1976 through January 1977.

As Dr. Carter has already noted, a total of 1,053 cases of the Guillain-Barre syndrome were found. Of these, 515 were in persons who had received swine flu vaccine and 505 were in persons who had not received flu vaccine.

Analysis revealed that recipients of swine flu vaccines experienced the syndrome at a rate several times higher than ordinarily expected. It appears that one case of the Guillain-Barre syndrom above the expected incidence was observed for each 100,000 flu vaccinations.

Because so little was known previously about the frequency of this syndrome, an interpretation of these findings is very difficult. One thing, however, is clear. Had we not established monitoring systems and had not over 40 million doses of vaccine been given in so short a time, an apparent association of this low order of magnitude would not have been discovered.

Even this appartent association of flu vaccine with the Guillain-Barre syndrom, unexpected and undesirable though it is, has opened important avenues of research which may help unravel this mysterious syndrome which has frustrated physicians for over 50 years.

The second major negative outcome of the program is the series of claims already referred to due to illnesses following vaccination. Of these, many relate to the Guillain-Barre syndrome.

Because of the need for swift action in initiating the program, the Federal Government assumed, via Public Law 94-380, unprecedented responsibility for liability for illness following vaccination.

Unquestionably, the Federal Government will thereby be involved in the long process of reviewing, litigating, and settling these claims.

It is my understanding that the Justice Department will appear before you today to discuss this current situation.

I would like to turn now to the costs of the program. Congress appropriated the sum of $135 million to carry out the program. Approximately $102.6 million has been obligated. Of the balance, $12 million was reappropriated by Congress for use in other public health programs. The balance available from the original appropriation is due to the amount and the provisional unit cost of the vaccines, both of which are less than originally estimated. While the final cost of vaccine and storage has not been determined, we anticipate that sufficient funds will be available.

Only with respect to the claims that may or may not be allowed in the future is there any possibility of significant cost to the Government beyond what was budgeted.

Please recall that at the outset of the program, serious complications caused by influenza immunization were not known, hence major financial claims were not expected. The combination of the prodigiously rapid output of immunizations plus a system for monitoring illness after vaccination brought to light an apparent low risk of the Guillain-Barre syndrome. This apparent statistical association has been a key factor responsible for many of the claims filed.

There are four aspects of the swine flu program I feel have distinct ramifications for future activities. The first is the decision-making process. The GAO has examined the process in 1976 and makes a concrete recommendation that formal points be preestablished at which the basic policy decision is reevaluated in light of new information or lack of it. Such reevaluations in effect were made for the national influenza immunization program through a series of congressional hearings and almost daily they were made by professionals trying to operate the program in the face of seemingly unending problems.

We agree formalizing a system of preplanned periodic policy evaluation deserves serious consideration.

Second are issues of compensation and liability.

The most pressing questions in the wake of the program are those which provoked Public Law 94-380; that is, who is liable if someone is injured by immunization, and what recourse does that person have for compensation for the injury?

Congress made it abundantly clear that Public Law 94-380 was not to be considered as a precedent for the future. Indeed, it directed an examination of alternatives for a careful permanent solution. HEW is preparing a document to be presented by October 15, as you have already heard.

At this point I would like to note the three policy objectives which must be pursued in making the necessary changes.

First of all, we must assure that vaccines are available to protect the citizens who need and want the protection. The refusal of the manufacturers to provide new vaccine without assurances that their liability be limited was the prime impetus for last year's law. Health care professionals, if they are to continue to immunize people, also must be assured that if they administer the vaccines carefully they will not be held liable for injuries resulting from immunization.

Since immunization confers direct benefits to society and not exclusively to the individuals, we must develop means of compensating those rare persons who are injured by the vaccine.

Finally, no medication is free of some inherent risk. We must expand our efforts to define these through more systematic surveillances of illness following vaccination via methods such as those introduced in the swine influenza immunization program.

Effective solutions on a long-term basis to these problems do not lie in time consuming, costly, and often inequitable adversary proceedings in the courts. A societal responsibility exists to provide a fair settlement ot persons injured without the necessity for litigation.

I would like to turn now to the matter of informed consent. Irrespective of the liability and compensation issues, persons re-

ceiving vaccine should receive meaningful information on the benefits and risks of immunization. To do this is not simple. Complex medical information must be presented in language understandable py persons without medical backgrounds.

Furthermore, a balanced picture of both risks and benefits, including the risk of not being immunized, is required.

At the present time these needs are compounded by a third, the need to provide this information in a way which reduces a litigant's ability to prove in court that he was not adequately warned about the risks of immunization—it goes almost without saying that few people sue if after failing to be immunized they are subsequently ill.

Concurrent review of the program as done by the GAO was helpful and their report was carefully considered and generally sound, in our opinion.

One of the weaknesses of the report, in my opinion, is that it porceeds almost exclusively from the position that the function of the information consent process is to defend the Government in court. They question the adequacy of our procedures in this respect.

However, I believe they have underemphasized the role of the procedure in providing information on which a reasonable person could make a reasonable choice. We must regain a balanced perspective on this, otherwise the construction of statements which are adequate documents for legal defense will fail completely to provide a lucid understanding of the information needed by a person to be immunized or a parent of such a person.

Fourth, an outcome of significant ramifications for the future is the fact that an epidemic did not occur. We knew that this outcome was possible and said so repeatedly.

In the past, all discoveries of major variations of flu viruses were made in conjunction with pandemics. We now have one example in which a major variant appeared that produced one human epidemic at Fort Dix and did not spread further. Unfortunately, that knowledge doesn't help much.

However, we do know that influenza pandemics take a large toll of lives and huge financial outlays for medical care. We also know that another pandemic of some sort is inevitable. It is too early yet to presume that it will not be swine flu. Therefore, we are taking the necessary steps to maintain the existing supplies of swine flu vaccine for future use if needed.

In closing, Mr. Chairman, I concur in the importance of pondering our recent experience—which in many ways was arduous and frustrating—especially in the context of previous responses to threats of influenza pandemics.

In 1957 and again in 1968 the country moved cautiously but the influenza virus did not. In 1976, the country moved quickly but the influenza virus did not. Some would say that the virus is ahead three touchdowns to none. Nevertheless, faced with a similar challenge again, I hope we will not shirk the necessary prudent decisive action. For if we wait until all questions are answered and all implications are clear, we will always find ourselves too late with too little in the fight against influenza.

Thank you, Mr. Chairman. I will be happy to try to respond to any questions.

[Testimony resumes on p. 65.]

[Dr. Millar's prepared statement and attachments follow:]

STATEMENT OF J. DONALD MILLAR, M.D., DIRECTOR, BUREAU OF STATE SERVICES, CENTER FOR DISEASE CONTROL, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Introduction and Background.

Mr. Chairman and members of the Committee, it is a pleasure to appear before you to review our experience in attempting, for the first time in history, to prevent the possibility of widespread death and disability from a potential influenza pandemic. It was this Committee which, on March 31, 1976, heard the evidence of the emergence of a new strain of swine influenza-like virus (labeled A/New Jersey/76) and our concerns that this strain might produce an influenza pandemic. It was this Committee which helped to lead efforts throughout the summer months to resolve the impasse of liability protection for influenza vaccine manufacturers and health workers involved in the program. It was also this Committee which investigated our initial difficulties in providing an adequate supply of influenza vaccine to the States in hearings last September. It, therefore, seems appropriate to me that in this forum we begin a review of the past 18 months' arduous and in many ways frustrating experience. I hope this review can be constructively used to address issues which will confront any future attempt at a major national effort in preventive medicine. These issues include liability and the need for compensation for injuries resulting from vaccination, informed consent, public information and research, and their complicated interactions in the rapidly changing atmosphere of a potential epidemic. The challenge is to address these issues and resolve them in advance in such a way that national health emergencies can be met headon and in time.

In Act III, Scene 2, of Shakespeare's Julius Caesar, Mark Anthony eulogizes Caesar saying, "The evil that men do lives after them, the

good is oft interred with their bones!" One concludes that at the present moment those aspects of the National Influenza Immunization Program perceived as negative are still uppermost in the minds of the public. The successes accomplished by the program, if not "interred with the bones " are at least attracting far less attention than its problems.

Major Accomplishments.

Because of this, I would like to now cite some of the undersung positive accomplishments of the National Influenza Immunization Program of 1976.

1. The first is the immunity provided to our people, especially those at "high risk" of dying from influenza. In the light of the problems, delays, and controversies swirling around this program from its inception, a remarkably large proportion of Americans were immunized. Among the group of people considered to be at "high risk" of death and disability from influenza, approximately 40 percent received the bivalent vaccine providing protection against swine flu and A/Victoria flu (Fig. I). This is about twice the coverage level ever previously achieved among this group of citizens. Furthermore, the protective effect of the bivalent vaccine against epidemics of A/Victoria influenza was documented in an outbreak in Florida; the vaccine was shown to be 83 percent effective in preventing potentially fatal A/Victoria influenza among

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residents of a nursing home there. Among the total population, above the age of 18, 32 percent were immunized. This is several times higher than was accomplished in 1968, the only previous time when influenza immunizations were provided on a large scale. You will recall that in that instance immunizations had hardly begun when the full force of the Hong Kong influenza epidemic erupted throughout the country in October.

2. Second is the remarkable responsiveness of State and local health departments in implementing the national program. Perhaps the most encouraging aspect of the 1976 program was the performance of State and local health agencies throughout the country. They proved again that they are capable of a rapid, appropriate response, and massive efforts in the face of a clear national need. It has been popular in recent years in some quarters to criticize State and local health departments and to impugn their ability to move rapidly and effectively. However, despite delays in the availability of influenza vaccine, despite the complexity of the vaccine's immunologic behavior and hence the need for various complicated immunization recommendations, despite a shortage of the only vaccine formulation suitable for young people, and despite a continuous media barrage emphasizing these and other problems, the health departments established

programs which achieved an unprecedented success. More people were immunized in 2 1/2 months in the National Influenza Immunization Program than in any previous immunization program in this country's history, and that achievement is directly due to the efforts of State and local health departments (Fig. II).

3. Third, a major historic milestone in the practice of community preventive medicine was reached by implementing the principles of informed consent on a nationwide basis. This was achieved by requiring the use of information-consent forms and procedures for all swine influenza immunizations except those administered by private physicians to their individual private patients. Even in these settings, physicians frequently elected to use the informed consent procedure, and thereby to be afforded the liability protection provided by Public Law 94-380. I believe the principle of informed consent will remain an integral element in community immunization programs even though the legal significance of the documents may change. There is widespread acceptance of the notion that individuals presenting themselves or their children for immunization should understand the risks as well as the benefits of the procedure. Effective information documents must be developed to promote this growing understanding. This is much easier said than done, as I shall subsequently discuss.

4. Many other positive aspects of the program of 1976 must be recognized. The vaccine manufacturers produced 150 million doses of influenza vaccine, more than seven times their usual production. Before being offered to the public, the influenza vaccines of 1976 were subjected to the largest field trials in the history of influenza vaccines. As part of the National Influenza Immunization Program, a system was established for the first time to monitor illnesses which occurred following immunization, a mechanism which was sufficiently sensitive to identify a condition of very low incidence. The existence of the national program produced a profound increase in surveillance for influenza disease and finally, the implementation of the program directly involved an impressive range of American institutions, public, private, and voluntary.

Significant reviews and evaluations of the 1976 program will continue to provide productive interpretations of the program. You have discussed the intensive and concurrent review performed by the Government Accounting Office (GAO). As the historical evidence emerges, I feel that the National Influenza Immunization Program will prove to have been a highly significant and appropriate effort or in the words of the GAO Report, "an unprecedented venture in preventive medicine."

Major Problems.

There were numerous well publicized legal, logistical and contractual problems in implementing the National Influenza Immunization Program.

Some of these were brought to this Committee as they emerged as obstacles to timely completion of the program.

Special criteria and procedures for determining costs for vaccine contracts were required because, under Public Law 94-380,monovalent swine influenza vaccine was to be provided to the Government at cost, and a reasonable profit was permitted on the A/Victoria/75 component of the bivalent vaccine. Like so many other aspects of this program, we and the manufacturers were faced with uncommon situations which required special solutions, and these took time. It should be emphasized, however, that negotiation of these issues did not affect the supply of vaccine, once the basic problem of liability protection was resolved in August 1976. Letter contracts were signed in September 1976 with all four manufacturers, and production and distribution of vaccine proceeded. The signing of definitized contracts to replace the letter contracts was delayed by a combination of reasons, one being a ruling by the Internal Revenue Service regarding the taxability of the manufacturers' Self Insurance Retention Fund. The vaccine manufacturers' accounting mechanisms were not designed to meet the requirements of the Government's cost accounting standards. Therefore, a waiver was requested. Once the waiver was granted, three finalized contracts were signed. The fourth contract is still being delayed because of a dispute about who pays for the production of several lots of vaccine made from the wrong seed virus.

There are two major developments which must be viewed as serious negative outcomes of the program. In the long run, however, even these may result

in significant benefits in clearly defining problems of vaccination campaigns or in producing understanding of previously mysterious disease processes.

1. Guillain-Barre Syndrome and other illnesses following vaccination.

The most dramatic unexpected problem which arose during the program was the discovery of an apparent statistical association between influenza immunization and the Guillain-Barre Syndrome (GBS). The Guillain-Barre Syndrome is an uncommon condition of unknown cause characterized by a transient "ascending paralysis," i.e., the paralysis begins in the legs and later involves the trunk, the arms, and the neck. For most people this condition is transient. However, it is fatal in 5 percent and produces rare residual paralysis in another 5 percent. Although the cause of GBS has never been known, two-thirds of persons with this condition report some health event, disease or accident in the weeks preceding onset; at least 150 different such "antecedent conditions" have been described. To the point here, however, is the fact that we identified an apparent statistical association between influenza immunization and the Guillain-Barre Syndrome. While a specific causal link between immunization and GBS has not been defined, the epidemiologic and statistical associations are significant.

As part of the National Influenza Immunization Program, we established at the outset a system to encourage individuals

and physicians to report any health problems occurring after immunization. These reports were made to local and State health authorities and from them to us. In mid-November we received a report from the State of Minnesota of a person who developed the Guillain-Barre Syndrome following influenza immunization. An investigation was carried out by health officials in Minnesota to identify all cases of the syndrome which had occurred there in recent months. No evidence for an association with immunization was found. On December 2, an Alabama physician reported three cases of the Guillain-Barre Syndrome, all among persons living in close proximity to each other. An investigation was initiated in Alabama and the investigation in Minnesota was reopened; a week later another inquiry was initiated in New Jersey when a case was reported there. At about the same time we asked eight other States to initiate similar investigations although no cases had been reported at that time in those States. By December 16, we had considerable data from four of the States; and in consultation with a number of outside experts, we decided to recommend suspension of the influenza immunizations until a nationwide investigation could be completed.

An intensive nationwide epidemiological investigation was initiated to determine if there was a significant association between influenza immunizations and the Guillain-Barre Syndrome.

The primary phase of this investigation consisted of a survey of neurologists in each of the 50 States to identify all cases of the Guillain-Barre Syndrome they had seen during the period October 1976 through January 1977. A second phase of the investigation, currently underway, includes the intricate study of immunological factors which may be associated with the disorder.

The first phase of the investigation, which began in mid-December, resulted in reports from all 50 States, the District of Columbia, and Puerto Rico. These reports yielded a total of 1,104 cases of the Guillain-Barre Syndrome with onsets during the surveillance period. Five hundred and thirty-five cases occurred in persons who had recently received swine influenza (A/New Jersey/76) vaccine, either by itself or in combination with A/Victoria/75 vaccine; and five hundred and thirty one cases occurred in persons who had received no influenza vaccines. Fifteen additional cases occurred in persons who had received other flu vaccines. The vaccination status in 8 cases remains unknown. Analysis of these data (Figs. III, IV, V) revealed that persons who received swine influenza vaccines experienced the Guillain-Barre Syndrome during the 10 weeks following immunization at a rate about 10 times higher than ordinarily expected (i.e., about one case per 1,000,000 persons per month). Viewed in another way, one extra case of the Guillain-Barre Syndrome above the expected incidence was observed for each 100,000 influenza immunizations. Because so

little was known previously about the frequency of the GBS, a clear interpretation of these findings is very difficult. One thing is clear, however; if we had not established a monitoring system and if 40 million doses of vaccine had not been given in so short a time, an apparent association of this low order of magnitude would not have been discovered.

The second phase of the investigation includes a detailed immunologic study of randomly selected patients in specific geographic locations. The study involves a sample of 150 previously identified GBS patients, all over 15 years of age, who are being compared with persons with similar characteristics who did not develop the condition. Immunologic tests will be performed to detect any perceptible differences. The epidemiological observations will also be extended by use of a more detailed interview concerning specific information on allergy, previous neurologic disorders, other immunizations, injections, surgery, or acute illnesses immediately prior to the onset of the Guillain-Barre Syndrome and to other questions suggested by the available surveillance information.

Thus, even the apparent association of influenza vaccine with the Guillain-Barre Syndrome, unexpected and undesirable though it is, has opened important avenues of research on the basic causes of the Guillain-Barre Syndrome. These may help in unraveling the nature of this mysterious syndrome, which has frustrated physicians for over 50 years.

In addition to the reports of the Guillain-Barre Syndrome, we received reports on other instances of health problems which occurred subsequent to immunization. With the exception of the expected occurrence of fevers, muscle aches, tenderness at the site of the injection, and one non-fatal case of an anaphylactic reaction, there is no evidence that any other conditions were associated, except temporally, with immunization. In no cases did any of these other health events occur at rates exceeding normal expectations in the population.

2. Liability and Claims.

The second major negative outcome of the program is a series of claims due to illnesses or deaths following vaccination. Many of these are associated with the occurrence of unexpected cases of the Guillain-Barre Syndrome. Because of the pressing need for swift action in initiating the program, the Federal Government assumed, via Public Law 94-380, unprecendented responsibility for liability in the event of injury or death due to immunization. Unquestionably, by assuming primary responsibility for claims filed as a result of the program, the Federal Government will be involved in a long and costly process of reviewing, litigating, and settling these claims. It is highly unlikely, however, that the costs will approach the billion dollar figure, which has been widely quoted. Since the Justice Department will be appearing before you today, I am sure they will provide a summary of the current situation related to claims.

Summary of Current Costs of the National Influenza Immunization Program.

I would like to briefly summarize the costs of the program to date. Of the $135,064,000 appropriated by Congress to carry out the National Influenza Immunization Program, approximately $101 million have been obligated. In addition, $12 million have been reappropriated by Congress for use in other public health programs. The balances available from the original appropriation occurred primarily because both the amount and provisional unit cost of the vaccines were less than originally estimated. While the final cost of vaccine and storage have not been determined, we anticipate that sufficient funds will be available.

Only with respect to claims that may or may not be allowed in the future, is there any possibility of significant cost to the Government beyond what was budgeted for the program. It should be remembered that at the start of the immunization program, serious complications were not known to be associated with influenza immunization. Hence, major financial claims logically were not expected. As noted, earlier, the combination of a system for monitoring illnesses after vaccination and a prodigious output of immunizations in a short time was required to bring the low risk of GBS to light. The discovery of this apparent statistical association during the campaign has been primarily responsible for many of the claims filed.

The Future.

I would like now to turn to four aspects of the National Influenza Immunization Program which have distinct implications for future

programs against potential epidemics.

1. The Decision-making Process.

Given the imprecise nature of our understanding of influenza, what lessons are there for us in making decisions in the future? HEW Secretary Joseph Califano is publicly committed to looking very carefully at this question. The GAO has examined the decision process in 1976 and makes one concrete recommendation: That formal decision points be preestablished at which the basic policy decision is to be periodically reevaluated in light of new information (or lack of it). Such reevaluations were made in effect for the National Influenza Immunization Program through a series of Congressional hearings; and also they were made almost daily by CDC professionals trying to operate the program in view of the limited occurance of influenza, particularly swine influenza, in the early fall and the seemingly unending implementation problems. Nonetheless, serious consideration should be given to formalizing a system of preplanned policy evaluation as suggested by GAO.

2. Compensation and Liability.

The most pressing questions requiring resolution in the wake of the National Influenza Immunization Program are those which provoked the special legislation in August of 1976; i.e., who is liable if someone is injured by immunization and what recourse does a person have to obtain compensation for that injury?

Public Law 94-380 established a program to cope with these issues in the particular context of the threat presented by swine flu, but at the same time made it clear that examination should be made of alternative approaches so that a more carefully considered permanent solution to these questions could be found. The law calls upon the Department of Health, Education, and Welfare to report to Congress on alternative methods of allocating liability and compensating the injured. Since that time these issues have received careful attention by individuals both inside and outside the Government. An interim working draft has been submitted to Congress and a final document will be produced by October 15.

I will not attempt to trace the background which led up to the legal situation that now faces us, nor to summarize the various alternatives which are potentially available. Instead, I would like to draw your attention to certain policy objectives which must be pursued if changes in the existing system are to be made.

First, and most importantly, it must be our objective to insure that sufficient vaccines continue to be manufactured, distributed, and administered in the face of increased concern by manufacturers over their liability for vaccine-related side effects. The manufacturers' refusal to supply vaccines without assurance that their liability would be limited was the primary impetus for last years' legislation protecting them against losses in the swine flu program. While this issue is currently being adequately addressed in the routine immunization programs by the Federal Government's assumption of the duty to warn vaccinees about risks and benefits, it is entirely possible that the liability issue

will surface again in the future as an impediment to vaccine supply. In addition, health care professionals and administering agents who also fear increased liability must be assured that if they perform their tasks carefully, they will not be held responsible for injuries resulting from immunization programs.

Secondly, since individuals who participate in immunization programs benefit not only themselves, but also the community at large, we must develop some means of assuring compensation for those who suffer vaccine-related injuries and have no other means of recovery. The Department is currently examining the structure and cost of a number of compensation plans, and these will be in our October 15 report.

Finally since no medication or biological is free from some degree of inherent risk, we must continue and expand our efforts to identify the inherent risks associated with vaccination and to develop ways to anticipate and prevent them in order to minimize the number of persons injured. Although CDC gathers a substantial amount of data concerning immunization programs, these efforts could be broadened and made more systematic. States administering the vaccine under Federal influenza immunization grants were asked to report to CDC illnesses and injuries occurring after vaccination. Modifications of this system are being developed to encompass all immunization programs.

Because of the difficulty in gathering data concerning the costs of various alternatives for addressing the liability and compensation issues, and because the Office of Management and Budget would require cost information

on any recommendations involving an additional expenditure of Department funds, the Department is unable at this time to recommend a specific solution for these problems. We intend to present the alternatives in detail in our October 15 report and to outline available cost estimates. We hope that the data available then will be sufficiently reliable to allow us to recommend a particular approach to this problem.

3. Benefit-Risk Information

Irrespective of solutions to the compensation and liability issues, persons receiving vaccines must receive meaningful information as to the benefits and risks of immunization. A method of accomplishing this is by no means simple or straight forward. One aspect of the problem is the need to distill very complex medical information into language understandable by a wide array of persons without medical backgrounds. Another aspect is the need to present a balanced picture of both risks and benefits, including the risks of not being immunized. At the present time, these two needs are compounded by a third: The need to provide this information in a way which minimizes a litigant's ability to prove in court that he or she was not adequately warned about the risks of immunization. It goes almost without saying that few people sue, if, after failing to be immunized, they subsequently become ill. I do not want to minimize the need to avoid costly financial losses associated with immunization. However, I believe our primary responsibility to the public is to conduct preventive health programs free of an overly defensive posture because of fear of lawsuits.

One of the difficulties with the GAO report is the narrow-gauge discussion of our implementation of informed consent requirements. They proceed almost exclusively from the position that the function of the information-consent process is to defend the Government in court. Their criticisms derive from probes at the adequacy of our procedure in respect to this one function while under emphasizing adequacy in providing information on which a reasonable person can make a reasonable choice. We must regain a balanced perspective on the use of informed consent documents. Otherwise, the construction of statements to serve as adequate documents for legal defense will fail completely to provide a lucid understandable summary of the information needed by the parent or individual to be immunized. We have recently carried out field tests of information and consent procedures for other vaccines. Results are being tabulated and analyzed. I regret to report that we have not yet found totally satisfactory ways to adequately serve these conflicting needs.

4. Understanding the epidemiology of influenza.

An outcome of significant ramifications for the future is the fact that we carried out a most extensive preventive health program against an epidemic which did not occur. We knew full well that this outcome was possible and said so repeatedly. Our understanding of the behavior of influenza virus was far from complete when the decision was made. The continued absence of epidemic swine flu unfortunately has contributed very little to our ability to predict the behavior of influenza. In the past all discoveries of major variations of influenza viruses were made in association with pandemics; we now have one example in which a major

new variant of influenza appeared, produced one sizeable human outbreak at Fort Dix, and did not spread in the ensuing influenza season. That knowledge doesn't help us a great deal.

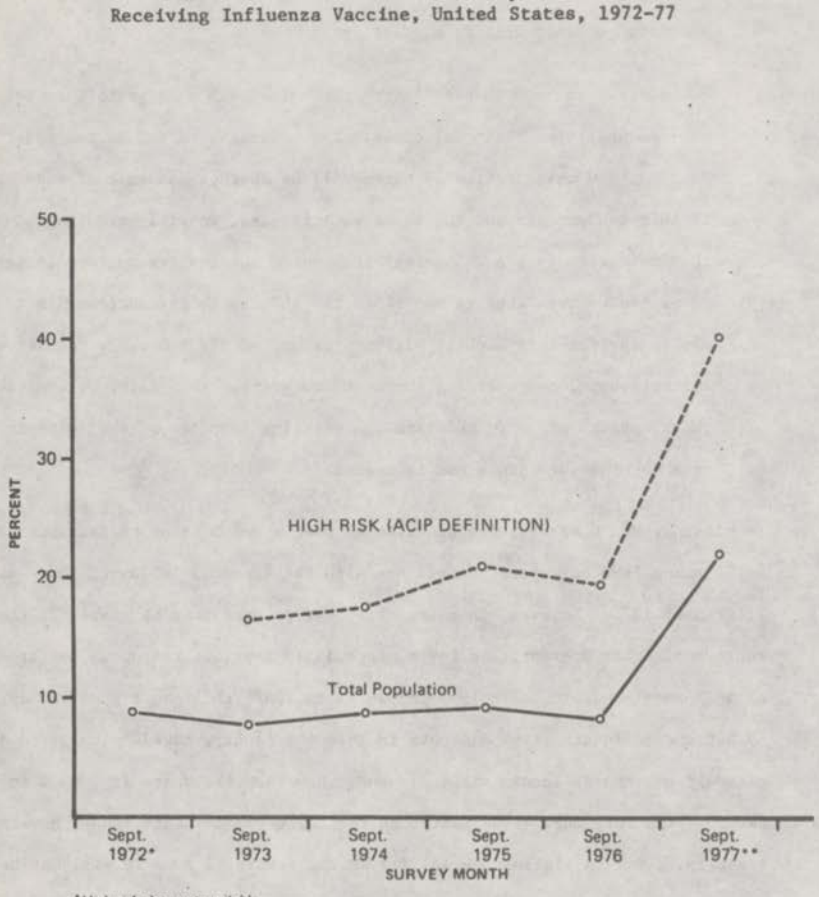
However, we do know that influenza pandemics take a large toll in loss of life and large financial outlays for medical care and income loss. We also know that inevitably there will be another pandemic of some sort. If this pandemic is not due to swine influenza, we will have learned that not every type A influenza virus which mutates its surface antigens is explosive even when it has shown the ability to spread from man to man in environments such as military bases. It is too early to make any such presumptions regarding the next few years. Therefore, we are taking the necessary steps to maintain the existing supplies of the swine influenza vaccine for future use if needed.

In closing, Mr. Chairman, I would like to note my commitment to the importance of learning from our recent experience with the National Influenza Immunization Program of 1976. However, in doing this, the program must be viewed in the context of other preventive efforts, especially previous responses to threats of influenza pandemics. In 1957 and again in 1968, this country moved cautiously but the influenza virus did not; in 1976 the country moved quickly and decisively but the influenza virus did not. Some say the score is 3 to 0 in favor of the influenza virus, although for quite different reasons. Nevertheless, faced with a similar possibility in the future, I hope we will not hesitate to take necessary prudent, decisive, defensive action. If we wait until all questions are answered and all implications are clear, we will always find ourselves too late with too little in the fight against influenza.

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Figure I

Percent of Persons with History of
Receiving Influenza Vaccine, United States, 1972-77



*High risk data not available
**Projected

FIGURE II

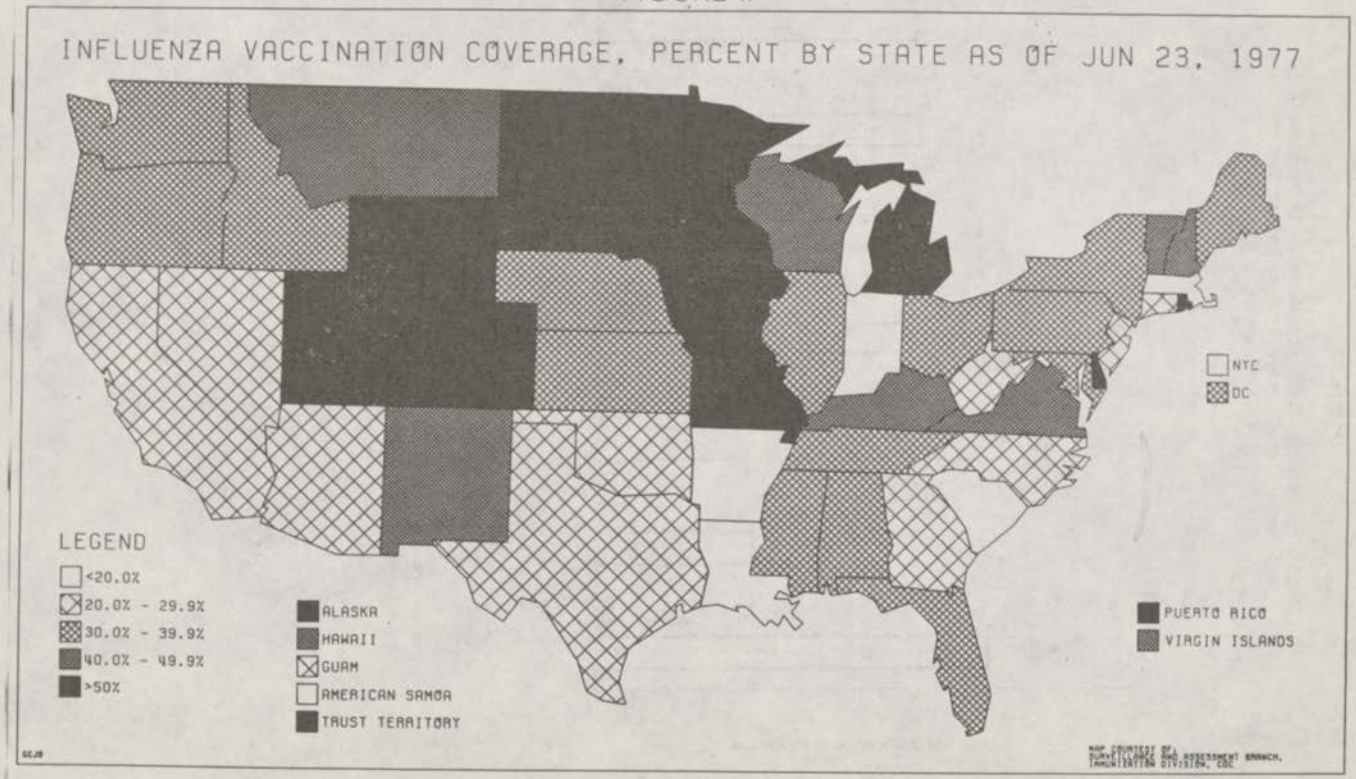
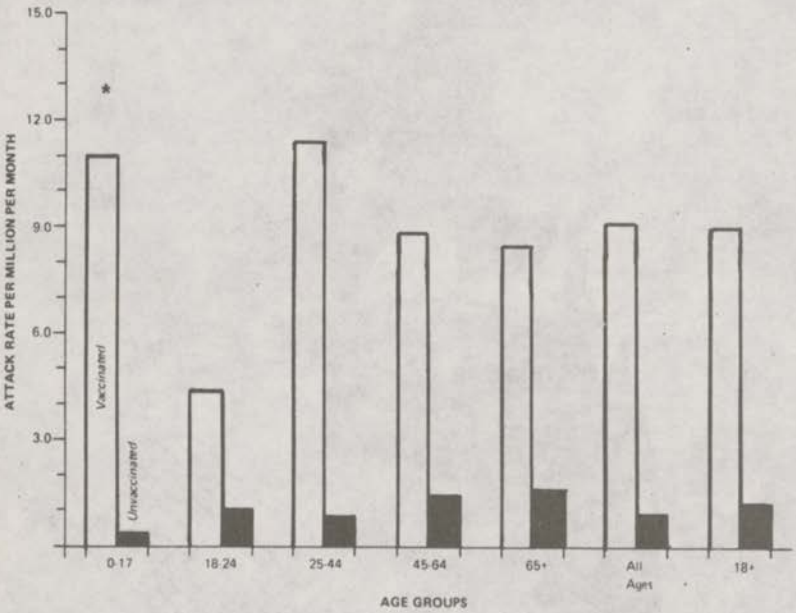

INFLUENZA VACCINATION COVERAGE, PERCENT BY STATE AS OF JUN 23, 1977
LEGEND
<20.0%
20.0% - 29.9%
30.0% - 39.9%
40.0% - 49.9%
>50%
ALASKA
HAWAII
GUAM
AMERICAN SAMOA
TRUST TERRITORY
NYC
DC
PUERTO RICO
VIRGIN ISLANDS

Figure III

Guillain-Barre Syndrome Attack Rates in Vaccinated and Unvaccinated Groups by Age, United States
October 1976 - January 1977



* Because so few persons in this age group were vaccinated the apparent difference lacks statistical significance.

FIGURE IV

Guillain-Barre Syndrome Attack Rate for Population >17 years of age,
by week of onset after A/New Jersey Influenza Vaccination
United States, Oct. 1976-Jan.1977

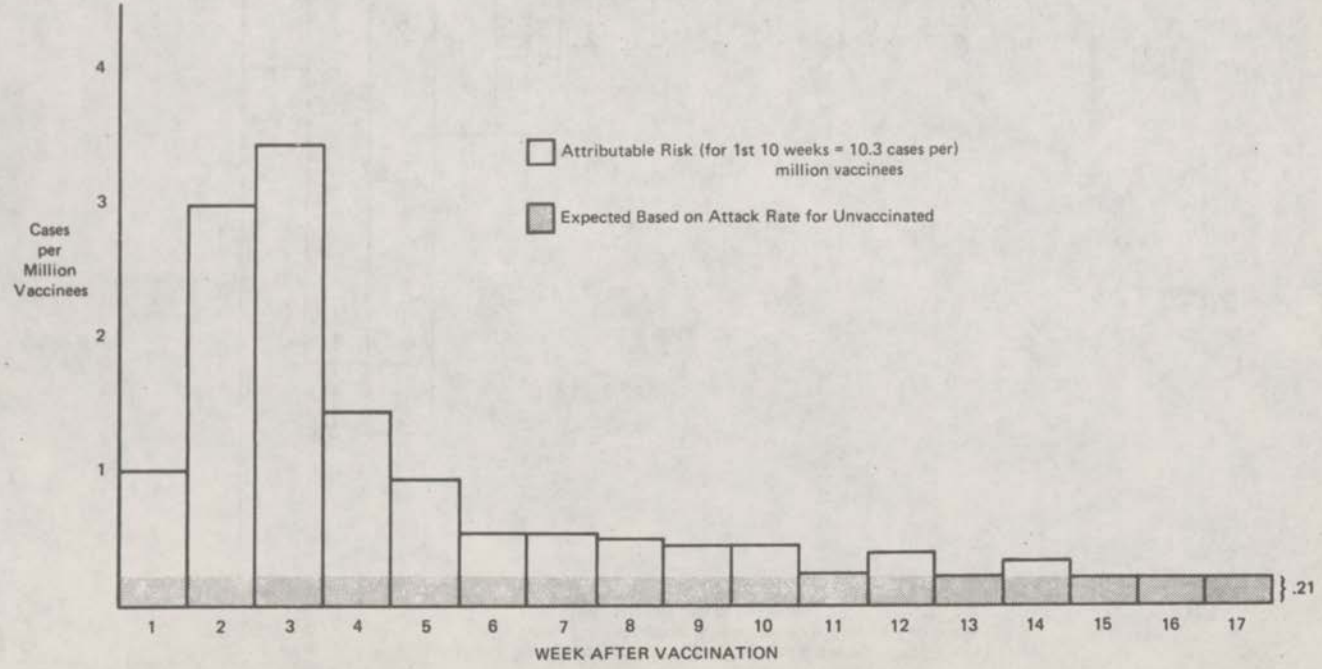
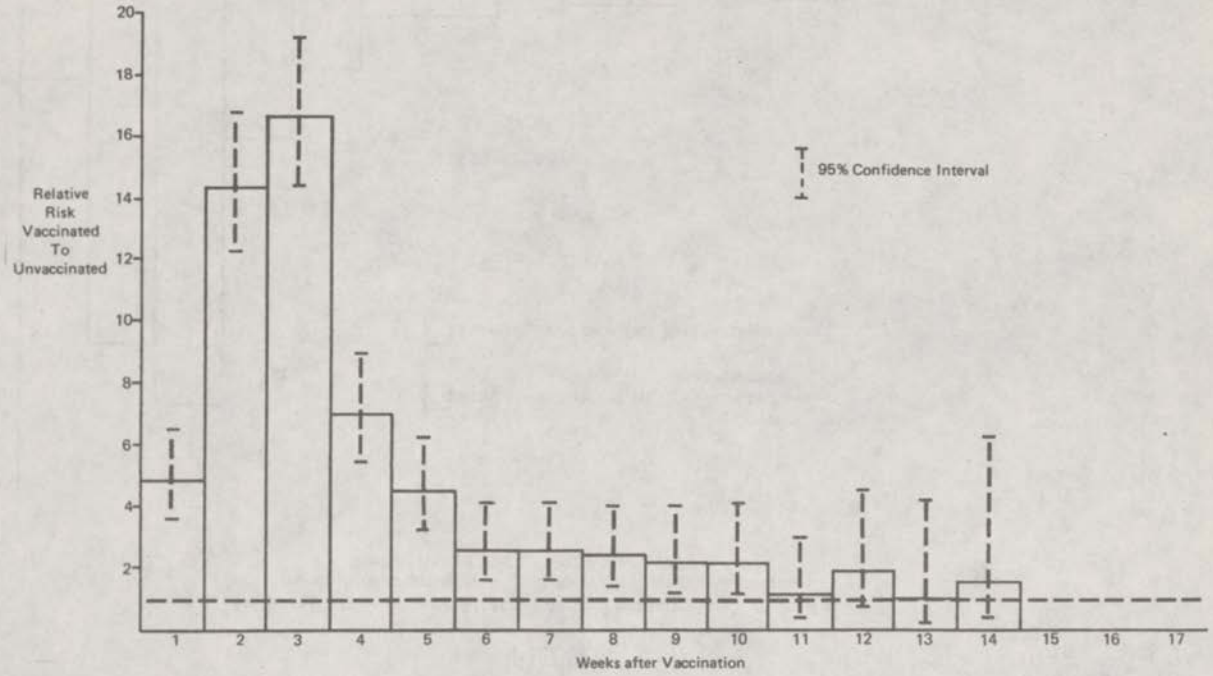


FIGURE V

Guillain-Barre Syndrome Relative Risks for Population >17 Years of Age,
By Week of Onset After A/New Jersey Influenza Vaccination,
United States, Oct.1976-Jan.1977



Mr. ROGERS. Thank you very much, Dr. Millar.

What has been the cost of the vaccine?

Dr. MILLAR. The estimated final costs for the vaccine would be $67 million.

Mr. ROGERS. What is it per dose?

Dr. MILLAR. 37 cents per dose, or 42 cents per dose if self-insurance retention funds are included.

Mr. ROGERS. What about the bivalent vaccine, what is the cost of bivalent?

Mr. BRADFORD. Mr. Chairman, they varied somewhat between manufacturers. We could provide that. Bivalent costs more than the monovalent.

[The following information was received for the record:]

NATIONAL INFLUENZA IMMUNIZATION PROGRAM
VACCINE CONTRACT AND INSURANCE COSTS

	Parke-Davis	Merrell-Natl	Merck, SD	Wyeth
Monovalent Vaccine				
Price/50 Dose Vial	$9.43	$8.58	$12.00	$15.09
Number of Doses	2,200,000	32,700,000	26,600,000	2,439,000
Cost	$414,920	$5,611,320	$6,384,000	$736,090
Provisional Price/50 Dose Vial	$ .189	$ .172	$ .240	$ .302
Price/10 Dose Vial	$1.51	$1.85	$2.80	$2.99
Number of Doses	2,800,000	22,300,000	14,100,000	2,395,000
Cost	$422,800	$4,125,500	$3,948,000	$716,105
Provisional Price/10 Dose Vial	$ .151	$ .185	$ .280	$ .299
Total Doses	5,000,000	55,000,000	40,700,000	4,834,000
Provisional Average Price/Dose	$ .168	$ .177	$ .254	$ .300
Bivalent Vaccine				
Price/50 Dose Vial	$19.01	$19.11[1]	$20.00[1]	$24.37
Number of Doses	2,300,000	3,310,000	3,000,000	7,207,000
Cost	$874.460	$1,265,082	$1,200,000	$3,512,692
Provisional Price/50 Dose Vial	$ .380	$ .382	$ .400	$ .487
Price/10 Dose Vial	$4.34	$3.97	$4.50	N/A
Number of Doses	24,400,000	2,690,000	2,300,000	0
Cost	$10,589,600	$1,067,930	$1,035,000	
(1,000,000 Doses @17¢/dose)	$17,000			
Provisional Price/10 Dose Vial	$ .434	$ .397	$ .450	N/A
Total Doses	27,700,000	6,000,000	5,300,000	7,207,000
Provisional Average Price/Dose	$ .414	$ .389	$ .422	$ .487
Total Vaccine Cost	$12,318,780	$12,069,832	$12,567,000	$4,964,887

NATIONAL INFLUENZA IMMUNIZATION PROGRAM
VACCINE CONTRACT AND INSURANCE COSTS
(continued)

	Parke-Davis	Merrell-Nat'l	Merck, SD	Wyeth
Charges Not Covered in Per Dose Costs				
1. Self-Insurance Retention Fund	$ 2,500,000	$ 2,500,000	$ 2,500,000	$ 2,500,000
2. Insurance Premiums[2]	2,176,648	2,181,372	2,192,709	2,176,693
3. Transportation Costs	0	0	0	27,087
Totals	$ 4,676,648	$ 4,681,372	$ 4,692,709	$ 4,703,780
Dollar Amount Provided in Contract	$16,995,428	$16,751,204	$17,259,709	$ 9,668,667
Total Doses Provided in Contract	31,754,000	62,756,780	50,562,180	11,925,900

Total Contract Awards[3]	$ 67,090,384
Total Doses of Vaccine Purchased	156,998,860
Average Per Dose Cost of Vaccine	$0.427

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[1] Merrell-National & Merck, Sharp and Dohme produced Bivalent Vaccine without profit.

[2] Difference in Insurance Premiums caused by Surplus Line Taxes charged by the State where the Insurance Policies were written.

[3] Each contract provided for 15% variance in vaccine production. These figures include total committments of the Government for vaccine (157 million doses), which exceeds estimated production projections which were contained in the contracts by 4%.

Mr. ROGERS. I understand. What is the range of the bivalent cost?

Dr. MILLAR. I am afraid we will have to provide that. It is probably here but I can't find it at the moment.

Mr. ROGERS. Does anybody know from HEW?

Dr. MILLAR. No.

Mr. ROGERS. Does anybody know?

Mr. BRADFORD. Not at the table.

Mr. ROGERS. We don't have the figures?

Mr. BRADFORD. Yes. We don't have them with us.

Mr. ROGERS. I would think we try to be reasonable with everyone but we are going into an investigation of swine flu and you can't tell us what the vaccine costs per dose. This is one of the problems the committee is concerned with. I am going to dismiss this group and call on the Department of Justice. Please bring back sufficient information for the committee to resume questioning.

Would the Department of Justice come forward. Immediately after the Department of Justice we will call on HEW.

We have with us now witnesses from the Department of Justice, Mr. Irwin Goldbloom, who is Deputy Assistant Attorney General, Civil Division, Department of Justice, and Mr. Neil Peterson, who is Assistant Chief, Torts Section, Civil Division.

We welcome you gentlemen to the committee. Your statement will be made part of the record in full. You may proceed.

STATEMENT OF NEIL R. PETERSON, ASSISTANT CHIEF, TORTS SECTION, CIVIL DIVISION, DEPARTMENT OF JUSTICE, ACCOMPANIED BY IRWIN GOLDBLOOM, DEPUTY ASSISTANT ATTORNEY GENERAL, CIVIL DIVISION

Mr. PETERSON. Good afternoon, Mr. Chairman, members of the subcommittee. My name is Neil R. Peterson and I am the Assistant Section Chief in charge of swine flu litigation in the Tort Section of the Civil Division of the Department of Justice. I appreciate the opportunity to appear before the subcommittee today.

If I may, before I begin my remarks, I will outline their context. I am, in effect, the person with immediate responsibility for the processing of administrative claims in the Justice Department and for the defense of swine flu litigation. As such, I will explain the Justice Department's involvement with the national swine flu immunization program of 1976. A separate witness, Mr. Goldbloom, will address the budgetary aspect of the Department's involvement in the program.

Initially, after the passage of Public Law 94-380 I was involved in rendering opinions to literally hundreds of health care providers, health care organizations, departments of various State and local governments, and public persons and organizations concerning the meaning and interpretation of the swine flu legislation and the Department's position in regard to it. The positions adopted by me on behalf of the Department during that period were coordinated in some measure with representatives of this subcommittee and with the Department of Health, Education, and Welfare. This function continued from August to November of 1976.

By October 1976, through an agreement with the Department of Health, Education, and Welfare, the Department of Justice had committed itself to process the administrative claims which would be submitted by those persons claiming personal injury or wrongful death as a result of inoculations with swine flu vaccine. I should explain that under the Federal Tort Claims Act, whose procedures were adopted for purposes of the swine flu program, the Department of Health, Education, and Welfare would have been the agency with processing responsibility for the administrative claims. However, it appeared to all concerned at the time that much greater efficiency would be achieved if the Department of Justice were to process the administrative claims in this one instance. Accordingly, the Department has been fulfilling this function in addition to its normal litigating responsibilities.

Pursuant to that interdepartmental agreement, it was further agreed that the Public Health Service Claims Office, the office to which the claims would normally have been submitted, would refer all inquires and claims to the Department of Justice. To date the Department has received 3,865 inquiries. These are maintained on file and are associated with any later claims which are transmitted to the Department. As of September 9, 1977, the Department has received 815 claims for processing.

The processing routine is as follows: Upon receipt of the claim, it is reviewed by an attorney to determine whether it is a valid claim. If it is not, the claimant or attorney submitting the claim is advised in writing of the deficiencies of the claim and advised specifically what to do to correct the deficiencies. Approximately 20 percent of the claims received to date have been invalid for one or more reasons. Almost all such claims which have been returned to the claimant or an attorney have subsequent been returned as valid claims.

Once we have a valid claim, our first act is to write the claimant or claimant's attorney to request supplementary information which we need for processing the claim. If the injured person has been treated by a physician or hospital we also request that a release of medical records form be executed and returned to us. Upon receipt of that form we correspond directly with the doctor and/or hospital involved to obtain copies of all their medical records.

Upon receipt of the supplemental information from the claimants or claimant's attorneys and of all of the medical records we refer the medical records to physicians for review. The doctors are asked to make two determinations—

First: whether the injury alleged is within or without the parameters of the warning statement which all vaccinees were supposed to have signed, or of the parameters of a reaction or sequela which could ensue after any flu vaccination; and,

Second: whether there was reasonable medical causation between the vaccine and the injury alleged. A claim must satisfy both conditions to be considered further, that is, it must be outside of the parameters of the warning statement or of a typical reaction, and the injury must be medically caused by the vaccine.

Any claim which passes the medical criteria will then be considered for legal liability. This process involves a review of applicable State law to determine whether the United States in its own right

or as a substituted defendant in the stead of a program participant would be liable.

At this point an appropriate recommendation is made to the Department of Health, Education, and Welfare. This recommendation can take one of three courses:

1. A recommendation for denial based upon medical and/or legal reasons.
2. A recommendation for payment of the claim as submitted.
3. A recommendation for negotiation to effectuate a compromise.

A dispositive letter is also transmitted to the Department of Health, Education, and Welfare compatible with the recommendation. The Department of Health, Education, and Welfare then reviews the file and the recommendation and, if it agrees with the recommendation, tramsmits the dispositive letter to the claimant or the claimant's attorney. To date there have been final dispositions of 86 claims. Another 30 to 35 claims are in the process of having recommendations prepared, another 40 claims are being reviewed by the physicians, and another 40 to 50 claims are ready for transmittal to the physcians. In the remaining claims we have either not received the supplementary information from the claimant, or the doctors or hospitals have not transmitted the medical records to us as yet.

Since the review process has been in operation long enough to run efficiently, the average time required for the complete Department of Justice processing is approximately 2½ to 3 months. I mention this fact because, under the Federal Tort Claims Act, if the agency involved does not make a determination within 6 months, the claimant may go to court. Obviously, there are some claims which we cannot and will not be able to adjudicate within 6 months. However, in the vast majority of such instances our inability to reach a determination in a timely manner will be due to the failure of claimants and their attorneys to respond with supplemental information in a timely fashion and our inability to secure prompt responses from physicians and hospitals. The Department of course has no control over these variables.

Claims are currently being filed at the rate of about 20 per week and I would anticipate this rate to increase in the future. This is not untoward or unanticipated. Many of the initial claimants were persons submitting claims themselves and their natural inclination would be to do so promptly. In cases of individuals who have retained attorneys, we would normally expect to receive their claims relatively later after the date of alleged injury. I cannot give you a precise projection of how many claims will be filed, but I would reasonably project that approximately 2,500 claims will be filed. I have prepared one list showing the dollar amounts of the various types of claims which have been received by the Department of Justice up to September 12, 1977. I have also prepared another list showing a summary of the various types of injuries for which claims are being made. You may include these lists as exhibits if you so desire.

Mr. ROGERS. Without objection, they will be made a part of the record [see p. 72].

The other involvement of the Department has been in relation to the defense of suits filed against program participants. To date,

there have been 21 such suits filed. The thrust of each of these actions, either initially or in response motions to substitute the United States and to dismiss the actions for failure to file administrative claims, has been to attack the constitutionality of the swine flu legislation. These attacks have alleged deprivation of Fifth Amendment due process rights, Seventh Amendment jury trial rights, Tenth Amendment States' interest abridgement, and Fourteenth Amendment equal rights protection violations. I have prepared a list of these suits, listing the type of injury alleged in each, the amount of money sought, and the current status of each action. You may include this list as an exhibit if you so desire.

Mr. ROGERS. Without objection, [see p. 74].

Mr. PETERSON. Briefly, we have been successful in the three cases which have been resolved to date. The original decision was in the case of *Sparks* v. *Merck, Sharpe & Dohme Orthopedics, Inc.,* 431 F. Supp. 411. The *Sparks* case is currently on appeal in the Tenth Circuit on an expedited calendar with the government's brief being due on September 24, 1977. All other litigation in Oklahoma has been stayed pending the appeal in *Sparks.* The case of *Stephens* v. *Wyeth Laboratories, Inc., et al.,* in Alabama was dismissed on the authority of the *Sparks* decision. The third case decided favorably was *Wolfe* v. *Merrill National Laboratories, Inc.,* in Tennessee.

This concludes my prepared remarks and I would be glad to endeavor to answer any questions that you or other members of the subcommittee or staff might have.

Thank you, very much.

[The attachments to Mr. Peterson's statement follows:]

CLAIMS RECEIVED AT DEPARTMENT OF JUSTICE

PERSONAL INJURY	743	$325,671,708.61
WRONGFUL DEATH	67	$1,032,948,178.89
PROPERTY DAMAGE	6	$355.54

SUMMARY OF INJURIES CLAIMED UNDER SWINE FLU IMMUNIZATION PROGRAM

	NO. OF CLAIMS FOR PERSONAL INJURY AND WRONGFUL DEATH	INJURY ALLEGED
I.	190	GUILLAIN-BARRE SYNDROME Including: 171 Non-fatal cases of Guillain-Barre 19 Wrongful Death cases of Guillain-Barre 190 TOTAL
II.	162	OTHER NEUROLOGICAL OR POSSIBLE NEUROLOGICAL DISORDERS Including: 144 Paralysis or Numbness of Extremeties or Face 18 Specific Central Nervous System Disorders (encephalitis, meningocephalitis, polyneuropathies, etc.) 162 TOTAL
III.	156	FLU-LIKE SYMPTOMS Including: (fever, chills, nausea, dizziness, headache, muscle aches, malaise)
IV.	74	LOCALIZED REACTIONS AT THE INJECTION SITE Including: 52 Local skin reactions on arm (rash, swelling, hematoma, marks) 22 Local nerve damage at injection site 74 TOTAL
V.	42	CARDIOVASCULAR DISORDERS (myocardial infarction, stroke, vascular disease, etc.) Including: 24 Wrongful Death cases arising from cardiovascular disorders 18 Non-fatal cases 42 TOTAL

	NO. OF CLAIMS FOR PERSONAL INJURY AND WRONGFUL DEATH	INJURY ALLEGED
VI	20	RESPIRATORY DISORDERS (Non-fatal) (pneumonia, respiratroy pain, respiratory infection, pleurisy, etc.)
VII.	23	LOSS OF CONSORTIUM Including: Claims filed separately from the main personal injury claim.
VIII.	107	MISCELLANEOUS CLAIMS Including:
		22 Fainting soon after vaccination
		14 Dermatological reactions, general (allergic, body rash, hives, etc.)
		9 Vision problems
		24 Miscellaneous Wrongful Death claims (neither Guillain-Barre nor cardio-vascular)
		38 Assorted injuries (arthritis, hepatitis, pancreatitis, sexual impotence, kidney problems, hearing disorders, propery damage, etc.)
		107 TOTAL
IX.	42	CLAIMS NOT STATING A SPECIFIC INJURY
	816	TOTAL CLAIMS FILED AS OF SEPTEMBER 12, 1977

SEPARATE TABULATION OF WRONGFUL DEATH CLAIMS

There have been 67 Wrongful Death claims filed, with the following breakdown:

24 Cardiovascular Disorders

19 Guillain-Barre Syndrome

24 Other or unstated causes

67 TOTAL Wrongful Death Claims

LIST OF SUITS

1. Wayne Young v. Wyeth, et al. (4 manufacturers), USDC ED OK, $5,450,000 (personal injury, presumably Guillain-Barre).
   Status: Stayed pending decision in Sparks.

2. W. A. Parks v. Wyeth, et al. (4 manufacturers) USDC ND OK, $931,500.00 (personal injury - paralysis).
   Status: Stayed pending decision in Sparks.

3. Lavesta E. Parks v. Wyeth, et al. (4 manufacturers) USDC ND OK, $238,560 (personal injury - paralysis).
   Status: Stayed pending decision in Sparks.

4. Lawrence Baker v. Wyeth, et al. (4 manufacturers) USDC WD OK, $6,012,000 (wrongful death - paralysis)
   Status: Stayed pending decision in Sparks.

5. Emily A. Spruell v. Wyeth, et al. (4 manufacturers) USDC ED OK, $6,249,000 (personal injury - presumably Guillain-Barre).
   Status: Stayed pending decision in Sparks.

6. Marvin Ray Moore v. Wyeth, et al. USDC WD OK, $1,460,000 (personal injury - paralysis).
   Status: Stayed pending decision in Sparks.

7. George Jarrett, etc. v. Wyeth, et al. USDC ND AL, $2,000,000 (wrongful death - Guillain-Barre).
   Status: Dismissed voluntarily after Stephens decision.

8. Katherine G. Wolfe, et al. v. Merrill National Laboratories, Inc., USDC MD TN, $3,000,000 (personal injury - Guillain-Barre).
   Status: Dismissed by the court.

9. Willmah L. Rieger v. Wyeth Laboratories, et al. USDC WD OK, $6,001,541.36 (wrongful death)
   Status: Stayed pending decision in Sparks.

10. Donna J. Sparks v. Merck, Sharpe & Dohme Orthopedics, Inc., et al., USDC WD OK $6,675,210 (personal injury - paralysis)
    Status: Dismissed by the court.
    On appeal in the Tenth Circuit.

11. Linda J. Stephens v. Wyeth Laboratories, et al., USDC ND AL, Amended Complaint $2,000,000 (personal injury)
Status: Dismissed by the court.

12. Vivian Cruson v. Merck, Sharpe & Dohme
USDC WD OK, $6,176,967.20 (personal injury - paralysis)
Status: Stayed pending decision in Sparks.

13. Cynde Haag v. Wyeth Laboratories, et al.
USDC WD OK, $6,001,796.93 (wrongful death - paralysis).
Status: Stayed pending decision in Sparks.

14. Jack D. Vesco v. Merck, Sharpe & Dohme
USDC D NV, $10,000.00 (personal injury - Guillain-Barre).
Status: Briefed and stayed pending decision on administrative claim.

15. Ivo Jones v. Wyeth Laboratories, Inc., et al.
USDC WD AR, $6,252,720.00 (personal injury - paralysis).
Status: Briefed and waiting argument before the court.

16. Marie and Donald Ducharme v. Merrill-National
USDC WD LA, $2,604,000.65 (personal injury - loss of use of the left upper extremity).
Status: Argued September 13, 1977

17. Delcy M. Kimbrell v. Wyeth Laboratories, Inc., et al.
USDC WD OK, $6,447,020.00 (personal injury - paralysis).
Status: Stayed pending decision in Sparks.

18. Roger A. Mitiguy v. Merck, Sharpe & Dohme
USDC D. VT, $902,994.00 (personal injuires)
Status: Briefed and waiting argument before the court.

19. Sylvia Ary v. Wyeth Laboratories, Inc., et al.
USDC ED OK, $6,174,499.56 (personal injury - paralysis).
Status: Stayed pending decision in Sparks.

20. Sharon Brashier v. Wyeth Laboratories, Inc., et al.
USDC WD OK, $6,379,800.00 (severe back pain entire length of her spine).
Status: Stayed pending deicision in Sparks.

21. Lyda Bradley v. Wyeth Laboratories, Inc., et al.
USDC ED OK, $6,091,920.00 (blurred vision, hearing impaired, pain throughout body).
Status: Stayed pending decision in Sparks.

98-930 O - 78 -- 6

Mr. ROGERS. Thank you very much.

Now, I believe we will also have a statement about the budget question.

Mr. GOLDBLOOM. We have no prepared statement but are prepared to answer any questions that the subcommittee might have.

Mr. ROGERS. It is my understanding that a supplemental appropriation was awarded to Justice by the Congress for the specific purpose of dealing with swine flu claims. Is that correct?

Mr. GOLDBLOOM. That is correct, Mr. Chairman.

Mr. ROGERS. I understand that you requested 28 positions, which were specifically funded. Are those people on board now?

Mr. GOLDBLOOM. Not all of the positions have been filled.

Mr. ROGERS. How many positions have been filled?

Mr. GOLDBLOOM. As of the present time there are 6 attorneys working approximately full time on the swine flu claims and litigation, plus a section chief, a new section chief for the Tort Section, who is working a substantial amount of his time. There are three secretaries and two law clerks working on it plus some other support personnel.

I should say that we feel that our response to the swine flu claims program is more than adequate in connection with the claims that have materialized as of this date and should the claims be increased in any more appreciable amount than that indicated by Mr. Peterson, we would be able to put more resources on than we have as of now.

Mr. ROGERS. Are these 6 people part of the 28 additional positions that were authorized?

Mr. GOLDBLOOM. Yes, they would be considered part of the 28. We should say that we had people working on the swine flu claims and swine flu matters before Congress appropriated any money specifically for that program.

Mr. ROGERS. Were these six hired specifically for the swine flu program? In other words, were they personnel you already had and simply had them working on the swine flu, is that right? Or were they hired specifically for swine flu?

Mr. GOLDBLOOM. Well, no, they were not hired specifically——

Mr. ROGERS. As a matter of fact, I understand you have only hired one person. Isn't that correct?

Mr. GOLDBLOOM. Well, let me explain it this way, Mr. Chairman.

Mr. ROGERS. Could you first give me a yes or no and then explain?

Mr. GOLDBLOOM. I don't believe we have hired anyone specifically for the swine flu program.

Mr. ROGERS. Even though it was authorized?

Mr. GOLDBLOOM. Well, in this regard.

We had made commitments as far back as last December to some 25 attorneys to come to work in the Department starting in June of this year for nonspecific assignments and it was our intention at the time of the supplemental appropriation to assign such of those attorneys who were undesignated for any specific assignment to the swine flu program as they arrived.

We have designated eight of those attorneys in terms of their arrival date for the swine flu program.

Mr. ROGERS. When do they arrive?

Mr. GOLDBLOOM. I am sorry, sir.

Mr. ROGERS. When do they arrive?

Mr. GOLDBLOOM. They have been arriving periodically starting in June of this year. Some, all of them have not arrived as of yet.

Mr. ROGERS. How many more individuals will you hire out of the supplemental appropriation?

Mr. GOLDBLOOM. Well, to the extent that we feel that we will need attorneys to work on the swine flu litigation, we will hire them and add them to this——

Mr. ROGERS. How many slots do you still have left out of the 28 authorized in the supplemental appropriation bill?

Mr. GOLDBLOOM. As I indicated, we had 11 personnel working on the program now, not including the section chief. To the extent that we would need more personnel and they would come out of that 28 positions, it would be the difference between——

Mr. ROGERS. What I am trying to get at is, will you be turning back the money or are you using the money; has the money already been allocated? That is what I am trying to find out.

Mr. GOLDBLOOM. The money has not been allocated to it. To the extent that we have attorneys working in the tort section, some of them may be working in other areas——

Mr. ROGERS. Have you used the appropriation, or are you going to use it, or will it be returned, since you are not having to hire attorneys?

Mr. GOLDBLOOM. I don't know the answer to that.

Mr. ROGERS. Who knows that?

Mr. GOLDBLOOM. I don't believe——

Mr. ROGERS. Suppose we recess while I vote and you find the answer to my question for us. I want to put in the record how many attorneys have been employed using the supplemental, what you are not going to use, and what funds will be turned back. We just want to spread it on the record.

The committee stands in recess for ten minutes.

[Brief recess.]

Mr. ROGERS. The subcommittee will come to order. Mr. Goldbloom, you may proceed with your answer.

Mr. GOLDBLOOM. If I may explain, Mr. Chairman, we prepared a supplemental appropriations request on the basis of estimates as to the amount of claims that would be forthcoming as a result of this program.

Originally, when the budget request was first prepared, at the initial outset of the program, we estimated, on the basis of claims, assuming a total nationwide immunization program, we used estimates that were prepared by the Congressional Budget Office.

Mr. ROGERS. You used our estimates?

Mr. GOLDBLOOM. The estimates of the prospective, potential claims and it is my understanding that the original figure that we started to work with was some 17,200 claims. By the time, however, that the supplemental appropriations request got through the OMB process, and was actually presented to the Congress, the program had been terminated. This was in February, I believe, 1977.

At that time, we adjusted our estimates and also our supplemental request for appropriation based upon the decreased number of

innoculations, and based upon an adjusted number of potential claims.

We figured on the basis of advice from Congress, and the basis of some 5,000 claims at that time, in February of this year. As it happens, the claims have not materialized in the same rate as we had anticipated. I think, as Mr. Peterson advised the committee this morning, there have been some 816 thus far, and we estimate some 2,500 claims in toto, even though there is no way of knowing for certain.

The response of the Department of Justice to swine flu claims was, in a sense, a unique type of budgeting for the Department of Justice in that virtually all of our budgeting is based upon generalized expectations about resource requirements for the future as we have to necessarily respond to litigation at some point down the road.

In this case, we were able to come up with some estimates. We feel that our response to the claims that have been made has been more than adequate. Indeed, we think that our response in terms of our handling of the claims has, in a sense, been a bright spot of our total operation in terms of some 20,000 to 25,000 cases in the Civil Division which the Department presently administers.

Now, how do we, as attorneys, in responding to litigation or claims have to meet our responsibilities? We do it by going with the ebb and flow of litigation requirements that are put on to us on a daily basis. As I indicated earlier, we had five people working full time on the swine flu matters before Congress ever gave us any supplemental appropriation. To the extent that these people were working, they were detracting from other claims and other programs for which, in a sense, the Congress had given us budgetary authorization and approval.

Now, I want to try to answer your question this way. We are increasing and have increased the staffing in our tort section, which is the place where these swine flu claims are being processed. We have increased over the past year, over its previously authorized strength, some six attorneys who I am not suggesting are working on swine flu claims, but are working in the tort claims field.

We expect to increase our attorney strength in the tort claims section beyond what it is today. As these swine flu claims mature, have to be processed, and have to be litigated, actually litigated, there will be attorneys, and the swine flu claims will be, I am certain, satisfactorily handled from the Government's point of view.

As I understand it, as of today there is only one case in court which deals with the merits of the swine flu claim. For us to devote 19 attorneys and 9 support personnel today to the swine flu matters would be, perhaps, irresponsible to our other responsibilities that we have in our tort section, particulary the fact that we have tremendous disaster litigation, asbestos litigation. But if tomorrow those 19 attorneys are needed, or by next week, or the following week, they will be there. They will be reassigned and able to work on this litigation.

Mr. ROGERS. Has the systems manager position been used yet?

Mr. GOLDBLOOM. No; it has not; and let me explain, for example, in one respect why it has not. For example, there were funds allocated for computers, for the use of computers, which we have every intention of using but we have not made the commitments yet.

There is a section chief assigned in the tort section, and the whole computer aspect of our response to the swine flu matters is undergoing a reevaluation. But we have the anticipation of using the computer, and those funds will be utilized for the computer.

Mr. ROGERS. You have used the 28 slots? You don't need 28 attorneys to handle 800-odd claims?

Mr. GOLDBLOOM. There are not 28 attorneys. There are 19 attorneys. We don't need them today. We may need them in 2 months.

Mr. ROGERS. But the money is gone?

Mr. GOLDBLOOM. The money is gone on the understanding that if an attorney is hired, and is working on a medical malpractice litigation, he is learning to try medical malpractice cases for the next 6 months. In 6 months, if he has to try a swine flu case——

Mr. ROGERS. You have hired 28 people that were to be assigned to swine flu. So you have hired them all, but you have not yet assigned them to swine flu?

Mr. GOLDBLOOM. I want to make this clear, so that I am not misleading you.

In February 1977, we had no vacancies in the civil division. We were at our fully authorized strength. We had made commitments at that point to 43 attorneys in the division, 43 attorneys who had not come to work in the Department as of that date.

We could anticipate that between February 1977 and, and let us say, today, there would be resignations, retirements, people leaving for one reason or another, and there would be new attorneys coming in. To the extent that we needed to hire and place attorneys in the swine flu program, based on our estimates made and which we told the Congress, those attorneys were there to be asigned to the swine flu program, which is different, I might say, from the suggestion that I believe has been made that on the day after Congress appropriated the money, and the President signed the bill, we went out and hired all those attorneys, that we went out and hired 19 attorneys. This is not how the process works, or functions in our hiring and allocation of attorneys program.

Mr. ROGERS. The Congress authorized 28 positions to work on swine flu. You have six working. What happened to the others?

Mr. GOLDBLOOM. Some of them may be working on aviation cases.

Mr. ROGERS. But they have been hired. Have you filled all 28 positions?

Mr. GOLDBLOOM. I don't know what our strength is today vis-a-vis our authorized strength. These are constantly fluctuating.

Mr. ROGERS. I know that there may be differences of 1 or 2, but basically have you filled the 28 slots?

Mr. GOLDBLOOM. I don't want to say that we went out and deliberately hired.

Mr. ROGERS. I want to know. I am not implying that anything is wrong. There may be, the way we are going through this. All I

want to do is find out if you have used the slots that we have given you. Have you hired to fill those slots; that is all I am asking.

Mr. GOLDBLOOM. We hired attorneys in the civil division of the Department of Justice.

Mr. ROGERS. Did you use the slots appropriated for the 28 people in the supplemental?

Mr. GOLDBLOOM. Yes; in the broad sense.

Mr. ROGERS. If they are used, they are gone. Do you have any slots left?

Mr. GOLDBLOOM. They are not gone. They are there.

Mr. ROGERS. But the slots that were going to be filled, have been filled. You simply don't have them working on swine flu. So you have used this money for other purposes in the Department.

Mr. GOLDBLOOM. Well.

Mr. ROGERS. That is all I want to know.

Mr. GOLDBLOOM. Well, I don't consider, Mr. Chairman, that an attorney who is not needed to work on a claims case today, because there is no need for his work today on processing claims cases, but may be learning to try medical malpractice cases and will be available to try medical malpractice, or swine flu cases in 6 months, that he is gone.

Mr. ROGERS. I understand that you do not feel that way. I might tell you that the Congress might differ with you. When we authorize specific positions for specific programs, that money should be used in that manner. I understand your position.

It is encouraging that you have not had to hire for the swine flu program because the claims have not amounted to as many as you anticipated. So I think that this is a plus. I hope that this will continue.

I just wondered what was done with the money that was allocated which was not used, and how the Department was using that money and allocating those personnel who are not working on swine flu as authorized specifically by the appropriations bill.

Mr. GOLDBLOOM. I can assure you, Mr. Chairman, that we are working defending the Government against our liability in tort suits as well as other types of litigation. The money has not been frittered away or used in any kind of frills.

Mr. ROGERS. I did not say that, but I am not sure that the Congress would have authorized those positions, had it not been for the justification of an anticipated caseload that has not yet developed. That is all I am saying. So we can check on that later.

You mentioned computers. Has anything ever happened with programing the computers with the various State laws and how they apply?

Mr. GOLDBLOOM. My understanding is, Mr. Chairman, that inquiries have been made, and are continuing to be made. The new section chief who has an industrial engineering background is reviewing it.

Mr. ROGERS. Is the recommendation to do this?

Mr. GOLDBLOOM. I think it is.

Mr. ROGERS. It has been decided?

Mr. GOLDBLOOM. I don't know if it has been decided.

Mr. ROGERS. Who has been the section chief?

Mr. GOLDBLOOM. Up until August 15 of this year, Mr. Kruze.

Mr. ROGERS. Is he leaving?

Mr. GOLDBLOOM. He has been made special litigation counsel and Mr. Axelrad is now the chief.

Mr. ROGERS. How long do you think it will take him to make this adjustment?

Mr. GOLDBLOOM. I have not discussed it with him. I know that he is devoting his attention to it now.

Mr. ROGERS. Would you let us know when this is done? I think that this could certainly have a bearing on the time element that is required to process claims, if you could get all of the information needed on the computer.

How are you proceeding, as far as the applicable State law? Do you have all that information assembled?

Mr. PETERSON. Mr. Chairman, in those relatively few cases where we have gotten to a question of the applicability of State law, we have used the facilities of the Department of Justice for research, but it has been done on an individual basis.

Mr. ROGERS. It would certainly be speeded up if you computerized the information.

Mr. PETERSON. The research, initially, would not be speeded up by having the computer. We would still have to do the research and put it on the computer. Its use would be speeded in the second application to a specific set of facts.

Mr. ROGERS. What is your experience as to the cost of processing each claim? Has that been broken out?

Mr. PETERSON. That has not been broken out, sir, as a specific cost item. I know the original Congressional Budget Office figures were based on Veterans' Administration claims experienced with medical malpractice.

Mr. ROGERS. Was that about $2,500?

Mr. PETERSON. They said that it was about $600 per claim. I would certainly estimate that our costs, so far, are substantially below that.

Mr. ROGERS. If you could let us have those figures for the record, it would be helpful.

[The following letter was received for the record:]

ASSISTANT ATTORNEY GENERAL
CIVIL DIVISION

Department of Justice
Washington, D.C. 20530

16 DEC 1977

Honorable Paul G. Rogers
House of Representatives
Washington, D. C. 20515

Dear Congressman Rogers:

During questioning of Mr. Neil R. Peterson of this Division at a hearing held by your Subcommittee on September 16, 1977, Mr. Peterson was asked to supply such figures as we had pertinent to the cost per claim of processing claims by this Department under the Swine Flu statute.

Mr. Peterson has previously advised the Department of Health, Education, and Welfare (Center for Disease Control) that Swine Flu Program expenses (without inclusion of ancillary expenses such as equipment, space costs, a percentage of SLUC, etc.) were $89,174 for the period October 1, 1976 to June 30, 1977. Of that amount, Mr. Peterson has estimated that approximately $72,100 would have related to the processing of particular claims. As of June 30, 1977, there were approximately 590 claims pending which had been received at various times during the period December 1976 through June 30, 1977. These claims were in varying stages of processing.

Since June 30, 1977, approximately 463 claims have been received in the Department, and they are in varying stages of processing. Since the commencement of the program, 182 claims have been fully processed by the Department of Justice and forwarded to HEW. As of this time, HEW has taken final action in 143 of the matters referred to it by the Department of Justice. Our Tort Section staff has been gearing up not only for the processing of swine flu claims but also for the important tasks involved in the handling of the issues presented. These tasks include the gathering and development of factual

information regarding the program, the development of expert analyses susceptible of use in the litigation, and the development of litigation positions and strategy which will be necessary when the claims mature for actual disposition by the courts. Because the entire staff devoted to swine flu matters have been involved across the entire spectrum of activities as outlined above and due to the fact that our record-keeping system does not isolate costs incurred with respect to the handling of specific claims, it would be difficult to furnish you with meaningful cost figures relating to the processing of specific claims.

With respect to your inquiry of December 7 to the Attorney General requesting overall program cost figures, we are attempting to isolate these costs and will endeavor to respond to you prior to January 6, 1978.

Please let me know if there is any further information we can provide.

Very truly yours,

Barbara Allen Babcock

BARBARA ALLEN BABCOCK
Assistant Attorney General

Mr. ROGERS. Have any of the records you have rejected been in relation to Guillain-Barre?

Mr. PETERSON. They have not, Mr. Chairman.

Mr. ROGERS. Have you adopted any position on how to deal with those cases?

Mr. PETERSON. We have not taken any final position as yet, sir.

Mr. ROGERS. I hear that you may be moving, Mr. Peterson.

Mr. PETERSON. Yes, sir.

Mr. ROGERS. To another position in the Department?

Mr. PETERSON. Yes. I will be becoming a special litigation counsel for the Civil Division probably within a month.

Mr. ROGERS. Don't we still need you in this program?

Mr. PETERSON. The process has been established. It is an ongoing function at this time within the Tort Section. I understand that part of my responsibilities as Special Litigation Counsel may be to actually litigate the first few swine flu cases.

Mr. ROGERS. Would you have any objection to the committee asking the Attorney General that you do that?

Mr. PETERSON. No, sir.

Mr. ROGERS. With your background, it would be helpful. We will just write a little note to the Attorney General, telling him that we hope that we will not lose your talent in handling those cases.

Mr. Waxman?

Mr. WAXMAN. If you wish a member of the committee to dissent, I will be glad to do it on your behalf. I would hope that swine flu would not become a career for either of us, but I wonder if it might still be.

You mentioned that there is an average of 20 claims a week?

Mr. PETERSON. Yes, sir.

Mr. WAXMAN. How long a period of time has that been the figure? Has that been a steady 20 a week?

Mr. PETERSON. I would say for the past 2 months, at least.

Mr. Waxman, the claims originally came in quite a deluge in March and April, and then they leveled off quite substantially, then they have come to their present level in July and August. Looking toward the future—I understand by reading the Wall Street Journal, yesterday, that there are certain plaintiff committees forming in the city of New York, and elsewhere—I would anticipate, based upon that, that the projections I gave the committee would be accurate, and there would be more cases filed in the future.

Mr. WAXMAN. I understand that there is even a swine flu newsletter that has come out. So it is going to be a career for some lawyers, handling these cases over the years, it might take to get final adjudication. Is that correct?

Mr. PETERSON. I would not expect the program to last substantially longer than 5 years for the defense of all the litigation.

Mr. WAXMAN. Do you have any idea on the potential liability of the United States Government from all these claims?

Mr. PETERSON. No, sir. I cannot estimate what it might be. I can tell you that there have been claims filed totaling approximately $1.3 billion, which includes, by the way, one $1 billion claim. So to that extent, that claim has skewed all of the statistics, and it is not meaningful to project any future occurrences based on the inclusion of that type of a claim.

I would also comment that traditionally it has been our experience, especially with attorneys involved, that they claim high and settle low. So the $300 million remaining is not a truly indicative figure of what the Government exposure would be in the program, even if we had to pay every claim.

Mr. WAXMAN. Did I understand you correctly to say that those claims do not include the claims resulting from Guillain-Barre syndrome?

Mr. PETERSON. No, it includes the claims resulting from Guillain-Barre. That is in one of the lists that I have appended to my statement, which shows the specific breakdown.

Mr. WAXMAN. For death cases involving Guillain-Barre, if I remember correctly, in the past we relied on State tort law.

Mr. PETERSON. Yes.

Mr. WAXMAN. Do you know whether claims are being filed more on a product liability basis as opposed to a negligence basis?

Mr. PETERSON. The claims and the claim forms which are used ask claimants to describe only the nature of the injury they have received. They do not, as such, request the claimant to set forth the theory upon which he is proceeding. That would not be done until the given claim would go to suit stage, where you would have the complaint filed, which would set out theories of liabilities.

As a practical matter, I would estimate that most claims will be filed especially on a strict liability basis.

Mr. WAXMAN. Most of them are filed on a strict liability basis. Can you foresee the United States Government going against the drug manufacturers on a negligence theory, which is the only basis by which they would be held liable, as opposed to the United States Government being held liable?

Mr. PETERSON. I have been asked the question often, Mr. Waxman. To the best of my knowledge, I, at the present time, see no indication that would lead me to believe that there has been manufacturer's negligence.

Mr. WAXMAN. Even if there had not been manufacturer's negligence, using the word "negligence" and the legal definition of that word, there still could be claims that will be successfully pressed against the United States for liability.

Mr. PETERSON. Yes, there can be.

Mr. WAXMAN. These would be primarily based on strict liability, which says that you did not get what you were warranted, if it is a warranty situation, because you went in for a vaccination, and you got some bad result from it. There does not need to be proof of negligence.

Mr. PETERSON. There are two specific theories, Mr. Waxman, and you are combining both of them. Breach of warranty is different from strict liability. The liability, under the strict liability theory, would be under this type of program mainly on the concept of a duty to warn.

Mr. WAXMAN. Under either circumstances, the Government will bear the loss and not the drug manufacturers. Isn't that correct?

Mr. PETERSON. Initially, but then if we can prove negligence over against the manufacturer, then we would proceed against the manufacturer, or indeed for that matter, against any program participant, including health care organizations, and health care providers.

Mr. WAXMAN. The drug manufacturers have purchased insurance for $8-plus million in case they are held liable. Do you think it is likely that insurance companies are going to be called upon to spend any of that money to cover claims that will be brought against the drug manufacturers for their liability?

Mr. PETERSON. I see no basis at present, as I said, for an indication of manufacturer liability. If that continues, obviously, then the money would not be used.

Mr. WAXMAN. As a practical matter, when we passed that special law to handle the liability situation for the swine flu program, didn't we pick up for any liability that results from bad results from the program. When I say, we, I mean the United States Government.

Mr. PETERSON. No, sir, not in toto because of the reservation of the cause of action over for negligence. I might point out a few of the instances in which this conceivably could have occurred, and undoubtedly has, in some circumstances.

For instance, giving an injection with a dirty needle, leading to a reaction; or a dirty gun; or following inadequate swabbing of an arm to remove all the bacteria from it; or putting the needle into a nerve, a vein or an artery, and causing injury in that manner.

These things are all obvious indications of negligence. The Government, if it were found liable in those instances, as it undoubtedly would be, would have a cause of action over against the person giving that shot.

Mr. WAXMAN. So the cause of action you are talking about is not to the drug manufacturer, but to the people administering the drug, the local officials of local governments.

Mr. PETERSON. No, not totally, Mr. Waxman.

Mr. WAXMAN. Most of them.

Mr. PETERSON. Many of them also fall in the category of volunteers, private physicians, and nurses who volunteered to help local health care organizations, and also individual physicians who gave the shots in their own offices, but with informed consent and without charging, who would, therefore, be program participants.

Mr. WAXMAN. So the suits where the Government may not be the one paying the bill for a bad result, will not be against any of the manufacturers but it will be a suit against a volunteer?

Mr. PETERSON. That is the way it looks at present. In the realm of all possible hypotheticals, as the chairman mentioned earlier today, there was the possibility also of there having been a bad lot of vaccine. If such were to have occurred, then there would be the basis for a suit against the manufacturer. That is one instance in which the manufacturer would undoubtedly be sued by the United States.

Mr. WAXMAN. I think that your testimony has been very helpful. You anticipate that in 5 years we will know the total liability that the taxpayers will have paid for this program. I guess, we may be back here in 5 years to discuss what could have been done with that money in some of the other worthwhile Government projects, and feel even more frustration as opposed to the upbeat tone that we got from HEW on their report of the swine flu program, that seemingly wonderful experiment in preventive medicine.

Mr. ROGERS. Mr. Maguire?

Mr. MAGUIRE. Thank you, Mr. Chairman.

I do not have much in the way of questions, but I do have a recollection. I wonder if anyone could confirm that. I seem to remember that we had testimony, perhaps it was not directly from the justice Department, but from Dr. Cooper at HEW or some other HEW representative, that there would not be a need for any additional personnel at the Justice Department.

Does anybody recall whether, in fact, we did have such testimony? Perhaps the gentleman from the Justice Department has researched all past exchanges, and can give an answer to that.

Mr. PETERSON. The only possible suggestion I can give you, Mr. Maguire, is the type of information which is detailed in the Con-

gressional Budget Office Advisory to the Congress on the cost of the administrative process in dealing with the swine flu claims.

There were projections made as to payouts, and as to the administrative costs incurred in processing the claims on an administrative level. It was originally thought that that function would be with the Department of Health, Education, and Welfare. So these projections would have applied to it as of that time.

Obviously, there is no projection as to the Department of Justice's involvement because we would not normally have begun our involvement until after the administrative claims process had been concluded.

Mr. MAGUIRE. One final question.

Mr. ROGERS. There was a supplemental appropriation request for 28 additional slots.

Mr. MAGUIRE. I know that.

Mr. ROGERS. They have been hired, but they have not yet been assigned to the swine flu program. They would be subject to call, I assume, if they are needed. They have hired one additional person to work on the swine flu program as of this date, but the individuals can be assigned as cases develop, as I understand it.

Mr. GOLDBLOOM. Yes.

Mr. MAGUIRE. I have one final question on the discussion we had a year ago. There was constant emphasis on the point that the number of claims that might be filed were unpredictable, particularly with respect to what was described as nuisance suits.

I think that members of this committee, of who I was one, felt that the danger of a proliferation of such suits was significantly less than what was being suggested by some of the witness from both the manufacturers and the insurance companies.

I wondered, in detailing what, in fact, has occurred thus far, 815 claims and 21 suits, whether you feel that that exceeded your expectations, or did it measure up to the number you anticipated.

How would you rate those numbers compared to what you might have anticipated a year ago?

Mr. PETERSON. Mr. Maguire, dealing specifically with my own projection for 2,500 claims versus the 815 we actually have in the house at the present time, I would say that my projections at this date are less than they were originally. To compare my figures or my projections with what the insurance industry presented to the committee, I don't know how many claims they were projecting, but I know they gave the committee a cost estimate of up to $23 billion for the defense of what would be termed "frivolous claims."

If I could assure the committee of anything, I could assure it of the fact that the cost of defending against such frivolous claims, whatever that means, by the Justice Department, would not begin to approach one 1,000th of what the insurance company projected.

Mr. MAGUIRE. Thank you.

Mr. PETERSON. I might also say, Mr. Maguire, that those projections are based upon what we know by way of hindsight. We know from hindsight that there appears not to have been what in the manufacturing industry would be called a hot lot, or a bad batch of vaccine which would injure many people because of some inherent defect in it.

Mr. MAGUIRE. Thank you.

Thank you, Mr. Chairman.

What about suits? You commented on claims, what about suits?

Mr. PETERSON. Those suits which have been filed to date, the 21 which are itemized in the list that I have provided to the committee, are suits which admittedly do seek money damages, but whose primary purpose at this point is serving as a vehicle to attack the constitutionality of the statute.

In my view, they do not as such constitute suits on the merits, such as you would have from the lapse of 6 months without a decision on an administrative claim, or from a denial of a claim.

Those suits, eventually, if the courts uphold our position, will have to be turned into administrative claims and follow the regular claim process the same as all the other claims.

Mr. MAGUIRE. Thank you, Mr. Chairman.

Mr. ROGERS. The statute of limitation on claims or suits would be for what period of time?

Mr. PETERSON. Two years.

Mr. ROGERS. If the person were inoculated, it would be 2 years from that date?

Mr. PETERSON. Yes; sir.

Mr. WAXMAN. Would the gentleman yield?

Mr. ROGERS. Yes.

Mr. WAXMAN. Isn't that determined by State law?

Mr. PETERSON. Under the swine flu statute, the procedures and provisions of the Federal Tort Claims Act are made applicable. One of them is the statute of limitation applicable to the Federal Tort Claims Act which is a 2-year limitation.

Now this will differ in some respects from State law provisions. For instance, warranty actions in many States are often permitted to be filed up to 6 years after a specific sale, and some instances 20 years. But this will never be here under the swine flu program.

Mr. MAGUIRE. Mr. Chairman, if I might have an opportunity to raise one more question.

Mr. ROGERS. Certainly.

Mr. MAGUIRE. Thank you, Mr. Chairman.

In looking at the claims, we note that none of those based on the Guillain-Barre syndrome have been dismissed, as was possible in a number of other cases.

In that connection, I want to ask you if you feel that the defect in the consent forms, that is not showing the possibility of neurologic disorders, which I gather there was some basis for believing could be a potential side effect now prejudices the Government's position with respect to the adjudication of the claims?

Mr. PETERSON. Sir, my answer will take two forms, to give you a complete answer.

First of all, respectfully, although it is called such, and it has been called such by HEW and the committee, I would prefer to term that document which was signed by people as a warning statement rather than as a consent form.

Mr. MAGUIRE. Fine.

Mr. PETERSON. If you understand the background, what happened is, the Government assumed the manufacturers' liability under the rules. This statement is in fulfillment of that duty to

warn. It is not as such, specifically, an informed consent such as you would sign before an operation.

Mr. MAGUIRE. I accept that correction.

Mr. PETERSON. With that in mind, what must be in the warning statement is often determined retrospectively in the courts, unfortunately. What must be in it is determined by a balancing of the risk versus the benefit. The way the courts have interpreted this, they have said: If you have a significant risk, that is, a risk of death, for instance, although it occurs statistically only in a small number of cases, perhaps you should have that in your warning statement.

On the other hand, if you have a relatively more minor reaction, in a relatively larger number of cases, you may not need to put that in your warning statement.

The statement as it is phrased does include sequel up to and including death. I would certainly think that death is the ultimate injury. I would think that it would be more severe an injury than nerve damage. Morever, the incidence of neurological reactions following, the use of nonlive virus, in my understanding, is significantly less than with other live virus vaccines.

Accordingly, I do not feel that the failure specifically to mention Guillain-Barre or neurologic disorders in the warning statement should necessarily prejudice the Government's defense of the cases.

Mr. MAGUIRE. I would not have expected you to say anything else, but I am glad for that assurance.

Mr. ROGERS. Let me ask you about the wrongful death claims. I see 67 claims amounting to $1,032,000,000. It is my understanding that one of those suits is for $1 billion. Is that right?

Mr. PETERSON. I believe that is correct. I discussed that with Mr. Waxman. The one claim has been filed for $1 billion. I indicated that, in my view, the filling of that claim totally threw the statistics out of proportion.

I also indicated that of the remaining approximately $300 million in claims that we have, attorneys generally claim high, and settle low. So even the $300 million is in no sense an indication of the Government's exposure even if we were to pay every claim.

Mr. ROGERS. How many cases have actually been handled to date?

Mr. PETERSON. Suits on the merits, there is one currently pending, which has just been filed.

Mr. ROGERS. If you would keep the committee advised, it would be helpful. If you would let us have a rundown of the names of people working on this problem for the Department, and those who would be called on to come in as needed, it would be helpful.

We thank you so much. We are grateful to you.

[The following letter was received for the record:]

United States Department of Justice
WASHINGTON, D.C. 20530

DEPUTY ASSISTANT
ATTORNEY GENERAL
CIVIL DIVISION

DEC 13 1977

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

Dear Mr. Chairman:

You previously requested a list of all personnel in the Civil Division who are presently working on matters arising out of the Swine Flu Program. This information, as furnished to me by the Torts Section, is supplied below.

Attorneys who currently work on virtually a full-time basis on swine flu matters are:

Thaddeus Hodgdon
Wallace Kleindienst
John Myers
Leon Taranto
Russell Welsh

In addition, Section Chief Jeffrey Axelrad and Deputy Chief of the Torts Section Alexis Panagakos devote a substantial portion of their time to swine flu matters.

Paralegal personnel devoting a substantial portion of their efforts to swine flu matters are:

Estie Lipsit
Sandra Manners (virtually full time)
Janice McCleod

Secretaries who devote a majority of their time to swine flu work are:

Sonia Lacks
Marlene Rush
Lynne Talley

In addition, many other secretaries (approximately ten during the past sixty days) have done typing of swine flu correspondence on a part-time basis.

I trust that this letter supplies the information which you requested.

Sincerely yours,

IRWIN GOLDBLOOM
Deputy Assistant Attorney General

[The following correspondence was subsequently received for the record:]

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NINETY-FIFTH CONGRESS

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Congress of the United States
House of Representatives
Subcommittee on Health and the Environment
of the
Committee on Interstate and Foreign Commerce
Washington, D.C. 20515

October 5, 1977

Honorable Griffin Bell
The Attorney General
Justice Department
Washington, D.C.

Dear Mr. Attorney General:

Representatives of the Justice Department appeared before the Subcommittee on Health and the Environment at our September 16 oversight hearing into the Swine Flu program of 1976. At that time, the Subcommittee received an insufficient response to our question concerning the status of the 28 positions funded by a supplemental appropriation made to meet the Department's specific request for dealing with swine flu program claims.

I would appreciate your personal review of this situation: the basis for the Justice Department's specific request for handling swine flu claims; the supplemental appropriation which was made to meet that request; the actual use of those appropriated funds; and your assessment as to whether or not those funds were used for the positions and other specific purposes for which they had been appropriated.

In addition, Congressman Henry Waxman has requested that the Justice Department respond to the following two questions he has posed in relation to insurance aspects of the swine flu program:

1. Even though the McCarran Act declares the business of insurance to be a state rather than a federal matter for purposes of regulation, isn't the way the insurance companies held up the Swine Flu Program an anti-trust violation which either the Justice Department or the FTC under recent case law could pursue?

2. Is there any way, if the action of the insurance companies constituted an anti-trust violation, that their $8.4 million profit on the program can be recaptured by the federal government?

I would appreciate your written response for the hearing record by October 21, 1977. Your attention to this request is most appreciated.

Kind regards.

Sincerely yours,

Paul G. Rogers

PAUL G. ROGERS, M.C.
Chairman, Subcommittee on
Health and the Environment

PGR:rd

United States Department of Justice

OFFICE OF THE ASSOCIATE ATTORNEY GENERAL

WASHINGTON, D.C. 20530

OCT 28 1977

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

Dear Mr. Chairman:

The Attorney General has asked that I respond to your letter of October 5, 1977, regarding the swine flu claims program in the Department of Justice. Your letter raises a number of questions regarding the basis for the Justice Department's specific request for handling swine flu claims and the allocation of resources within the Department in connection with the supplemental appropriation authorized by the Congress.

While I can fully understand and appreciate your concern, I have looked into this matter and am satisfied that the Department of Justice is adequately meeting its commitments under the swine flu claims program and appropriately discharging its responsibilities in the use of funds appropriated by the Congress.

Permit me to place the budget request in an historical context. When the swine flu inoculation program was first considered in the summer of 1976, the Department of Justice made certain resource estimates which were based on the anticipated massive influx of claims and litigation arising out of the inoculation of 120 million Americans. These estimates were based upon projections furnished to us by the Congressional Budget Office which predicted a potential of some 17,200 claims filed under the inoculation program as originally planned. But by January 1977, only 50 million inoculations had been administered. Thereafter, the Department's estimate regarding potential claims arising out of the program was adjusted downward to 5,000. Accordingly, in February 1977, the Department's budget request for a supplemental appropriation was submitted to the Congress and sought 28 positions, including 19 attorneys for the processing of swine flu cases and the handling of

related litigation. At this juncture, I wish to stress that all of our estimates were made in good faith, thought to be conservative, and premised upon the facts available to us at the time. In retrospect, it is clear that the projections on which the request was based were inaccurate. If you desire to review the details of the original estimates, I would be pleased to make them available to you.

As indicated by Department witnesses in testimony before your Committee on September 16, 1977, as of September 9, 1977, only 816 claims had been filed. At that time, Mr. Neil Peterson, one of the Department's witnesses, furnished the Committee with a complete listing of all of the pending litigation and the status of the claims being processed by the Department. Mr. Peterson also detailed that while the level of claims receipts differed quantitatively with that which was anticipated, so too did the pacing and substantive nature of the claims. Specifically, we did not anticipate claims involving the Guillain-Barre syndrome nor did we anticipate the extent of procedural delay which has attended the filings.

At the present time, in addition to the Section Chief of the Torts Section who is devoting a considerable amount of his time to the swine flu claims, there are five attorneys and seven support personnel whose work is largely devoted to swine flu claims and litigation. I am advised by Assistant Attorney General Babcock that the resources assigned to these matters are fully adequate to discharge our responsibilities. We expect that in due course additional personnel will be required and we will supply them from the resources that the 1977 Supplemental made available.

Nevertheless, there are presently only six cases pending before the courts which pose a question on the merits of liability for injury. It is important to note that these cases are only six of over 4,000 pending cases in the Torts Section and some 24,000 cases pending in the Civil Division at large.

This is, perhaps, an appropriate opportunity to interject another point I believe to be germane. Many of us were new to our positions at the Department of Justice, including myself and Ms. Babcock. In the months following our arrival, we have had occasion to question and re-evaluate the efficacy and suitability of certain inherited commitments and priorities. As might be expected, we have identified some

new areas of litigative concern which occasionally differ with those targeted by our predecessors. Unfortunately, one of our major problems has been that of insufficient resources in the litigating divisions and, too often, we find ourselves in the unenviable position of "robbing Peter to pay Paul." Thus, we have not applied all of the funds earmarked for the Torts Section in the swine flu supplemental to that program. For example, some of the monies have been redirected to the Frauds Section of the Civil Division in an effort to respond to new HEW initiatives to uncover and prosecute widespread misuse of the Medicare/Medicard programs. Conversely, had the impact of the swine flu program been greater than we projected, it would have been necessary to reassign personnel from other programs to handle the workload.

It is our experience that the requirements of litigation behoove us to assign our resources where they are most critically needed. There is no failproof way of accurately predicting the specific requirements for attorneys for use in litigation such as that arising out of the swine flu program. Our judgment was based on estimates. To the extent the attorneys have been hired and are obtaining training and experience in other related areas of litigation, they will provide a reservoir of talent and resoures for use in the swine flu program when additional attorneys are required.

Finally, you also ask whether the activities of the insurance companies involved in the Swine Flu Program may have violated the federal antitrust laws and, if so, whether their profits on the program could be recaptured by the federal government.

The Department is not sufficiently familiar with the activities of the insurance companies in this Program to express any views on whether serious antitrust questions are raised. However, we will make an inquiry into the matter to determine whether a formal investigation is in order, and will be certain to apprise you of our findings.

Very truly yours,

Michael J. Egan

MICHAEL J. EGAN
ASSOCIATE ATTORNEY GENERAL

Mr. ROGERS. Are the HEW people ready to come back now? We will pick up where we left off. Would you give us the cost for the bivalent vaccine?

STATEMENT OF J. DONALD MILLAR, M.D., HARRY M. MEYER, JR., M.D., AND WENDEL BRADFORD—Resumed

Dr. MILLAR. The cost for the bivalent vaccine will vary company by company. These are provisional figures. Nonetheless, the range for the bivalent vaccine is from 38 to 49 cents.

Mr. ROGERS. Would you, for the various companies, put the costs in the record? [See p. 66.]

Now, it is my understanding, that in accordance with the law and the agreement with the manufacturers, they were willing to manufacture the swine flu vaccine and produce it at cost. Production of A-Victoria vaccine, which had been an ongoing program with them, would be permitted to have profit. Is that correct?

Dr. MILLAR. I understand that two audits are underway and a third is beginning shortly.

Mr. ROGERS. What have those audits shown to date?

Dr. MILLAR. There are two companies who chose to produce the bivalent vaccine at no profit.

Mr. ROGERS. Could you name those companies?

Dr. MILLAR. Merck Sharp & Dohme, and Merrill-National.

Mr. ROGERS. They are not asking for profit?

Dr. MILLAR. No. You may be interested to know that there is a substantial difference, of course, in the range of expected costs for monovalent vaccine, the range for those vaccines is 15 to 30 cents per dose.

Mr. ROGERS. Fifteen to thirty cents. If you would supply for the record the name of the various companies, and could you let us have the potency values of those vaccines? I am not asking you to do it now, but for the record.

Dr. MILLAR. We will provide those for the record.

[Testimony resumes on p. 109.]

[The following information was received for the record:]

The four influenza vaccine manufacturers participating in the National Influenza Immunization Program were: Merck Sharp and Dohme, Merrill-National Laboratories, Parke, Davis and Company, and Wyeth Laboratories.

With respect to the potency of the vaccines produced, attached is a report entitled "Evaluation and Control of Vaccines for, the National Influenza Program" by Barry, *et al.* Summaries of the tests run and their results can be found in tables 1, 2, and 3 of that report.

EVALUATION AND CONTROL OF VACCINES FOR THE NATIONAL INFLUENZA IMMUNIZATION PROGRAM

(By David W. Barry, Ronald E. Mayner, Division of Virology; Jules M. Meisler, Division of Compliance; and Edward B. Seligmann, Jr., Division of Control Activities; Bureau of Biologics, Food and Drug Administration, Bethesda, Md.)

ACKNOWLEDGEMENTS

The authors wish to thank Mrs. Eva Brown for performance of the CCA tests, Dr. H. D. Hochstein for endotoxin analysis, and Dr. Joan C. May for the thimerosal and formaldehyde assays.

ABSTRACT

The National Influenza Immunization Program of 1976 offered an ideal opportunity to test the capability of the United States system for producing and distributing maximum amounts of inactivated influenza virus vaccine of carefully regulated quality. The four licensed manufacturers were able to porduce and distribute over ten million doses of vaccine per week over a 14 week period. Assays showed that these vaccines were comparable to or exceeded the quality of vaccines produced in recent years under less stressful circumstances.

Because of the extensive clinical trials conducted as part of the program it was possible to make an unprecedented evaluation of the significance of various laboratory tests of vaccine in relation to their pertinence in predicting immunogenicity and reactivity for man. This experience demonstrated the superiority of immunodiffusion methods as compared to the standard chick cell agglutinin method of vaccine potency assay. Qualitative differences in immunogenicity between whole virus and

disrupted virus vaccines were recognized that are not measured by *in vitro* potency tests. The results also indicated that influenza viral components are responsible for most febrile vaccine reactions.

INTRODUCTION

The safety, purity and potency of monovalent A/New Jersey and bivalent A/New Jersey, A/Victoria vaccines is controlled by licensing procedures for manufacturers of influenza vaccine and by lot by lot testing of these vaccines by the manufacturers and the Bureau of Biologics (BoB) of the Food and Drug Administration. The composition and immunogenicity of experimental A/New Jersey and A/Victoria influenza vaccines have been the subject of extensive clinical trials during the spring, summer and fall of 1976. The experimental vaccines may now be compared to licensed influenza vaccines released for use in the National Influenza Immunization Program (NIIP).The large number of licensed lots produced for the 1976–1977 influenza season and the magnitude of testing by the manufacturers and the BoB have permitted accurate determinations of the various components of influenza vaccines and have allowed us to examine the validity of our current procedures for the testing and evaluation of these vaccines. We have, in addition, been able to gain experience with a newer method of potency testing which may be a more accurate and reliable *in vitro* correlate of influenza vaccine immunogenicity.

The NIIP of 1976 has also provided us with precise information concerning the maximum production capability of manufacturers of influenza vaccines in the United Sates as well as the capacity of the government to evaluate and distribute these vaccines. Since the availability and administration of sufficient quantities of an effective vaccine of prime importance in the prevention of deaths during injluenza epidemics, a careful review of the time course of vaccine production, testing, and distribution this year may provide data which will guide us in preparing for future pandemics.

MATERIALS AND METHODS

Vaccines. Influenza vaccine manufacturers participating in the NIIP were: Merck Sharp and Dohme (MSD), Merrell-National Laboratories (MN), Parke, Davis and Comany (PD) and Wyeth Laboratories. MSD and MN produce zonally purified whole virus vaccines and PD manufactures a zonally purified, polysorbate–80 and ether-disrupted virus vaccine. Wyeth disrupts the virus with polysorbate–80 and tri–N–butylphosphate after chromatographic purification. Samples of bulk lots were shipped or delivered to the BoB as part of normal testing and evaluation-for-approval procedures. Only these tests which had been completed by December 16, 1976 are included in the present report.

Chick Cell Agglutination (CCA) potency testing. CCA determinations were performed as previously described (1) and modified (2) to include a standard reference-Reference Influenza Vaccine for CCA Assay Lot 1975. Test vaccine to reference (V/R) ratios thus obtained were multiplied by the assigned value of Reference Vaccine (2400 CCA units/ml) and the results expressed as CCA units/per adult dose (0.5 ml).

Laurell Rocket Immunoelectrophoresis Test. Quantative immuno-electrophoresis (IEP) was performed according to the method of Laurell (6) as modified for hemagglutinin (HA) quantitation (7). Briefly, 1% agarose (Induboise, A 37) slabs containing hyperimmune goat antisera to bromelain-pruified A/NJ/76 hemagglutinin (8) were cast in plexiglass templates. Vaccines were treated with Triton X–100 R (0.4% final concentration) for 30 minutes at room temperature and 10μl aliquotas were dispensed into 3 mm diameter wells punched into IEP slabs. Duplicate samples were electrophoresed for 8 hours at 350v, 40 ma at 0.1 mfd using an Ortec R power supply (Ortec Inc., Oak Ridge, TN). Plates were fixed and stained for 15 minutes in 0.1% Amido Black in 2.5% acetic acid and 35% methanol. Gels were destained in tap water and rocket-shaped zones of antigen-antibody complexes were measured. Estimates of sample HA content were calculated by least squares regression based on four dilutions of a standardized reference vaccine.

Total protein. Protein determinations were performed according to the method of Lowery et al. (3) using crystallized bovine serum albumin (Sigma Chemical Co.) as a standard. Because thimerosal increases the amount of protein detected by this method at a rate of 0.74 μg protein/μg thimerosal (R. E. Mayner, unpublished observations), this amount was calculated and subtracted from the absolute protein values.

Limulus amebocyte lysate (LAL assays). Assays for endotoxin were performed according to methods previously describe (4) using a single lot of lysate #2, Reference Endotoxin Lot #1B, and Reference Influenza Vaccine for Endotoxin Assay, lot #E–1. This vaccine contained 1.043 μg endotoxin/0.5 ml dose using the present

lysate lot #2 (Mean of 186 tests). Four replicate tests were performed on each vaccine and on each of the references. The geometric mean of the test vaccine was divided by that of the reference vaccine to obtain the concentration of endotoxin in the test vaccine relative to that in the reference vaccine. In addition, the concentration of endotoxin in the test vaccine was expressed in μg per 0.5 ml dose of vaccine by means of parallel titration of the Reference Endotoxin.

Formaldehyde assays. Quanitiation of free formaldehyde was performed according to the colorimetric method of Nash using Hantzsch reagent (5).

Thimerosal. The thimerosal content of vaccines was determined as mercury by the cold vapor atomic adsorption method (9, 10) using a Coleman MAS-50 mercury analyzer (Perkin-Elmer Co., Norwalk, CN). Vaccine samples were cold digested in a mixture of 5% potassium permanganate and concenrated sulfuric acid prior to analysis.

Other Tests. Sterility and guinea pig and mouse general safety tests were performed as prescribed in the Code of Federal Regulations (11).

Production time figures. The number of lots received during a given week were summarized for that week as were the lots approved for release by the BoB. Manufacturers were contacted to determine the week during which an individual lot had been shipped from its factory, warehouse or distribution center to a location designated by the Center for Disease Control (CDC). Vaccination rates were obtained from the CDC weekly assessment report on influenza immunization. The mean time required for production, testing, and distribution was quantitated by comparing the cumulative number of doses in each stage at weekly intervals.

RESULTS

Tests performed on each lot of influenza vaccine by the manufacturer and the BoB are indicated on Table 1. The manufacturer performed all tests on each bulk lot and on samples of final container material where applicable. All lots were tested by the BoB for sterility, guinea pig and mouse safety, identity, potency, formaldehyde, endotoxin and protein content. Random analyses of thimerosal and virus inactivation were also performed by the BoB. Barium, polysorbate and tri-N-butylphosphate analyses were performed by the manufacturer only when the material had been used in vaccine production. Some of the tests, such as sterility, virus inactivation and guinea pig and mouse safety tests require six to seven days for completion, whereas it was possible to complete the other tests in one day. All lots submitted to the BoB passed sterility, guinea pig and mouse safety, identity and inactivation tests.

The quantity of various components of the influenza vaccines are shown on Table 2. Protein determinations showed a wide diversity of values with a low mean value of 36.9 μg/dose for the MN monovalent A/New Jersey vaccine to a high of 193.1 μg/dose for the Wyeth monovalent vaccine. A similar range was noted for the bivalent A/New Jersey-A/Victoria vaccines. Mean formaldehyde concentrations ranged between 2.1 and 15.6 μg/dose and were consistent with the individual manufacturer's license protocol for the production of influenza vaccine. Thimerosal values were all within the required range of 50 ± 10 μg/0.5 ml dose. Endotoxin levels were generally lower than in vaccines studied previously (12) with mean levels ranging from a low of 0.007 μg/dose to a high of 0.082 μg/dose.

Results of the potency testing by chicken cell agglutination (CAA) techniques showed that all monovalent vaccines had a mean somewhat greater than the minimal limit of 200 CCA units/0.5 ml adult dose. The range was rather narrow with a low of 208.8 for MSD and a high of 231.6 for Wyeth. Likewise, all of the bivalent vaccines contained somewhat more than the minimum requirement of 400 CCA units. Since CCA testing is the most common source of differences in results between the manufacturers and the BoB, since it is the most common cause of rejection of a lot, and since it has been relied upon as the measure of vaccine potency, a more detailed analysis of CCA testing is presented in Table 3. Significant differences may be noted between the results of both MSD and MN in testing their monovalent vaccines and MN in the testing of their bivalent vaccine when compared to the testing performed by the BoB. No significant differences between PD and the BoB were found in the testing of monovalent or bivalent vaccines; however, wide differences were noted between BoB results and those of Wyeth.

In Table 4 data are presented indicating the amount of A/NJ hemagglutinin in the monovalent and bivalent vaccines produced by the various manufacturers. As was true for the vaccines used in the clinical trials, MSD vaccines contained significantly more and Wyeth significantly less hemagglutinin than vaccines produced by the other manufacturers. Values for each individual manufacturer showed little variation as indicated by the relatively small standard errors.

The number of vaccine lots submitted to the BoB and the number volutarily withdrawn by the manufacturer from consideration for release as of December 16, 1976 are shown in Table 5. These voluntary withdrawals were based on the finding by the BoB of lots which tested below the minimum requirement of 200 CCA units for the monovalent or 400 CCA units for the bivalent vaccine. No lots were withdrawn for failure to meet requirements other than CCA. The 11.6% withdrawal figure is consistent with rates of withdrawal occurring during previous years. These withdrawn lots represent the equivalent of approximately 17,000,000 doses; however, most of the lots withdrawn were subsequently fortified with virus concentrates and then resubmitted to the BoB as a new lot. Therefore, the withdrawal of lots because of low potency did not appear to diminish substantially the total equivalent number of doses (150,034,580) submitted to the BoB by December 16.

As mentioned previously, safety, sterility and inactivation tests require 6 to 7 days to complete, and were performed by both the manufacturer and the BoB on the bulk lots. The manufacturer also tested final container material for safety, sterility and identity. Sequential testing would therefore have caused undue delay in the availability of influenza vaccines. To circumvent this difficulty, concurrent testing by the manufacturer and the BoB was initiated and this resulted in a minimum of delay. Mean time intervals of vaccine testing, shipping and administration are indicated in Table 6, which shows that an average of 16 days elapsed between the receipt of a lot by the BoB and its approval; only an additional 5.8 days elapsed between approval of the lot and shipment of the final container to the destination designated by the CDC. There was an additional 49.7 day mean interval between initiation of shipment by the manufacturers and actual administration to recipients. In figure 1 data are presented illustrating the production capacity of the United States influenza vaccine manufacturers. This was in the range of approximately 10,000,000 doses per week for a period of over 14 weeks. The figure also illustrates that the testing capacity by the BoB and the distribution capacity of the manufacturer roughly paralleled this rate. The rate of administration of vaccine in the program was in the range of 4,000,000 to 5,000,000 doses per week.

DISCUSSION

The BoB has been engaged for a number of years in research designed to evaluate the safety, purity, potency and effectiveness of inactivated influenza vaccines, and extensive laboratory analysis of those used in the NIIP has expanded our knowledge of the viral and non-viral constituents of these vaccines. These studies demonstrated, for example, that monovalent A/New Jersey and bivalent A/New Jersey-A/Victoria vaccines contain approximately the same amount of protein as earlier zonally purified vaccines (12) and considerably less than in non-zonally purified vaccines (13) manufactured before the late 1960's. Only Wyeth vaccine, which is chromatographically but not zonally (14) purified contained small amounts (5-7.5 μgm/dose) of ovalbumin by single radial immunodiffusion (15, R. E. Mayner, unpublished observations), and also contained higher levels of total protein than the other manufacturers' vaccines. Clinical trials, however, demonstrated that Wyeth vaccine induced extremely low rates of adverse reactions, confirming Salk's earlier observations (16) that some component of the virus and not contaminating host protein was responsible for the acute systemic and febrile reactions sometimes observed after influenza immunization.

Some influenza vaccines produced in the past few years, including the Reference Influenza Vaccine for Endotoxin Assay (lot #E-1), have contained more than 1.0 μg of endotoxin/0.5 ml dose. Although a number of clinical studies have also shown a lack of correlation between the amount of endotoxin in recent influenza vaccines and the adverse reactions in humans follwing their use (12,17,18,19), manufacturers have been encouraged to institute a variety of measures to decrease the probability and quantity of bacterial contamination during influenza vaccine production. The finding of low levels of endotoxin in present influenza vaccines gives evidence of the success of their efforts. Although the Reference Influenza Vaccine for Endotoxin Assay contains 1.043 μg of endotoxin per 1200 CCA units of virus and therefore might be expected to have considerably higher values of endotoxin than present vaccines which contain only 200 to 400 CCA units of virus, calculations of the nanograms of endotoxin per CCA unit will indicate this is not the sole explanation for the near absence of endotoxin in present vaccines. The reference endotoxin vaccine has 0.87 ng of endotoxin per CCA unit, whereas the present vaccines contain between 0.03 to 0.36 ng per CCA unit and therefore only about one-third to less than one-thirtieth the proportionate amount of endotoxin as vaccines used in the recent past.

With the introduction of a standard reference into the CCA test, this measure of potency became more reliable (2), but difficulties in obtaining equivalent results between laboratories have nevertheless occasionally occurred. The present data confirm this finding and indicate that significant differences sometimes occurred between the CCA results obtained by MSD and MN and the BoB. However, the actual difference in means between the BoB's results and those of MN in the testing of their monovalent vaccine, for example, is only 7% of the total CCA unitage of the vaccine, well within the coefficient of error of the test (20). On the other hand, the large standard deviation obtained both by the BoB and Wyeth during the testing of representative numbers of both monovalent and bivalent vaccines indicated difficulties on the part of both parties in the precise and consistent determination of potency of this manufacturer's vaccine.

In spite of the generally good correlation of CCA results between the BoB and the manufacturers the test nevertheless remains an indirect one, dependent in part on the affinity of a particular strain of influenza virus for chicken red blood cells. The number of viral particles in preparations containing the same CCA unitage has consequently been found to vary widely (21). A direct measure of the viral hemagglutinin content of inactivated influenza vaccine, as suggested by Schild et al. (22) would enable us to circumvent these difficulties. We have found that the adaptation of the "rocket" electrophoresis test of Laurell (7) to the quantitation of influenza HA is easy to perform and yelds accurate and reproducible results in our laboratory. In addition, the relevance of the results of this test to human immunogenicity has been well demonstrated by the fact that vaccines, such as those produced by MSD, which have a high HA/CCA ratio are also those which are most immunogenic in individuals with little prior antigenic experience with influenza, either through natural infection or immunization (23). The quantity of HA however, is not the sole determining factor in the induction of hemagglutination-inhibiting antibody in such individuals since split-product vaccines containing similar amounts of HA as a whole virus product induce lower levels of antibody in immunological "virgins" (23). Since the HA/immunogenicity ratios for each individual manufacturer's vaccine are fairly constant for each age group with its differing antigenic experience, it is now theoretically possible to predict, with a fair degree of certainty, the immunogenicity of particular influenza vaccines for a population of defined age and prior influenza experience. Manufacturers of influenza vaccine as well as the BoB have now begun using the immunoelectrophoresis test as a laboratory measure of potency of A/New Jersey and other antigens. Should the test continue to yield accurate, reproducible, reliable and relevant results, then consideration will be given to the use of immunoelectrophoresis as the official test of influenza vaccine potency.

In responding to the threat of the A/Hong Kong (H3N2) epidemic of 1968, manufacturers produced only about 10 million doses per month (24); similarly about 50 million doses were prepared in the 5-month period before the 1957 epidemic (25). Past experience had indicated that 3 to 4 months elapse between the first receipt of a strain and the production of a significant number of doses (24). Manufacturers were given approved A/NJ/8/76 seed stocks on February 20, 1976. Although the exact amount of lead time now required by the manufacturers to produce sufficient basic stocks of allantoic fluid vaccine concentrates this year cannot be accurately calculated because of the delays engendered by the requirement for the passage of indemnification legislation (26), it may be estimated to be in the range of 1–2 months. This estimate is supported by the fact that over 5,000 doses were available as early as April 1976 for the clinical trials conducted under the auspices of the U.S. Public Health Service (27, 28). The ability of the manufacturers to then produce, test and distribute 10 million doses of vaccine per week for at least several months is now well established. There appear to be several reasons underlying the greatly increased production this season compared to past epidemic seasons. One of the most important was the early production and use of a high-growth recombinant in this year as opposed to 1957 or 1968 when such recombinants were not used (29). This recombinant, which retained the HswN$_1$ surface antigenic characteristics, was produced by Dr. Edward Kilbourne of the Mount Sinai School of Medicine by recombining A/Ft. Dix/741/76 with A/PR/8/34 and was supplied to the manufacturers on February 27, 1976. It produced a much higher titer of virus when grown in the allantoic cavity of embryonated eggs and therefore allowed for a more favorable dose per egg ratio than had been possible with the original A/NJ/8/76 virus even after a number of egg passages. Other factors which also contributed to increased vaccined production were the assurance of a market for all vaccine produced, and greatly increased efforts including production timetables which involved 24 hour per day, 7 day per week schedules. This experience in dealing with the logistical problems of producing, testing and distributing over 150 million doses of vaccine

should be useful in estimating the capability to provide vaccines when future pandemics occur.

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Table 1

Tests Performed on Influenza Vaccine Lots

Manufacturer		Bureau of Biologics
Bulk Lot	Final Container	Bulk Lot
Sterility (7)*	Sterility (7)	Sterility (7)#
Guinea Pig Safety (7)	Guinea Pig Safety (7)	Guinea Pig Safety (7)#
Mouse Safety (7)	Mouse Safety (7)	Mouse Safety (7)#
Identity	Identity	Identity#
Inactivation (6)		Inactivation (6)
Potency (CCA)†		Potency (CCA)#
Formaldehyde		Formaldehyde#
Endotoxin (LAL)‡		Endotoxin (LAL)#
Protein§		Protein#
Thimerosal		Thimerosal
Barium"		Barium"
Polysorbate"		Immunoelectrophoresis§
Tri-N-Butyl Phosphate"		

* Number in parentheses indicates minimum number of days to perform test.
† Chicken cell agglutination test.
‡ Limulus amebocyte lysate test.
§ Not required by regulation.
" Not applicable to all manufacturers.
Test applied to all lots by BoB.

Table 2

Summary of Test Results on Commercial Influenza Vaccines

Manufacturer*	Total Protein†	Formaldehyde†	Thimerosal†	Endotoxin†	CCA‡
		Monovalent A/NJ/76 Vaccines			
MSD	67.1 ± 9.7§ (42)"	3.2 (42)	49 (10)	.023 (40)	208.8 ± 10.8 (47)
MN	36.9 ± 7.7 (73)	2.1 (71)	51 (12)	.040 (72)	219.6 ± 18.0 (78)
PD	43.7 ± 11.2 (3)	10.5 (2)	45 (1)	.082 (3)	226.8 ± 1.2 (5)
Wyeth	193.1 ± 37.6 (8)	15.6 (8)	51 (5)	.007 (8)	231.6 ± 24.8 (10)
		Bivalent A/NJ/76 - A/Victoria/75 Vaccines			
MSD	157.4 ± 19.0 (10)	3.9 (9)	51 (2)	.042 (9)	430.8 ± 26.4 (10)
MN	91.6 ± 14.9 (10)	5.2 (10)	51 (1)	.020 (10)	426.0 ± 21.6 (10)
PD	51.0 ± 4.6 (28)	11.2 (26)	49 (7)	.058 (28)	436.8 ± 32.4 (29)
Wyeth	242.3 ± 22.7 (16)	15.1 (16)	46 (5)	.009 (16)	448.8 ± 61.2 (16)

* Abbreviations for manufacturers are: MSD-Merck Sharp & Dohme; MN-Merrell-National Laboratories; PD-Parke, Davis and Company.

† µgm/0.5 ml adult dose.

‡ Chicken Cell Agglutination (CCA) units per 0.5 ml adult dose.

§ Indicates one standard deviation.

" Number in parentheses indicates number of lots tested by BoB.

Table 3

Chicken Cell Agglutination (CCA) Test Results

	Manufacturer's Results				Bureau of Biologics' Results				
Name*	Number†	Mean‡	±(SD)	Range	Number	Mean	±(SD)	Range	P"
Monovalent A/NJ/76 Vaccines									
MSD	49	213.6	9.6	201.6 - 240.0	47	208.8	10.8	199.2 - 228.0	<.05
PMI	78	236.4	18.0	200.4 - 280.8	78	219.6	18.0	199.2 - 279.6	<.001
PD	5	222.0	12.0	202.8 - 229.2	5	226.8	1.2	205.2 - 273.6	NS
Wyeth	10	264.0	44.4	217.2 - 328.8	10	231.6	34.8	199.2 - 291.6	NS
Bivalent A/NJ/76 - A/Victoria/75 Vaccines									
MSD	10	429.6	13.2	408.0 - 447.6	10	430.8	26.4	402.0 - 487.2	NS
PMI	10	480.0	30.0	428.4 - 537.6	10	426.0	21.6	403.2 - 469.2	<.001
PD	29	428.4	14.4	408.0 - 464.4	29	436.8	32.4	399.6 - 516.0	NS
Wyeth	16	565.2	78.0	475.2 - 740.4	16	448.8	61.2	399.6 - 608.4	<.001

* Abbreviations for manufacturers as indicated in Table 2.
† Indicates number of samples tested.
‡ All values in terms of CCA units/0.5 ml adult dose.
" When mean value of manufacturer and BoB are compared; NS indicates differences not statistically significant.

Table 4

Hemagglutinin Content of A/New Jersey Component of
Influenza Vaccines as Determined by Immunoelectrophoresis

	Monovalent A/NJ/76 Vaccines				Bivalent A/NJ/76 - A/Victoria/75 Vaccines			
Manufacturer*	Number†	Mean‡	SD	SE	Number	Mean	SD	SE
MSD	44	35.6	5.68	.86	9	36.2	4.54	1.50
		p<.001				p<.001		
MN	68	15.4	2.86	.36	11	19.0	4.34	1.3[illegible]
		NS				p<.05		
PD	5	14.8	.76	.34	28	16.0	3.06	.58
		p<.001				p<.001		
Wyeth	10	12.2	.74	.24	15	8.8	2.78	.7[illegible]

* Abbreviations for manufacturers as indicated in Table 2.
† Indicates number of samples tested.
‡ All values given in terms of µg A/NJ hemagglutinin/0.5 ml adult dose.

Table 5

Amount of Vaccine as of December 16, 1976

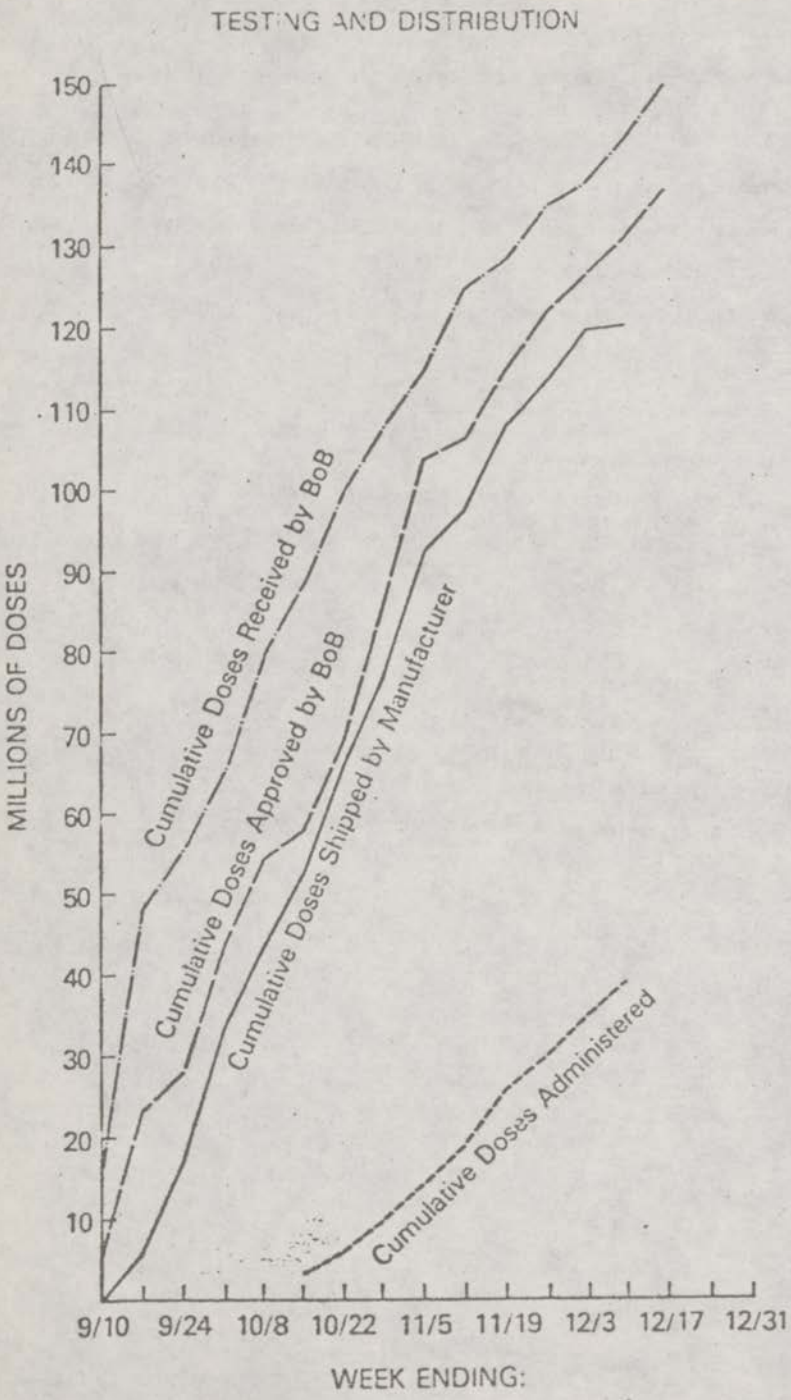
	Monovalent	Bivalent	Total
Number of lots tested	154	78	232
Number of Doses	104,791,826	45,242,754	150,034,580
Number of lots withdrawn	14	13	27
Percent of lots withdrawn	9.0	16.7	11.6

TABLE 6

Intervals During Manufacture, Testing and Distribution of Influenza Vaccines for the National Influenza Immunization Program

Event	Interval in Days
Receipt of lot by BoB	0
Release of lot by BoB	16.0
Shipment of final container by manufacturer	5.8
Distribution and Administration	49.7

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TESTING AND DISTRIBUTION
MILLIONS OF DOSES
150
140
130
120
110
100
90
80
70
60
50
40
30
20
10
Cumulative Doses Received by BoB
Cumulative Doses Approved by BoB
Cumulative Doses Shipped by Manufacturer
Cumulative Doses Administered
9/10
9/24
10/8
10/22
11/5
11/19
12/3
12/17
12/31
WEEK ENDING:

Mr. ROGERS. One of the major criticisms of the program, was the decisionmaking process. Who was involved in reviewing policy. I believe that you have alluded to the problem in your testimony. Would you elaborate on that a little?

What steps have been taken to try to correct that problem?

Dr. MILLAR. Under ordinary circumstances, the process involves the answer to two questions. What will the vaccine contain, and who will receive the vaccine? Under ordinary circumstances, these questions are addressed by two different processes; the Bureau of Biologics in association with certain outside consultants addresses the question of what should be in the vaccine, and the CDC in consultation with its outside consultants addresses the question of who should receive it. Generally speaking, the latter occurs after the Bureau of Biologics has made a determination concerning content of the vaccine.

However, in situations where there is a significant change in the virus, such as occurred in 1957 and 1968 and 1976, there have been significant additions to this process in one form or another.

In 1957 and 1968 the Surgeon General's staff, task forces, or analogues thereto, were asked to deal with the broader policy issue: Should there be some government support for vaccination and how universal should that vaccination be?

In 1976 this additional policy process involved largely the hierarchy of HEW, a special panel of advisors to the President and, of course, congressional action. The eventual program which was produced by those decisions was very similar to the program recommended by the CDC to HEW, based on its consultation with the Advisory Committee on Immunization Practices.

Mr. ROGERS. Mr. Waxman?

Mr. WAXMAN. Thank you, Mr. Chairman.

Dr. Millar, the report that you gave earlier states that on the basis of historical evidence submitted, "I feel that a national influenza immunization program will prove to have been a highly significant and appropriate effort and a positive venture in preventive medicine."

I believe your testimony, if anything, could be termed upbeat. It reminds me of the characterization of prohibition of alcoholic beverages in the 1920's as a noble experiment, but let's not forget that that experiment failed.

Would you term the swine flu program a success, a successful program sponsored by the taxpayers of this country?

Dr. MILLAR. I think the swine flu program represents an appropriate response to the facts that were before the decisionmakers in February and March of last year. The problem is that one still did not know what all the ramifications of a major variant of the influenza virus, were. One can only say at this point that whereas we had previous experiences in which major new variants always occurred in conjunction with pandemics, we now have one experience of something different than that.

We have that additional information with which to confront the next such challenge. I was not at that point involved in the decisionmaking process, but I feel very strongly that there was no acceptable alternative to the course of action that was taken.

Mr. WAXMAN. Let me explore some of the details of the program with you. As I understand it, signed contracts with the vaccine manufacturers have only been entered into as of August of this year. Is that correct?

Dr. MILLAR. That is correct. Signed contracts in the sense of final contracts have only recently been signed with three of the companies. However, letter contracts have existed since early in the program with all the companies. I must apologize to the committee for not having with me a contracting expert, but it is my impression that letter contracts are quite meaningful documents, and indeed we would be happy to provide those, for the record, if that is desirable.

Mr. ROGERS. I think that it would be helpful to have those for the record.

[Testimony resumes on p. 346.]

[The following information was received for record:]

THE SIGNING OF LETTER CONTRACTS

As indicated in the testimony, most of the special contractural requirements of Public Law 94-380 were met by the middle of September 1976, and the Department and manufacturers were moving toward signing contracts. Several issues, however, were difficult to resolve. They are summarized below:

1. Tax status of the self insurance retention fund. The manufacturers were concerned that if this payment of $2.5 million was taxable in the year it was received (1976), most of it would be required to meet the tax imposed. HEW agreed to seek a ruling on this from the Internal Revenue Service. This ruling was requested on November 17, 1976, and a decision was received on April 8, 1977. In essence, IRS ruled that the fund was taxable in the year it was used and not the year it was received. Since this fund could only be used to meet certain legal expenses as specified by Public Law 94-380 and the provisions of each contract, the effect of this ruling was that the fund would always be offset by expenses, resulting in a "tax wash-out." A copy of this ruling is enclosed.

2. Production of "Shope" influenza virus vaccine. This issue related only to one manufacturer (Parke-Davis and Company) and involved the question of Government payment of costs incurred in the production of approximately 6.0 million doses of vaccine, at a cost of about $1.2 million, produced from a laboratory strain of the influenza virus (Shope) which was not approved for use in the 1976-77 program. On November 22, 1976, Parke-Davis submitted a request for payment to the Department. After a review of the facts was completed on August 24, 1977, the Secretary found that the production of the vaccine could not be explained by any of the reasons provided by Parke-Davis. Therefore, the Government could not consider the costs involved as legitimate costs under the contract. These costs have been disallowed by HEW and Parke-Davis has appealed the HEW decision to the Armed Services Board of Contract Appeals (ASBCA) which has been designated by the Secretary to hear appeals of this nature. The ASBCA will review the facts and circumstances surrounding the Parke-Davis claim for payment and the HEW decision and will render a final opinion of the allowability of the production cost. Once the final judgment has been rendered, a "definitized contract" can be signed with Parke-Davis replacing the existing "letter contract" presently binding the Government and this vaccine manufacturer.

3. Waiver of cost accounting standards. The normal procedure for procuring vaccine is to negotiate a price based on established catalogue or market prices. A supply contract is then awarded on a firm, fixed price basis. The cost accounting standards are not applicable when this procedure is used.

Enactment of Public Law 94-380 required the cost of swine flu vaccine to be determined on a retrospective basis through audit to preclude (or in the case of A/Victoria/75 antigens, to limit) payment of profit. Because of this requirement, the contracts could not be awarded on a firm, fixed price basis, but rather a cost-reimbursement contract was called for. In this type of contract, the price is not established based upon catalogue or market price, and the cost accounting standards become applicable. For reasons discussed below, application of the cost accounting standards was ultimately considered inappropriate.

Significant standards normally included in cost type contracts are: Consistency in estimating, accumulating, and reporting costs; consistency in allocating costs incurred for the same purpose; allocation of home office expenses to segments; capitalization of tangible assets; accounting for unallowable costs; cost accounting period; use of standard costs for direct material and direct labor.

The use of many of those standards is generally predicated on accumulating and reporting costs consistent with the manufacturers' normal cost accounting practices. The vaccine manufacturers, prior to the swine flu program, did not accumulate or report costs on a product-by-product basis. Therefore, their normal accounting practices did not lend themselves to the kind of cost accounting generally associated with these unusual cost type contracts. Although the manufacturers did take steps to establish accounting systems to be able to isolate and report costs of producing swine flu vaccine, in order to use the actual cost accounting standards, they would have had to reestablish their entire accounting system. In addition, it is important to understand that those standards are on *a way* to calculate costs, not *the only* way.

The Department, therefore, elected to permit the manufacturers to establish special cost accounting procedures for the swine flu program without modifying their cost accounting system on a company-wide basis. Such a step would have been excessively costly to the manufacturers and the Government, and was not justified for this one-time special procurement.

In conducting the audits referred to in the answer to question number 4, the Department will, of course, verify that costs have been accounted for in accordance with generally accepted accounting principles and practices.

Faced with these outstanding issues and the need to proceed with vaccine deliveries, the Department and the manufacturers agreed to sign "letter contracts" until such time as the outstanding issues were resolved and "definitized contracts" could be signed. Copies of these "letter contracts" are attached. They contain binding provisions governing all legal aspects of the procurement of vaccine, although there was mutual agreement on the need for further negotiation or clarification on the issues outlined above. Agreements on two of these issues resulted in "definitized contracts" with all manufacturers except Parke-Davis in August 1977.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

OFFICE OF THE
GENERAL COUNSEL

NOV 17 1976

Mr. John Withers
Assistant Commissioner, Technical
Room 3042
Internal Revenue Service
12th & Constitution Ave., N.W.
Washington, D.C. 22024

Dear Mr. Withers:

The Department of Health, Education and Welfare is in the process of negotiating contracts with four pharmaceutical manufacturers to obtain swine flu vaccine to implement the National Swine Flu Immunization Program of 1976 (P.L. 94-380). Although the Department currently has contractual documents obligating the manufacturers to deliver and the Government to pay the reasonable costs for the vaccine, these documents contemplate a more definitive contractual arrangement containing agreements regarding the various cost aspects of the contracts.

We currently intend to provide the manufacturers with a total of $10,000,000 to be used for self-insurance purposes. As a result of the insurance industry's refusal to provide liability coverage below a prescribed minimum of $2,500,000 for each manufacturer, the pharmaceutical manufacturers have been forced to become self-insurers for that amount. Since the authorizing legislation contemplates, in effect, a cost-type contract for the swine flu program, any costs incurred by the contractors for self-insurance are reimbursable by the Government. After studying numerous approaches to the mechanics of the self-insurance aspect, the Department and the manufacturers concluded that the best method, and possibly the only practicable method, was to provide the manufacturers with a fund for self-insurance which could only be used for specified purposes and which was required to be returned to the Government, less any authorized expenditures, by August 31, 1985. Since this approach would provide the manufacturers with a total of $10,000,000, we felt that it would be in the best interest of both the Government and the public to have this money placed in commercial banks earning interest at prevailing commercial rates. The attached proposed contract article was written to reflect this approach.

The question has been raised, however, whether the manufacturers would have to pay tax on either the funds provided for self-insurance or the earned interest. Although the parties negotiated the clause pertaining to the self-insurance fund with the understanding that it would not be taxable income, this Department cannot, of course, speak authoritatively on tax matters.

Accordingly, we request a determination by the Service whether the funds to be provided the contractors, or the interest earned thereon, would be considered taxable income if those funds are administered in accordance with the attached contract article. Since we have reached agreement with our contractors on all of the other contract clauses, we would appreciate an expeditious response. If you desire any additional information please contact either me or Mr. Ronald B. Guttmann (FTS 245-7744) of my staff.

Copies of this letter have been sent to counsel for the four manufacturers, and we will, of course, furnish them with copies of the reply we receive from the Service.

Sincerely yours,

William H. Taft, IV
General Counsel

Attachment

ARTICLE XV

B.1 The cost of the premium for the liability insurance which is solely attributable to this Program is not included in the vaccine price. (See Article IX B; Payment.) In the event that the insurance premium for liability insurance, or any part thereof, is refunded to the contractor under any retrospective, experience-rating plan or similar rating plan, it shall be refunded to the Government not later than thirty (30) days after receipt by the contractor.

B.2 Any money provided to the contractor by the Government for a self-insurance retention fund ("Fund") (see Article IX B; Payment) shall be segregated in a separate account in a federally insured commercial bank with assets in excess of $100,000,000. Said Fund shall be invested in an interest bearing arrangement or arrangements, e.g., Certificates of Deposit, at the bank's prevailing interest rates. In the event any payment by the contractor is required to be made from the invested principal of the Fund prior to the stated maturity date or dates of such invested principal, the total proceeds of such liquidated investment or investments shall be deemed to apply first to principal and secondly to interest. To the extent such total proceeds

are less than the original invested principal, the difference shall be charged against all other accrued interest due the Government. Payments shall be made only from the principal of said account and only for self-insurance losses and related expenditures of the contractor as follows:

(1) All sums which the United States shall have the right to recover from the contractor as damages because of personal injury or death under section 317(k)(7) of the Public Health Service Act (42 U.S.C. 247(b)), and any costs of litigation or attorney fees incurred by the contractor attributable thereto; and

(2) All payments made by the contractor for expenses (other than office expenses or expenses for salaries of employees of the contractor) incurred in the investigation, negotiation, settlement, or defense of any claim or suit alleging personal injury or death arising out of a vaccination received under the National Swine Flu Immunization Program of 1976 and made pursuant to section 317(k)(7) of the Public Health Service Act (42 U.S.C. 247(b)).

Such losses and related expenditures are more particularly described in the insurance policy between the contractor and its respective insurers. Any interest earned on the Fund shall be reinvested with the balance of the principal remaining in the Fund. Any amount provided the contractor by the Government for the Fund, which is not expended by August 1, 1985, including accrued interest to such date, shall be returned to the Government not later than August 31, 1985.

B.3 In the event the contractor is required to pay a claim by the Government pursuant to section 317(k)(7) of the Public Health Service Act (42 U.S.C. 247(b)) after the contractor has returned the unexpended amount provided for self-insurance, including accrued interest, such claim shall be deemed satisfied up to the amount of principal returned to the Government. Therefore, the total of the payment made from the Fund by the contractor and the credits provided to the contractors by the Government, after the unexpended principal and accrued interest have been returned to the Government, shall not exceed $2,500,000.

B.4 It is the understanding of the parties to this contract that since the Fund may only be expended for the reasons stated in B.2 above, and since the unexpended principal of the Fund, including accrued interest, shall be returned to the Government under the circumstances set forth above, they do not constitute income to the contractor.

8 APR 1977

Mr. William H. Taft, IV
General Counsel
Department of Health, Education, and Welfare
330 Independence Avenue, S.W.
Washington, D.C. 20201

Mr. Jim Ranson
(202) 566-4495
T:C:C:2:1

Dear Mr. Taft:

This is in reply to your letter dated November 17, 1976 in which you request information regarding the transfer of certain funds in the factual setting described below.

Pursuant to Public Law No. 94-380, 94th Cong., 2d. Sess., (August 12, 1976), the Federal government instituted the National Swine Flu Immunization Program of 1976 (Program) authorizing the Secretary of Health, Education, and Welfare (HEW) to contract for the procurement of swine flu vaccine.

As required by Public Law No. 94-380, the United States assumes liability, under the Federal Tort Claims Act, Public Law No. 89-506, 89th Cong., 2d. Sess., (July 18, 1966), for claims submitted after September 30, 1976, for personal injury or death arising out of the administration and use of the vaccine based upon the acts or omissions of a manufacturer. If a payment is made by the United States to a claimant, the United States may recover from a manufacturerthat portion of the damages paid and expenses incurred resulting from the failure of a manufacturer to perform its obligations under the procurement contract, or from its negligence.

Under the program each manufacturer obtained insurance coverage from a commercial insurer for claims and related expenses incurred in excess of 2.5 million dollars. It was determined that the additional cost for coverage of the first 2.5 million dollars would be in excess of 3.2 million dollars. Since any reasonable insurance premium incurred by the manufacturers to cover the first 2.5 million dollars of potential liability would be an allowable cost under the cost criteria governing the contracts, HEW determined that the establishment

of an insurance fund for the manufacturers with Funds advanced by the United States would be less costly than obtaining insurance to cover the first 2.5 million dollars of liability from commercial insurers.

The insurance fund agreement provides that: (1) the manufacturers must place the amounts advanced by the United States in a segregated account in a federally-insured commercial bank; (2) the fund must be invested in an interest-bearing arrangement; (3) payment from the fund must be made only from the invested principal of the fund; and (4) payments may be made only for specified losses and related expenditures. Payments from the principal of the fund are limited to: (1) sums that the United States has the right to recover from a manufacturer as damages under the program; and (2) payments made by a manufacturer for expenses (other than office expenses or expenses of salaried employees of the manufacturer) incurred in the investigation, settlement, or defense of any claim or suit, or in the investigation of a case reasonably likely to result in such a claim or suit. Any interest earned on the fund is to be reinvested with the balance of the principal remaining in the fund. Any amount in the fund that is not distributed before August 1, 1985, including all interest accrued to that date, must be returned to the United States not later than August 31, 1985. In no event can the total payments from the fund to a manufacturer exceed 2.5 million dollars. The program is on a cost reimbursement basis that allows no profit to be realized by the manufacturers.

Section 61(a)(1) of the Internal Revenue Code of 1954 ("Code") provides that gross income means all income from whatever source derived, including compensation for services, fees, commissions, and similar items.

Section 162(a) of the Code states that there shall be allowed as a deduction all the ordinary and necessary expenses paid or incurred during the taxable year in carrying on any trade or business.

Payment of the liability of one contracting party by the other contracting party pursuant to the terms of the contract generally results in gross income to the party whose liability is paid. See Old Colony Trust v. Commissioner,

Mr. William H. Taft, IV

279 U.S. 716 (1929), VIII-2 C.B. 222(may)

It would appear that, with respect to transactions governed by Public Law No. 94-350, the funds advanced by the United States are includible in the gross income of the manufacturers under section 61 of the Code in the taxable year in which, and to the extent, the funds are withdrawn from the special account by the manufacturers. It would also appear that the manufacturers may deduct under section 162(a) of the Code amounts paid or incurred by them (1) in satisfaction of damage recoveries owing to the United States, or (2) for expenses incurred in the investigation, settlement, or defense of any claim or suit, or in the investigation of a case reasonably likely to result in such a claim or suit.

The information contained in this letter constitutes general information only and is not a specific ruling on any matter.

Sincerely yours,

(Signed) John L. Crawford

Chief, Corporation Tax Branch

STANDARD FORM 30, REV. 1966
GENERAL SERVICES ADMINISTRATION
FPR (41 CFR) 1-16.101

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

PAGE 1 OF 1

1. AMENDMENT/MODIFICATION NO.	2. EFFECTIVE DATE	3. REQUISITION/PURCHASE REQUEST NO.	4. PROJECT NO. (If applicable)
Modification No. 2	10/27/76		

5. ISSUED BY — CODE

Center for Disease Control
255 East Paces Ferry Road, N. E.
Atlanta, GA 30305

6. ADMINISTERED BY (If other than Block 5) — CODE

Same as shown in Block 5.

ORIGINAL

7. CONTRACTOR NAME AND ADDRESS (Street, city, county, state, and ZIP Code) — CODE — FACILITY CODE

Merck Sharp & Dohme
Div. of Merck & Co., Inc.
West Point, PA 19486

8. ☐ AMENDMENT OF SOLICITATION NO. _____
DATED _____ (See Block 9)
☒ MODIFICATION OF CONTRACT/ORDER NO. Letter 200-76-0424
DATED 9/13/76 (See Block 11)

9. THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in block 12. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation, or as amended, by one of the following methods:

(a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided such telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

10. ACCOUNTING AND APPROPRIATION DATA (If required)

11. THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) ☐ This Change Order is issued pursuant to: _____

The Changes set forth in block 12 are made to the above numbered contract/order.

(b) ☐ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation data, etc.) set forth in block 12.

(c) ☒ This Supplemental Agreement is entered into pursuant to authority of 41 U.S.C. 252(c)(7)

It modifies the above numbered contract as set forth in block 12.

12. DESCRIPTION OF AMENDMENT/MODIFICATION

The following changes are made hereby to referenced contract:

1. Paragraph III - Quantities is changed to read as follows:

The number of doses, by vial sizes, to be furnished under the contract is:

Monovalent Vaccine		Bivalent Vaccine	
10-dose vials -	14,100,000	10-dose vials -	2,300,000
50-dose vials -	26,600,000	50-dose vials -	3,000,000
	40,700,000		5,300,000

2. The Availability Schedule is deleted in its entirety, and the attached Availability Schedule is substituted therefor.

Except as provided herein, all terms and conditions of the document referenced in Block 8, as heretofore changed, remain unchanged and in full force and effect.

15. ☐ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT ☒ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 4 COPIES TO ISSUING OFFICE

14. NAME OF CONTRACTOR/OFFEROR	17. UNITED STATES OF AMERICA
BY _____ (Signature of person authorized to sign)	BY _____ (Signature of Contracting Officer)
15. NAME AND TITLE OF SIGNER (Type or print): John R. Lyons President	16. DATE SIGNED: 10/22/76
	18. NAME OF CONTRACTING OFFICER (Type or print): John L. Williams
	19. DATE SIGNED: 10/21/76

AVAILABILITY SCHEDULE

The quantities by package size listed below shall be available for delivery on the dates shown:

A. Influenza Virus Vaccine, Monovalent
200 CCA units/A/New Jersey/76

	Cumulative 000 Doses		
	10-Dose	50-Dose	Total Doses
October 31, 1976	5,300	10,100	15,400
November 15, 1976	2,100	5,500	23,000
November 30, 1976	1,600	2,800	27,400
December 31, 1976	3,500	5,800	36,700
January 15, 1977	1,600	2,400	40,700

B. Influenza Virus Vaccine, Bivalent
200 CCA units each/A/New Jersey/76 - A/Victoria/3/75

	Cumulative 000 Doses		
	10-Dose	50-Dose	Total Doses
October 31, 1976	2,300	2,700	5,000
November 15, 1976	-	300	5,300

GENERAL SERVICES ADMINISTRATION
FPR (FPMR) (41 CFR) 1-16.101

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1 2

1. AMENDMENT/MODIFICATION NO.	2. EFFECTIVE DATE	3. REQUISITION/PURCHASE REQUEST NO.	4. PROJECT NO. (If applicable)
Modification No. 1	10/5/76		

5. ISSUED BY	CODE	6. ADMINISTERED BY (If other than Block 5)	CODE
HEW, PHS Center for Disease Control 255 East Paces Ferry Road, N. E. Atlanta, GA 30305		Same as shown in Block 5.	

ORIGINAL

7. CONTRACTOR NAME AND ADDRESS (Street, city, county, state, and ZIP Code)

CODE FACILITY CODE

Merck Sharp & Dohme
Division of Merck & Company, Inc.
West Point, PA 19486

8.
☐ AMENDMENT OF SOLICITATION NO. _____
DATED _____ (See Block 9)
☒ MODIFICATION OF CONTRACT/ORDER NO. Letter Contract 200-76-0424
DATED 9/13/76 (See Block 11)

9. THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in block 12. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation, or as amended, by one of the following methods:

(a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided such telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

10. ACCOUNTING AND APPROPRIATION DATA (If required)

NO CHANGE

11. THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) ☐ This Change Order is issued pursuant to: _____
The Changes set forth in block 12 are made to the above numbered contract/order.

(b) ☐ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation data, etc.) set forth in block 12.

(c) ☒ This Supplemental Agreement is entered into pursuant to authority of: 41 U.S.C. 252(c)(7)

It modifies the above numbered contract as set forth in block 12.

12. DESCRIPTION OF AMENDMENT/MODIFICATION

The purpose of this modification is to revise Article IX - Payment of the Letter Contract. Article IX of the Letter Contract is deleted in its entirety and the following Article IX - Payment is substituted therefor:

Article IX - Payment:

A. Payment shall be made within 30 days for all vaccine which has been accepted. Each invoice or voucher shall, as a minimum, identify the appropriate Delivery Order for which the delivery was made, the vaccine type and amount delivered, the unit price, the total price, and the vaccine lot number(s). All payments shall be on a provisional basis pending definitization of a contract. The following prices shall be used for provisional payments for vaccine:

	10-dose vials	50-dose vials
Bivalent Vaccine	$4.50	$20.00
Monovalent Vaccine	$2.80	$12.00

Except as provided herein, all terms and conditions of the document referenced in Block 8, as heretofore changed, remain unchanged and in full force and effect.

13.
☐ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT.
☒ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 4 COPIES TO ISSUING OFFICE

14. NAME OF CONTRACTOR/OFFEROR		15. UNITED STATES OF AMERICA	
BY _____ (Signature of person authorized to sign)		BY _____ (Signature of Contracting Officer)	
17. NAME AND TITLE OF SIGNER (Type or print) John E. Lyons President	16. DATE SIGNED 9/29/76	18. NAME OF CONTRACTING OFFICER (Type or print) John L. Williams	19. DATE SIGNED 10/5/76

STANDARD FORM 36, JULY 1966 GENERAL SERVICES ADMINISTRATION FED. PROC. REG. (41 CFR) 1-16.101	CONTINUATION SHEET	REF. NO. OF DOC. BEING CONT'D. Modification No. 1 Letter Contract 200-76-0424	PAGE 2	OF 2

NAME OF OFFEROR OR CONTRACTOR

Vouchers shall be submitted to the following address:

Center for Disease Control
Bureau of State Services
Immunization Division
1600 Clifton Road, N. E.
Atlanta, GA 30333

5. Payment for self-insurance retention and Insurance Premium on Liability shall be made within 30 days of receipt of contractor's invoice for same. The vaccine prices do not include the cost for self-insurance ($2,500,000) or premiums for liability insurance ($2,166,250) which are solely attributable to the National Swine Flu Immunization Program of 1976.

GENERAL SERVICES ADMINISTRATION
FED PROC REG (41CFR) 1-16.101

AWARD/CONTRACT

PAGE 1 OF 10

2. CONTRACT (Proc. Inst. Ident.) NO.	3. EFFECTIVE DATE	3. REQUISITION/PURCHASE REQUEST/PROJECT NO.	4. CERTIFIED FOR NATIONAL DEFENSE UNDER BDSA REG 2 AND/OR DMS REG. 1. RATING:
Letter Contract No. 200-76-0424			

5. ISSUED BY CODE	6. ADMINISTERED BY (If other than Block 5) CODE	7. DELIVERY
HEW, PHS Center for Disease Control 255 East Paces Ferry Road, N. E. Atlanta, GA 30305	Same as shown in Block 5.	☐ FOR DESTINATION ☒ OTHER (See below)

8. CONTRACTOR NAME AND ADDRESS (No., city, county, State, ZIP code) CODE / FACILITY CODE	9. DISCOUNT FOR PROMPT PAYMENT
Merck Sharp & Dohme Div. of Merck & Company, Inc. West Point, PA 19486	NONE - Terms: Net 30 days *Delivery shall be F.O.B. Destination within Consignee's Premises, to the points shown on Delivery Orders 10. SUBMIT INVOICES (4 copies unless otherwise specified) TO ADDRESS SHOWN IN BLOCK 5

11. SHIP TO/MARK FOR CODE	12. PAYMENT WILL BE MADE BY CODE
As directed on Delivery Orders.	Center for Disease Control Financial Management Office Atlanta, GA 30333

THIS PROCUREMENT WAS ☐ ADVERTISED, ☒ NEGOTIATED, PURSUANT TO: ☐ 10 U.S.C. 2304 (a)( ) ☒ 41 U.S.C. 252 (c)(7)

ACCOUNTING AND APPROPRIATION DATA

75X0943 PHS (Influenza Immunization)
6-6140/6944 4591 (26.11) $17,500,000

13. SCHED NO	14. SUPPLIES/SERVICES	17. QUANTITY	18. UNIT	19. UNIT PRICE	20. AMOUNT
1.	INFLUENZA VIRUS VACCINE, Monovalent, 200 CCA units, A/New Jersey/76 strain, and Bivalent, 200/200 CCA units, A/New Jersey/76-A/Victoria/3/75, to be supplied in accordance with the Scope of Work, Delivery Schedule, and terms set forth herein.				

TOTAL AMOUNT OF CONTRACT $

CONTRACTING OFFICER WILL COMPLETE BLOCK 22 OR 26 AS APPLICABLE

☒ 22. CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 3 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)

☐ 26. AWARD (Contractor is not required to sign this document.) Your offer on Solicitation Number _____, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual document is necessary.

23. NAME OF CONTRACTOR	27. UNITED STATES OF AMERICA
BY _____ (Signature of person authorized to sign)	BY John L. Williams (Signature of Contracting Officer)
24. NAME AND TITLE OF SIGNER (Type or print) John E. Lyons President	25. DATE SIGNED 9/10/76
	28. NAME OF CONTRACTING OFFICER (Type or print) JOHN L WILLIAMS
	29. DATE SIGNED 9/19/76

U.S. GOVERNMENT PRINTING OFFICE : 1977 O-226-926

STANDARD FORM 36, JULY 1966 GSA, SERVICES ADMINISTRATION FPMR (41 CFR) 1-16.101	CONTINUATION SHEET	NO. OF PAGES Letter Contract No. 200-76-0424	PAGE 2 OF 10

NAME OF OFFEROR OR CONTRACTOR

TICLE I - SCOPE OF CONTRACT:

- contractor shall manufacture and distribute influenza vaccine in accordance with the ecifications set forth below during the contract period to the points and in the quanti-es specified on Delivery Orders issued by the Center for Disease Control. The only obli-tions or responsibilities of the Contractor in connection with the National Swine Flu munization Program of 1976 are contained in this contract (with exception that the ntractor agrees to enter into good faith negotiations to definitize the contract.) There s no warranties, express or implied, imposed on the contractor except as ted in this contract.

TICLE II - SPECIFICATIONS:

Type of Vaccine:

The vaccine shall be Influenza Monovalent A/New Jersey/76 (Swine) and Bivalent A/New Jersey/76 (Swine) - A/Victoria/3/75 manufactured under a current establishment and product license as set forth below. Formulation standards, specifications and applicable tests of the vaccine shall be as set forth in the approved product license or as otherwise directed by the Food and Drug Administration.

Product Licensure:

The vaccine supplied under this contract shall be produced under U. S. Establishment License No. 2 and Amendment to the product license for influenza vaccine issued by the Bureau of Biologics. If, during the contract period of performance, the product or establisnment license is suspended or revoked for any reason, production of the vaccine shall be discontinued until such time as the license is renewed. In the event produc-tion is suspended for the above reason, the Government shall not be held liable for failure to procure the guaranteed minimum contained in this contract.

Shelf Life:

Delivered vaccine shall have an expiration date through August 1, 1977. The Government agrees to take all appropriate steps to see that the vaccine is not administered after August 1, 1977.

Containers:

Vaccine shall be contained in vials of 10-dose and 50-dose capacity, with 2ml overfill in the 50-dose vial and 0.9ml overfill in the 10-dose vial. Ten-dose vials shall have an internal neck size no smaller than about 7mm in diameter; 50-dose vials, about 13mm. Vials shall be supplied with stoppers made of nonpyrogenic, high-grade rubber. Cap size for the vials will match the diameter of the necks. Vaccine dosage will be 0.5ml.

Labeling:

Labeling of vials shall be in accordance with 21 CFR 610.60. In addition, the color of label for the monovalent vaccine shall be red with black or white markings, and the color of the bivalent vaccine shall be blue with black or white markings. Lot number shall be specified on each vial label. Text of the labels shall be supplied by the Government.

In addition, labels may bear the following:

Manufactured by Merck Sharp & Dohme, Division of Merck & Co., for the U. S. Government

F. Caps:

Caps shall be the same color as the vial labels - red caps or monovalent vials and blue caps on bivalent vials.

G. Packaging:

For shipping purposes, vials shall be packaged as follows:

10-dose vials - 10 vials Nested in the primary package.
50-dose vials - 20 vials Nested in the primary package.

Each package shall be labeled in accordance with Paragraph 55.2.2.2 - Intermediate Containers of Federal Standard 123D. In addition to the requirements of the referenced Federal Standard, the following is required:

A. Labeling shall show applicable lot numbers.

B. A paste-on label shall be attached to each package. Label shall conform to the sample supplied with RFP.

C. Package inserts shall be placed in each intermediate package, a total of 1 insert per vial per package. Inserts shall be in accordance with the letter from Director, Bureau of Biologics, dated August 20, 1976.

Preservation, packaging, and packing shall furnish a degree of protection to preclude damage to containers and/or contents thereof under normal shipping conditions, handling, etc., and shall conform to applicable carrier rules and regulations, including carriers handling overseas shipments.

Vaccine shall be shipped under refrigeration at a temperature between 2° and 15°C (34° to 60°F). Packing and packaging shall be such that this temperature is maintained during shipment and that shipments shall arrive at destination in undamaged condition.

H. Marking Provisions:

Shipping containers: Containers shall be marked in accordance with Federal Standard Number 123D, January 22, 1975, and shall contain as a minimum the following:

a. Quantity and Unit
b. Purchase Order Number
c. Item Name
d. Contractor Name and Address
e. Gross Weight
f. Lot Number(s)

ARTICLE III - QUANTITIES:

The number of doses, by vial sizes, to be furnished under the contract is:

Monovalent Vaccine		Bivalent Vaccine	
10-dose vials -	12,100,000 doses	10-dose vials -	1,500,000
50-dose vials -	23,700,000 doses	50-dose vials -	2,900,000
	35,800,000 doses		4,400,000

OF OFFEROR OR CONTRACTOR

ıriation in Quantity: A variation in the total quantity supplied hereunder ıll be accepted, provided that such variation is not more or less than ± 15% the contract quantity as specified above. If any excess is available for ·livery prior to the final delivery date (January 15, 1977), the contractor ıll notify the Government of any change in the availability of quantities soon as the status becomes known.

TICLE IV - DISTRIBUTION:

Delivery Points:

The contractor shall deliver the vaccine, F.O.B. Destination, Within Consignee's Premises, as directed on delivery orders, to approximately 200 points in the 50 states and Trust Territories.

Delivery Schedule:

Deliveries shall begin on or before October 1, 1976, with the total amount of bivalent and monovalent vaccine to be delivered in accordance with the attached Availability Schedule. All deliveries shall be completed on or before January 15, 1977.

Overseas Delivery Requirements:

Overseas shipping and delivery methods shall be utilized for delivery to those points located outside the Continental United States.

Time of Delivery:

Delivery shall be made at destination within 15 days after receipt of written or telephonic order.

Shipments shall be made in increments of 10,000 doses.

TICLE V - DELIVERY TERMS:

livery shall be made F.O.B. DESTINATION, WITHIN CONSIGNEE'S PREMISES, as defined below:

e term, "F.O.B. Destination, Within Consignee's Premises," to which this contract is bject, means:

) Delivery, free of expense to the Government to within the doors of the Consignee's premises specified in the contract or delivery instructions.

) That it shall be the responsibility of the contractor to do the following:

(1) Pack and mark in such manner as to afford adequate protection against normal transportation hazards and secure prompt delivery to the consignee, and comply with all packing and marking specifications of the contract;

(2) Properly prepare and distribute commercial bills of lading;

(3) Make delivery laid down within the doors of the consignee's premises specified in the contract or delivery instructions;

OF OFFEROR OR CONTRACTOR

(4) Pay and bear all transportation and accessorial charges for such delivery laid down within the doors of the consignee's premises specified in the contract or delivery instructions;

(5) Be responsible for any loss or damage occurring before delivery is laid down within the doors of the consignee's premises specified in the contract or delivery instructions.

ICLE VI - RETURN OF VACCINE:

requirement to accept unused vaccines at end of the contract period will be placed on ıtractor.

ICLE VII - METHOD OF ORDERING:

:cine shall be ordered by Delivery Orders, each of which will designate the vaccine ıered, quantity required, and destination. Orders may be placed by telephone and con- ıed in writing.

ICLE VIII - INSPECTION AND ACCEPTANCE:

:s of vaccine will be submitted by the contractor to the Bureau of Biologics for reviewing l testing. Following release of the lots, Bureau of Biologics will send a notification of ›roval to the project officer at the Center for Disease Control. Final inspection shall made at consignee's locations. Final acceptance/rejection will be made by the Center for ıse Control. Defective or damaged material received at consignee's locations will be ,..cted in accordance with Article 5 of the General Provisions.

ICLE IX - PAYMENT:

yment shall be made for all vaccine which has been delivered and accepted. Each invoice voucher shall, as a minimum, identify the appropriate Delivery Order for which the de- very was made, the vaccine and amount delivered, the unit price, the total price, and the t number(s). All payments shall be on a provisional basis pending definitization of a ıtract. Vouchers shall be submitted to the following address:

Center for Disease Control
Financial Management Office
255 East Paces Ferry Road, N. E.
Atlanta, GA 30305

ICLE X - PROJECT OFFICER:

e Center for Disease Control, Atlanta, Georgia, will designate an individual to perform as oject Officer during the period of performance of the contract. The Project Officer shall responsible for guidance in regard to the technical aspect of the contract, provide a int for liaison between the manufacturer and other Government agencies (Federal, State, ' ocal) and be the general focal point to address technical and logistical problems ı..ing to the performance under this contract. The Project Officer shall not have the

thority to make any commitments or authorize any changes which affect the contract price, ms, or conditions; any such changes shall be referred to the Contracting Officer for ion.

TICLE XI - PROJECT DIRECTOR:

e Contractor shall designate an individual who will serve as the point of contact garding the technical performance of the contract. This individual shall have the thority necessary to commit the company and shall be assigned responsibilities con- uent with requirements of the contract. The Government reserves the right to prove the Project Director and any successor to that position.

TICLE XII - DELINEATION OF RESPONSIBILITIES OF THE GOVERNMENT AND THE CONTRACTOR:

The parties recognize that the Government has initiated, planned, and is arranging for the implementation of the influenza immunization program. Because of the need to have the vaccine tested, manufactured, and delivered within a relatively short period of time in order that the population may be inoculated in an attempt to prevent an influenza epidemic, the Government has assumed certain responsibilities as specified herein which would ordinarily devolve upon the contractor. It is the intention of the parties that the contractor will be responsible solely for the performance of its obligations under Paragraph C herein. It is the purpose of this Article to delineate the separate responsibilities of the Government and the contractor.

In the light of the circumstances described in Paragraph A hereof, the Government shall be responsible for:

(1) The adequacy of the standards and specifications for the vaccine required to be delivered under this contract, including their compliance with all applicable requirements of law and regulation.

(2) The safety and suitability of materials provided to the contractor by the Government under or in connection with this contract.

(3) The investigation and determination of the safe and effective dosages and adequate directions for the use of the vaccine.

(4) The investigation and determination of the risks and benefits of inoculation with the vaccine.

(5) The development of an adequate statement of information respecting the risks and benefits referred to in subparagraph (4).

(6) The taking of all appropriate steps to assure that each individual to be inoculated (or, where appropriate, a parent or guardian of such individual) is adequately informed of such risks and benefits.

(7) The content of the labeling of the vaccine, including its compliance with all applicable requirements of law and regulation.

(8) The taking of all appropriate steps to assure that each person responsible for administering the vaccine has adequate notice of the labeling of the vaccine, provided that nothing herein shall limit the responsibility which the manufacturer otherwise has to assure that labeling is included in and delivered with each shipment of the vaccine.

DC REG [illegible]		No. 200-75-0424
OFFEROR OR CONTRACTOR		

(9) The arrangements for the implementation of the influenza immunization program, including the issuance of appropriate guidelines and information.

The contractor shall use due care and comply with all applicable laws and regulations in the manufacture and handling of the vaccine in accordance with the specifications herein.

ICLE XIII - DEFINITIZATION:

A fixed price, redeterminable type contract is contemplated. To accomplish this result, the contractor agrees to enter into negotiation promptly with the Contracting Officer over the terms of a definitive contract, which will include all clauses, terms, and conditions as may be mutually agreeable.

The schedules for definitization of this contract are set forth below:

Negotiation of price and other terms and conditions - On or before November 10, 1976.

Target date for definitization - on or before December 1, 1976.

If agreement on a definitive contract to supersede this letter contract is not reached by the target date set forth in B, above, or any extension thereof by the Contracting Officer, the Contracting Officer may, with the approval of the Head of the Procurement Activity, determine a reasonable price subject to appeal by the contractor as provided in the clause "Disputes" of this contract. The contract shall be governed by:

(1). All clauses, terms, and conditions contained in this letter contract except which by their nature are applicable only to a letter contract.

(2) All clauses required by law as of the date of this letter contract..

(3) Such other clauses, terms, and conditions as may be mutually agreed upon.

ICLE XIV - LIMITATION ON CONTRACTOR'S PROFIT:

In accordance with the provisions of P.L. 94-380, the contract price for the vaccine delivered under the contract shall be subject to renegotiation to eliminate any profit realized by the contractor on the swine flu vaccine and to limit the profit realized by the contractor on the A/Victoria/75 vaccine to a reasonable profit. The Secretary of Health, Education, and Welfare will issue criteria for the determination of the costs of the contractor for the vaccine delivered under this contract and for the determination of a reasonable profit on the A/Victoria/75 vaccine.

Any insurance premium amount of which is included in the price of the vaccine delivered under this contract and which is refunded to the contractor under any retrospective, experience-rating plan or similar rating plan shall be refunded to the Government not later than 30 days after receipt of the refund by the contractor. Any amount retained by the contractor for self-insurance which is included in the price of the vaccine delivered under this contract and not expended on or before August 1, 1985, shall be refunded to the Government not later than August 31, 1985. The amount refunded shall include accrued interest on any unexpended funds at the rate determined by the Secretary of the Treasury pursuant to Public Law 92-41, 85 Stat. 97 from the date the contractor

received payment from the Government for the vaccine delivered under this contract. In the event the contractor is required to pay a claim by the Government pursuant to Section 317(k)(7) of the Public Health Service Act after the contractor has refunded the unexpended amount retained for self-insurance, such claim shall be deemed satisfied up to the amount of such refund.

For the purposes of this Article, the contractor shall maintain and make available to the Secretary or his authorized representatives the records specified by the Articles of this contract entitled "Accounts, Audits, and Records"; Examination of Records by Comptroller General (Clause 10 of the General Provisions, SF-32); and Examination of Records by Department of Health, Education, and Welfare (Alterations to SF-32).

In the event the Contracting Officer determines that the contractor has realized any profit on swine flu vaccine or has realized more than a reasonable profit on A/Victoria/75 vaccine, the contract price shall be adjusted in accordance with the requirements of Paragraph A of this Article. Failure of the parties to reach agreement on the renegotiation of the contract price shall be subject to Clause 12 of the General Provisions, entitled "Disputes." The contractor shall make any necessary refunds to the Government not later than thirty days after receipt of the Contracting Officer's final decision. However, if the contractor takes an appeal from the Contracting Officer's final decision it may withhold the funds in question until said appeal is decided. In the event that the decision on appeal is that the Government is entitled to a refund, such refund shall be made within thirty days from the date of the decision, with accrued interest at the rate determined by the Secretary of the Treasury pursuant to Public Law 92-41, 85 Stat. 97 from the date of the contractor's receipt of the Contracting Officer's final decision

TLE XV - COOPERATION IN PROCESSING AND DEFENSE OF CLAIMS AND SUITS:

Pursuant to the provisions of P.L. 94-380, the contractor shall cooperate with the Government in the processing or defense of any claim or suit brought against the United States under the Federal Tort Claims Act based upon alleged acts or omissions of the contractor.

While any such claim is under consideration by the Department of Health, Education, and Welfare's Claims Officer, the contractor shall furnish information requested by the Claims Officer or his representatives as is reasonably necessary to enable the claim to be considered and determined.

Should any action be filed against the United States under the Federal Tort Claims Act based upon alleged acts or omissions of the contractor, the contractor shall render all reasonable cooperation to the Government in the defense of such action as may be requested by the Department of Justice or cognizant United States Attorney. Such cooperation shall include, where appropriate, making records and personnel of the contractor available for pretrial proceedings and for the trial of the action.

TICLE XVI - LIMITATION OF GOVERNMENT'S LIABILITY:

e contractor is not authorized to make expenditures or to incur obligations, in performance this contract, which exceeds $17,500,000. In the event of a termination of this ntract, the Government's liability shall not exceed $17,500,000.

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OF OFFEROR OR CONTRACTOR

'ICLE XVII- GENERAL PROVISIONS AND ALTERATIONS:

General Provisions (SF-32), April 1975 edition are hereby incorporated in this contract, are altered as follows:

Clause 21a, Small Business Subcontracting Program, is applicable if this contract eeds $500,000.00.

Clause 22a, Labor Surplus Area Subcontracting Program, is applicable if this contract exceeds $500,000.00

The attached clauses, listed below, are added to and made a part of the General Provisions:

A. Listing of Employment Openings
B. Minority Business Enterprises Subcontracting Program
C. Unsolicited Samples, Descriptive Literature, or Brand Name Reference
D. Examination of Records by Department of Health, Education, and Welfare
E. Federal, State, and Local Taxes, HEW-328
F. Employment of the Handicapped
G. Termination for Convenience
H. Price Reduction for Defective Cost or Pricing Data
I. Subcontracting Cost or Pricing Data
J. Audit
K. Accounts, Audits, and Records
L. Disclosure Statement - Cost Accounting Practices and Certification
M. Cost Accounting Standards
N. Cost Accounting Standards - Exemption for Contracts of $500,000.00 or Less - Certifications
O. Preaward Equal Opportunity Compliance Reviews
P. Clean Air and Water
Q. Equal Opportunity Clause

STANDARD FORM 36, JULY 1966 GENERAL SERVICES ADMINISTRATION 9 PROC. REG. (41 CFR) 1-16.101	CONTINUATION SHEET	REF NO OF DOC BEING CONTD Letter Contract No. 200-76-0424	PAGE 10 OF 10

NAME OF OFFEROR OR CONTRACTOR

AVAILABILITY SCHEDULE

The quantities by package size listed below shall be available for delivery on the dates FOLLOWS:

Influenza Virus Vaccine, Monovalent
200 CCA units/A/New Jersey/76

Cumulative 000 Doses

	10 Dose	50 Dose	Total Doses
October 15, 1976	1,500	3,000	4,500
October 29, 1976	3,000	5,300	12,800
November 15, 1976	3,600	8,000	24,400
December 3, 1976	1,000	2,000	27,400
January 15, 1977	3,000	5,400	35,800

Influenza Virus Vaccine, Bivalent
200 CCA units each/A/New Jersey/76 - A/Victoria/3/75

Cumulative 000 Doses

	10 Dose	50 Dose	Total Doses
September 30, 1976	-	800	800
October 15, 1976	1,300	800	3,100
October 29, 1976	-	1,300	4,400

GENERAL PROVISIONS

(Supply Contract)

1. DEFINITIONS

As used throughout this contract, the following terms shall have the meaning set forth below:

(a) The term "head of the agency" or "Secretary" as used herein means the Secretary, the Under Secretary, any Assistant Secretary, or any other head or assistant head of the executive or military department or other Federal agency; and the term "his duly authorized representative" means any person or persons or board (other than the Contracting Officer) authorized to act for the head of the agency or the Secretary.

(b) The term "Contracting Officer" means the person executing this contract on behalf of the Government, and any other officer or civilian employee who is a properly designated Contracting Officer; and the term includes, except as otherwise provided in this contract, the authorized representative of a Contracting Officer acting within the limits of his authority.

(c) Except as otherwise provided in this contract, the term "subcontracts" includes purchase orders under this contract.

2. CHANGES

The Contracting Officer may at any time, by a written order, and without notice to the sureties, make changes, within the general scope of this contract, in any one or more of the following: (i) Drawings, designs, or specifications, where the supplies to be furnished are to be specially manufactured for the Government in accordance therewith; (ii) method of shipment or packing; and (iii) place of delivery. If any such change causes an increase or decrease in the cost of, or the time required for, the performance of any part of the work under this contract, whether changed or not changed by any such order, an equitable adjustment shall be made in the contract price or delivery schedule, or both, and the contract shall be modified in writing accordingly. Any claim by the Contractor for adjustment under this clause must be asserted within 30 days from the date of receipt by the Contractor of the notification of change: *Provided, however,* That the Contracting Officer, if he decides that the facts justify such action, may receive and act upon any such claim asserted at any time prior to final payment under this contract. Where the cost of property made obsolete or excess as a result of a change is included in the Contractor's claim for adjustment, the Contracting Officer shall have the right to prescribe the manner of disposition of such property. Failure to agree to any adjustment shall be a dispute concerning a question of fact within the meaning of the clause of this contract entitled "Disputes." However, nothing in this clause shall excuse the Contractor from proceeding with the contract as changed.

3. EXTRAS

Except as otherwise provided in this contract, no payment for extras shall be made unless such extras and the price therefor have been authorized in writing by the Contracting Officer.

4. VARIATION IN QUANTITY

No variation in the quantity of any item called for by this contract will be accepted unless such variation has been caused by conditions of loading, shipping, or packing, or allowances in manufacturing processes, and then only to the extent, if any, specified elsewhere in this contract.

5. INSPECTION

(a) All supplies (which term throughout this clause includes without limitation raw materials, components, intermediate assemblies, and end products) shall be subject to inspection and test by the Government, to the extent practicable at all times and places including the period of manufacture, and in any event prior to acceptance.

(b) In case any supplies or lots of supplies are defective in material or workmanship or otherwise not in conformity with the requirements of this contract, the Government shall have the right either to reject them (with or without instructions as to their disposition) or to require their correction. Supplies or lots of supplies which have been rejected or required to be corrected shall be removed or, if permitted or required by the Contracting Officer, corrected in place by and at the expense of the Contractor promptly after notice, and shall not thereafter be tendered for acceptance unless the former rejection or requirement of correction is disclosed. If the Contractor fails promptly to remove such supplies or lots of supplies which are required to be removed, or promptly to replace or correct such supplies or lots of supplies, the Government either (i) may by contract or otherwise replace or correct such supplies and charge to the Contractor the cost occasioned the Government thereby, or (ii) may terminate this contract for default as provided in the clause of this contract entitled "Default." Unless the Contractor corrects or replaces such supplies within the delivery schedule, the Contracting Officer may require the delivery of such supplies at a reduction in price which is equitable under the circumstances. Failure to agree to such reduction of price shall be a dispute concerning a question of fact within the meaning of the clause of this contract entitled "Disputes."

(c) If any inspection or test is made by the Government on the premises of the Contractor or a subcontractor, the Contractor without additional charge shall provide all reasonable facilities and assistance for the safety and convenience of the Government inspectors in the performance of their duties. If Government inspection or test is made at a point other than the premises of the Contractor or a subcontractor, it shall be at the expense of the Government except as otherwise provided in this contract: *Provided,* That in case of rejection the Government shall not be liable for any reduction in value of samples used in connection with such inspection or test. All inspections and tests by the Government shall be performed in such a manner as not to unduly delay the work. The Government reserves the right to charge to the Contractor any additional cost of Government inspection and test when supplies are not ready at the time such inspection and test is requested by the Contractor or when reinspection or retest is necessitated by prior rejection. Acceptance or rejection of the supplies shall be made as promptly as practicable after delivery, except as otherwise provided in this contract; but failure to inspect and accept or reject supplies shall neither relieve the Contractor from responsibility for such supplies as are not in accordance with the contract requirements nor impose liability on the Government therefor.

(d) The inspection and test by the Government of any supplies or lots thereof does not relieve the Contractor from any responsibility regarding defects or other failures to meet the contract requirements which may be discovered prior to acceptance. Except as otherwise provided in this contract, acceptance shall be conclusive except as regards latent defects, fraud, or such gross mistakes as amount to fraud.

(e) The Contractor shall provide and maintain an inspection system acceptable to the Government covering the supplies hereunder. Records of all inspection work by the Contractor shall be kept complete and available to the Government during

the performance of this contract and for such longer period as may be specified elsewhere in this contract.

6. RESPONSIBILITY FOR SUPPLIES

Except as otherwise provided in this contract, (i) the Contractor shall be responsible for the supplies covered by this contract until they are delivered at the designated delivery point, regardless of the point of inspection; (ii) after delivery to the Government at the designated point and prior to acceptance by the Government or rejection and giving notice thereof by the Government, the Government shall be responsible for the loss or destruction of or damage to the supplies only if such loss, destruction, or damage results from the negligence of officers, agents, or employees of the Government acting within the scope of their employment; and (iii) the Contractor shall bear all risks as to rejected supplies after notice of rejection, except that the Government shall be responsible for the loss, or destruction of, or damage to the supplies only if such loss, destruction or damage results from the gross negligence of officers, agents, or employees of the Government acting within the scope of their employment.

7. PAYMENTS

The Contractor shall be paid, upon the submission of proper invoices or vouchers, the prices stipulated herein for supplies delivered and accepted or services rendered and accepted, less deductions, if any, as herein provided. Unless otherwise specified, payment will be made on partial deliveries accepted by the Government when the amount due on such deliveries so warrants; or, when requested by the Contractor, payment for accepted partial deliveries shall be made whenever such payment would equal or exceed either $1,000 or 50 percent of the total amount of this contract.

8. ASSIGNMENT OF CLAIMS

(a) Pursuant to the provisions of the Assignment of Claims Act of 1940, as amended (31 U.S.C. 203, 41 U.S.C. 15), if this contract provides for payments aggregating $1,000 or more, claims for moneys due or to become due the Contractor from the Government under this contract may be assigned to a bank, trust company, or other financing institution, including any Federal lending agency, and may thereafter be further assigned and reassigned to any such institution. Any such assignment or reassignment shall cover all amounts payable under this contract and not already paid, and shall not be made to more than one party, except that any such assignment or reassignment may be made to one party as agent or trustee for two or more parties participating in such financing. Unless otherwise provided in this contract, payments to an assignee of any moneys due or to become due under this contract shall not, to the extent provided in said Act, as amended, be subject to reduction or setoff. (The preceding sentence applies only if this contract is made in time of war or national emergency as defined in said Act and is with the Department of Defense, the General Services Administration, the Energy Research and Development Administration, the National Aeronautics and Space Administration, the Federal Aviation Administration, or any other department or agency of the United States designated by the President pursuant to Clause 4 of the proviso of section 1 of the Assignment of Claims Act of 1940, as amended by the Act of May 15, 1951, 65 Stat. 41.)

(b) In no event shall copies of this contract or of any plans, specifications, or other similar documents relating to work under this contract, if marked "Top Secret," "Secret," or "Confidential," be furnished to any assignee of any claim arising under this contract or to any other person not entitled to receive the same. However, a copy of any part or all of this contract so marked may be furnished, or any information contained therein may be disclosed, to such assignee upon the prior written authorization of the Contracting Officer.

9. ADDITIONAL BOND SECURITY

If any surety upon any bond furnished in connection with this contract becomes unacceptable to the Government or if any such surety fails to furnish reports as to his financial condition from time to time as requested by the Government, the Contractor shall promptly furnish such additional security as may be required from time to time to protect the interests of the Government and of persons supplying labor or materials in the prosecution of the work contemplated by this contract.

10. EXAMINATION OF RECORDS BY COMPTROLLER GENERAL

(a) This clause is applicable if the amount of this contract exceeds $10,000 and was entered into by means of negotiation, including small business restricted advertising, but is not applicable if this contract was entered into by means of formal advertising.

(b) The Contractor agrees that the Comptroller General of the United States or any of his duly authorized representatives shall, until the expiration of 3 years after final payment under this contract or such lesser time specified in either Appendix M of the Armed Services Procurement Regulation or the Federal Procurement Regulations Part 1–20, as appropriate, have access to and the right to examine any directly pertinent books, documents, papers, and records of the Contractor involving transactions related to this contract.

(c) The Contractor further agrees to include in all his subcontracts hereunder a provision to the effect that the subcontractor agrees that the Comptroller General of the United States or any of his duly authorized representatives shall, until the expiration of 3 years after final payment under the subcontract or such lesser time specified in either Appendix M of the Armed Services Procurement Regulation or the Federal Procurement Regulations Part 1–20, as appropriate, have access to and the right to examine any directly pertinent books, documents, papers, and records of such subcontractor, involving transactions related to the subcontract. The term "subcontract" as used in this clause excludes (1) purchase orders not exceeding $10,000 and (2) subcontracts or purchase orders for public utility services at rates established for uniform applicability to the general public.

(d) The periods of access and examination described in (b) and (c), above, for records which relate to (1) appeals under the "Disputes" clause of this contract, (2) litigation or the settlement of claims arising out of the performance of this contract, or (3) costs and expenses of this contract as to which exception has been taken by the Comptroller General or any of his duly authorized representatives, shall continue until such appeals, litigation, claims, or exceptions have been disposed of.

11. DEFAULT

(a) The Government may, subject to the provisions of paragraph (c) below, by written notice of default to the Contractor, terminate the whole or any part of this contract in any one of the following circumstances:

(i) If the Contractor fails to make delivery of the supplies or to perform the services within the time specified herein or any extension thereof; or

(ii) If the Contractor fails to perform any of the other provisions of this contract, or so fails to make progress as to endanger performance of this contract in accordance with its terms, and in either of these two circumstances does not cure such failure within a period of 10 days (or such longer period as the Contracting Officer may authorize in writing) after receipt of notice from the Contracting Officer specifying such failure.

(b) In the event the Government terminates this contract in whole or in part as provided in paragraph (a) of this clause, the Government may procure, upon such terms and in such manner as the Contracting Officer may deem appropriate, supplies or services similar to those so terminated, and the Contractor shall be liable to the Government for any excess costs for such similar supplies or services: *Provided*, That the Contractor shall continue the performance of this contract to the extent not terminated under the provisions of this clause.

(c) Except with respect to defaults of subcontractors, the

Contractor shall not be liable for any excess costs if the failure to perform the contract arises out of causes beyond the control and without the fault or negligence of the Contractor. Such causes may include, but are not restricted to, acts of God or of the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, freight embargoes, and unusually severe weather; but in every case the failure to perform must be beyond the control and without the fault or negligence of the Contractor. If the failure to perform is caused by the default of a subcontractor, and if such default arises out of causes beyond the control of both the Contractor and subcontractor, and without the fault or negligence of either of them, the Contractor shall not be liable for any excess costs for failure to perform, unless the supplies or services to be furnished by the subcontractor were obtainable from other sources in sufficient time to permit the Contractor to meet the required delivery schedule.

(d) If this contract is terminated as provided in paragraph (a) of this clause, the Government, in addition to any other rights provided in this clause, may require the Contractor to transfer title and deliver to the Government, in the manner and to the extent directed by the Contracting Officer, (i) any completed supplies, and (ii) such partially completed supplies and materials, parts, tools, dies, jigs, fixtures, plans, drawings, information, and contract rights (hereinafter called "manufacturing materials") as the Contractor has specifically produced or specifically acquired for the performance of such part of this contract as has been terminated; and the Contractor shall, upon direction of the Contracting Officer, protect and preserve property in possession of the Contractor in which the Government has an interest. Payment for completed supplies delivered to and accepted by the Government shall be at the contract price. Payment for manufacturing materials delivered to and accepted by the Government and for the protection and preservation of property shall be in an amount agreed upon by the Contractor and Contracting Officer; failure to agree to such amount shall be a dispute concerning a question of fact within the meaning of the clause of this contract entitled "Disputes." The Government may withhold from amounts otherwise due the Contractor for such completed supplies or manufacturing materials such sum as the Contracting Officer determines to be necessary to protect the Government against loss because of outstanding liens or claims of former lien holders.

(e) If, after notice of termination of this contract under the provisions of this clause, it is determined for any reason that the Contractor was not in default under the provisions of this clause, or that the default was excusable under the provisions of this clause, the rights and obligations of the parties shall, if the contract contains a clause providing for termination for convenience of the Government, be the same as if the notice of termination had been issued pursuant to such clause. If, after notice of termination of this contract under the provisions of this clause, it is determined for any reason that the Contractor was not in default under the provisions of this clause, and if this contract does not contain a clause providing for termination for convenience of the Government, the contract shall be equitably adjusted to compensate for such termination and the contract modified accordingly; failure to agree to any such adjustment shall be a dispute concerning a question of fact within the meaning of the clause of this contract entitled "Disputes."

(f) The rights and remedies of the Government provided in this clause shall not be exclusive and are in addition to any other rights and remedies provided by law or under this contract.

(g) As used in paragraph (c) of this clause, the terms "subcontractor" and "subcontractors" mean subcontractor(s) at any tier.

12. DISPUTES

(a) Except as otherwise provided in this contract, any dispute concerning a question of fact arising under this contract which is not disposed of by agreement shall be decided by the Contracting Officer, who shall reduce his decision to writing and mail or otherwise furnish a copy thereof to the Contractor. The decision of the Contracting Officer shall be final and conclusive unless, within 30 days from the date of receipt of such copy, the Contractor mails or otherwise furnishes to the Contracting Officer a written appeal addressed to the Secretary. The decision of the Secretary or his duly authorized representative for the determination of such appeals shall be final and conclusive unless determined by a court of competent jurisdiction to have been fraudulent, or capricious, or arbitrary, or so grossly erroneous as necessarily to imply bad faith, or not supported by substantial evidence. In connection with any appeal proceeding under this clause, the Contractor shall be afforded an opportunity to be heard and to offer evidence in support of its appeal. Pending final decision of a dispute hereunder, the Contractor shall proceed diligently with the performance of the contract and in accordance with the Contracting Officer's decision.

(b) This "Disputes" clause does not preclude consideration of law questions in connection with decisions provided for in paragraph (a) above: *Provided*, That nothing in this contract shall be construed as making final the decision of any administrative official, representative, or board on a question of law.

13. NOTICE AND ASSISTANCE REGARDING PATENT AND COPYRIGHT INFRINGEMENT

The provisions of this clause shall be applicable only if the amount of this contract exceeds $10,000.

(a) The Contractor shall report to the Contracting Officer, promptly and in reasonable written detail, each notice or claim of patent or copyright infringement based on the performance of this contract of which the Contractor has knowledge.

(b) In the event of any claim or suit against the Government on account of any alleged patent or copyright infringement arising out of the performance of this contract or out of the use of any supplies furnished or work or services performed hereunder, the Contractor shall furnish to the Government, when requested by the Contracting Officer, all evidence and information in possession of the Contractor pertaining to such suit or claim. Such evidence and information shall be furnished at the expense of the Government except where the Contractor has agreed to indemnify the Government.

14. BUY AMERICAN ACT

(a) In acquiring end products, the Buy American Act (41 U.S. Code 10 a–d) provides that the Government give preference to domestic source end products. For the purpose of this clause:

(i) "Components" means those articles, materials, and supplies, which are directly incorporated in the end products;

(ii) "End products" means those articles, materials, and supplies, which are to be acquired under this contract for public use; and

(iii) A "domestic source end product" means (A) an unmanufactured end product which has been mined or produced in the United States and (B) an end product manufactured in the United States if the cost of the components thereof which are mined, produced, or manufactured in the United States exceeds 50 percent of the cost of all its components. For the purposes of this (a) (iii) (B), components of foreign origin of the same type or kind as the products referred to in (b) (ii) or (iii) of this clause shall be treated as components mined, produced, or manufactured in the United States.

(b) The Contractor agrees that there will be delivered under this contract only domestic source end products, except end products:

(i) Which are for use outside the United States;

(ii) Which the Government determines are not mined, produced, or manufactured in the United States in sufficient and reasonably available commercial quantities and of a satisfactory quality;

(iii) As to which the Secretary determines the domestic preference to be inconsistent with the public interest; or

(iv) As to which the Secretary determines the cost to the Government to be unreasonable.

(The foregoing requirements are administered in accordance with Executive Order No. 10582, dated December 17, 1954.)

15. CONVICT LABOR

In connection with the performance of work under this contract, the Contractor agrees not to employ any person undergoing sentence of imprisonment at hard labor except as provided by Public Law 89-176, September 10, 1965 (18 U.S.C. 4082(c)(2)) and Executive Order 11755, December 29, 1973.

16. CONTRACT WORK HOURS AND SAFETY STANDARDS ACT—OVERTIME COMPENSATION

This contract, to the extent that it is of a character specified in the Contract Work Hours and Safety Standards Act (40 U.S.C. 327-333), is subject to the following provisions and to all other applicable provisions and exceptions of such Act and the regulations of the Secretary of Labor thereunder.

(a) Overtime requirements. No Contractor or subcontractor contracting for any part of the contract work which may require or involve the employment of laborers, mechanics, apprentices, trainees, watchmen, and guards shall require or permit any laborer, mechanic, apprentice, trainee, watchman, or guard in any workweek in which he is employed on such work to work in excess of eight hours in any calendar day or in excess of forty hours in such workweek on work subject to the provisions of the Contract Work Hours and Safety Standards Act unless such laborer, mechanic, apprentice, trainee, watchman, or guard receives compensation at a rate not less than one and one-half times his basic rate of pay for all such hours worked in excess of eight hours in any calendar day or in excess of forty hours in such workweek, whichever is the greater number of overtime hours.

(b) Violation; liability for unpaid wages; liquidated damages. In the event of any violation of the provisions of paragraph (a), the Contractor and any subcontractor responsible therefor shall be liable to any affected employee for his unpaid wages. In addition, such Contractor and subcontractor shall be liable to the United States for liquidated damages. Such liquidated damages shall be computed with respect to each individual laborer, mechanic, apprentice, trainee, watchman, or guard employed in violation of the provisions of paragraph (a) in the sum of $10 for each calendar day on which such employee was required or permitted to be employed on such work in excess of eight hours or in excess of his standard workweek of forty hours without payment of the overtime wages required by paragraph (a).

(c) Withholding for unpaid wages and liquidated damages. The Contracting Officer may withhold from the Government Prime Contractor, from any moneys payable on account of work performed by the Contractor or subcontractor, such sums as may administratively be determined to be necessary to satisfy any liabilities of such Contractor or subcontractor for unpaid wages and liquidated damages as provided in the provisions of paragraph (b).

(d) Subcontracts. The Contractor shall insert paragraphs (a) through (d) of this clause in all subcontracts, and shall require their inclusion in all subcontracts of any tier.

(e) Records. The Contractor shall maintain payroll records containing the information specified in 29 CFR 516.2(a). Such records shall be preserved for three years from the completion of the contract.

17. WALSH-HEALEY PUBLIC CONTRACTS ACT

If this contract is for the manufacture or furnishing of materials, supplies, articles, or equipment in an amount which exceeds or may exceed $10,000 and is otherwise subject to the Walsh-Healey Public Contracts Act, as amended (41 U.S. Code 35-45), there are hereby incorporated by reference all representations and stipulations required by said Act and regulations issued thereunder by the Secretary of Labor, such representations and stipulations being subject to all applicable rulings and interpretations of the Secretary of Labor which are now or may hereafter be in effect.

18. EQUAL OPPORTUNITY

(The following clause is applicable unless this contract is exempt under the rules, regulations, and relevant orders of the Secretary of Labor (41 CFR, ch. 60).)

During the performance of this contract, the Contractor agrees as follows:

(a) The Contractor will not discriminate against any employee or applicant for employment because of race, color, religion, sex, or national origin. The Contractor will take affirmative action to ensure that applicants are employed, and that employees are treated during employment, without regard to their race, color, religion, sex, or national origin. Such action shall include, but not be limited to, the following: Employment, upgrading, demotion, or transfer; recruitment or recruitment advertising; layoff or termination; rates of pay or other forms of compensation; and selection for training, including apprenticeship. The Contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices to be provided by the Contracting Officer setting forth the provisions of this Equal Opportunity clause.

(b) The Contractor will, in all solicitations or advertisements for employees placed by or on behalf of the Contractor, state that all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, or national origin.

(c) The Contractor will send to each labor union or representative of workers with which he has a collective bargaining agreement or other contract or understanding, a notice, to be provided by the agency Contracting Officer, advising the labor union or workers' representative of the Contractor's commitments under this Equal Opportunity clause, and shall post copies of the notice in conspicuous places available to employees and applicants for employment.

(d) The Contractor will comply with all provisions of Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, and of the rules, regulations, and relevant orders of the Secretary of Labor.

(e) The Contractor will furnish all information and reports required by Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, and by the rules, regulations, and orders of the Secretary of Labor, or pursuant thereto, and will permit access to his books, records, and accounts by the contracting agency and the Secretary of Labor for purposes of investigation to ascertain compliance with such rules, regulations, and orders.

(f) In the event of the Contractor's noncompliance with the Equal Opportunity clause of this contract or with any of the said rules, regulations, or orders, this contract may be canceled, terminated, or suspended, in whole or in part, and the Contractor may be declared ineligible for further Government contracts in accordance with procedures authorized in Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, and such other sanctions may be imposed and remedies invoked as provided in Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, or by rule, regulation, or order of the Secretary of Labor, or as otherwise provided by law.

(g) The Contractor will include the provisions of paragraphs (a) through (g) in every subcontract or purchase order unless exempted by rules, regulations, or orders of the Secretary of Labor issued pursuant to section 204 of Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, so that such provisions will be binding upon each subcontractor or vendor. The Contractor will take such action with respect to any subcontract or purchase order as the contracting agency may direct as a means of enforcing such provisions, including sanctions for noncompliance: *Provided, however*, That in the event the Contractor becomes involved in,

or is threatened with, litigation with a subcontractor or vendor as a result of such direction by the contracting agency, the Contractor may request the United States to enter into such litigation to protect the interests of the United States.

19. OFFICIALS NOT TO BENEFIT

No member of or delegate to Congress, or resident Commissioner, shall be admitted to any share or part of this contract, or to any benefit that may arise therefrom; but this provision shall not be construed to extend to this contract if made with a corporation for its general benefit.

20. COVENANT AGAINST CONTINGENT FEES

The Contractor warrants that no person or selling agency has been employed or retained to solicit or secure this contract upon an agreement or understanding for a commission, percentage, brokerage, or contingent fee, excepting bona fide employees or bona fide established commercial or selling agencies maintained by the Contractor for the purpose of securing business. For breach or violation of this warranty the Government shall have the right to annul this contract without liability or in its discretion to deduct from the contract price or consideration, or otherwise recover, the full amount of such commission, percentage, brokerage, or contingent fee.

21. UTILIZATION OF SMALL BUSINESS CONCERNS

(a) It is the policy of the Government as declared by the Congress that a fair proportion of the purchases and contracts for supplies and services for the Government be placed with small business concerns.

(b) The Contractor agrees to accomplish the maximum amount of subcontracting to small business concerns that the Contractor finds to be consistent with the efficient performance of this contract.

22. UTILIZATION OF LABOR SURPLUS AREA CONCERNS

(a) It is the policy of the Government to award contracts to labor surplus area concerns that (1) have been certified by the Secretary of Labor (hereafter referred to as certified-eligible concerns with first or second preferences) regarding the employment of a proportionate number of disadvantaged individuals and have agreed to perform substantially (i) in or near sections of concentrated unemployment or underemployment or in persistent or substantial labor surplus areas or (ii) in other areas of the United States, respectively, or (2) are noncertified concerns which have agreed to perform substantially in persistent or substantial labor surplus areas, where this can be done consistent with the efficient performance of the contract and at prices no higher than are obtainable elsewhere. The Contractor agrees to use his best efforts to place his subcontracts in accordance with this policy.

(b) In complying with paragraph (a) of this clause and with paragraph (b) of the clause of this contract entitled "Utilization of Small Business Concerns" the Contractor in placing his subcontracts shall observe the following order of preference: (1) Certified-eligible concerns with a first preference which are also small business concerns; (2) other certified-eligible concerns with a first preference; (3) certified-eligible concerns with a second preference which are also small business concerns; (4) other certified-eligible concerns with a second preference; (5) persistent or substantial labor surplus area concerns which are also small business concerns; (6) other persistent or substantial labor surplus area concerns; and (7) small business concerns which are not labor surplus area concerns.

23. UTILIZATION OF MINORITY BUSINESS ENTERPRISES

(a) It is the policy of the Government that minority business enterprises shall have the maximum practicable opportunity to participate in the performance of Government contracts.

(b) The Contractor agrees to use his best efforts to carry out this policy in the award of his subcontracts to the fullest extent consistent with the efficient performance of this contract. As used in this contract, the term "minority business enterprise" means a business, at least 50 percent of which is owned by minority group members or, in case of publicly-owned businesses, at least 51 percent of the stock of which is owned by minority group members. For the purposes of this definition, minority group members are Negroes, Spanish-speaking American persons, American-Orientals, American-Indians, American-Eskimos, and American Aleuts. Contractors may rely on written representations by subcontractors regarding their status as minority business enterprises in lieu of an independent investigation.

24. PRICING OF ADJUSTMENTS

When costs are a factor in any determination of a contract price adjustment pursuant to the Changes clause or any other provision of this contract, such costs shall be in accordance with the contract cost principles and procedures in Part 1-15 of the Federal Procurement Regulations (41 CFR 1-15) or Section XV of the Armed Services Procurement Regulation, as applicable, which are in effect on the date of this contract.

25. PAYMENT OF INTEREST ON CONTRACTORS' CLAIMS

(a) If an appeal is filed by the Contractor from a final decision of the Contracting Officer under the Disputes clause of this contract, denying a claim arising under the contract, simple interest on the amount of the claim finally determined owed by the Government shall be payable to the Contractor. Such interest shall be at the rate determined by the Secretary of the Treasury pursuant to Public Law 92-41, 85 Stat. 97, from the date the Contractor furnishes to the Contracting Officer his written appeal under the Disputes clause of this contract, to the date of (1) a final judgment by a court of competent jurisdiction, or (2) mailing to the Contractor of a supplemental agreement for execution either confirming completed negotiations between the parties or carrying out a decision of a board of contract appeals.

(b) Notwithstanding (a), above, (1) interest shall be applied only from the date payment was due, if such date is later than the filing of appeal, and (2) interest shall not be paid for any period of time that the Contracting Officer determines the Contractor has unduly delayed in pursuing his remedies before a board of contract appeals or a court of competent jurisdiction.

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Clause 21(a) SMALL BUSINESS SUBCONTRACTING PROGRAM

FPR 1-1.710-3(b)

(a) The Contractor agrees to establish and conduct a small business subcontracting program which will enable small business concerns to be considered fairly as subcontractors and suppliers under this contract. In this connection, the Contractor shall:

(1) Designate a liaison officer who will (i) maintain liaison with the Government on small business matters, (ii) supervise compliance with the Utilization of Small Business Concerns clause, and (iii) administer the Contractor's "Small Business Subcontracting Program."

(2) Provide adequate and timely consideration of the potentialities of small business concerns in all "make-or-buy" decisions.

(3) Assure that small business concerns will have an equitable opportunity to compete for subcontracts, particularly by arranging solicitations, time for the preparation of bids, quantities, specifications, and delivery schedules so as to facilitate the participation of small business concerns. Where the Contractor's lists of potential small business subcontractors are excessively long, reasonable effort shall be made to give all such small business concerns an opportunity to compete over a period of time.

(4) Maintain records showing (i) whether each prospective subcontractor is a small business concern, (ii) procedures which have been adopted to comply with the policies set forth in this clause, and (iii) with respect to the letting of any subcontract (including purchase orders) exceeding $10,000, information substantially as follows:

(A) Whether the award went to large or small business.

(B) Whether less than three or more than two small business firms were solicited.

(C) The reason for nonsolicitation of small business if such was the case.

(D) The reason for small business failure to receive the award if such was the case when small business was solicited.

The records maintained in accordance with (iii) above may be in such form as the Contractor may determine, and the information shall be summarized quarterly and submitted by the purchasing department of each individual plant or division to the Contractor's cognizant small business liaison officer. Such quarterly summaries will be considered to be management records only and need not be submitted routinely to the Government; however, records maintained pursuant to this clause will be kept available for review by the Government until the expiration of 1 year after the award of this contract, or for such longer period as may be required by any other clause of this contract or by applicable law or regulation.

(5) Notify the Contracting Officer before soliciting bids or quotations on any subcontract (including purchase orders) in excess of $10,000 if (i) no small business concern is to be solicited, and (ii) the Contracting Officer's consent to the subcontract (or ratification) is required by a "Subcontracts" clause in this contract. Such notice will state the Contractor's reasons for non-solicitation of small business concerns, and will be given as early in the procurement cycle as possible so that the Contracting Officer may give SBA timely notice to permit SBA a reasonable period to suggest potentially qualified small business concerns through the Contracting Officer. In no case will the procurement action be held up when to do so would, in the Contractor's judgment, delay performance under the contract.

(6) Include the Utilization of Small Business Concerns clause in subcontracts which offer substantial small business subcontracting opportunities.

(7) Cooperate with the Contracting Officer in any studies and surveys of the Contractor's subcontracting procedures and practices that the Contracting Officer may from time to time conduct.

(8) Submit quarterly reports of subcontracting to small business concerns on either Optional Form 61, Small Business Subcontracting Program Quarterly Report of Participating Large Company on Subcontract Committments to Small Business Concerns, or such other form as may be specified in the contract. Except as otherwise provided in this contract, the reporting requirements of this subparagraph (8) do not apply to small business contractors, small business subcontractors, educational and nonprofit institutions, and contractors or subcontractors for standard commercial items.

(b) A "small business concern" is a concern that meets the pertinent criteria established by the Small Business Administration and set forth in § 1-701 of the Federal Procurement Regulations.

(c) The Contractor agrees that, in the event he fails to comply with his contractual obligations concerning the small business subcontracting program, this contract may be terminated, in whole or in part, for default.

(d) The Contractor further agrees to insert, in any subcontract hereunder which may exceed $500,000 and which contains the Utilization of Small Business Concerns clause, provisions which shall conform substantially to the language of this clause, including this paragraph (d), and to notify the Contracting Officer of the names of such subcontractors.

Clause 22a

LABOR SURPLUS AREA SUBCONTRACTING PROGRAM

FPR 1-1.805-3(b)

(This clause is applicable if this contract exceeds $500,000.00)

(a) The Contractor agrees to establish and conduct a program which will encourage labor surplus area concerns to compete for subcontracts within their capabilities. In this connection, the Contractor shall:

(1) Designate a liaison officer who will (i) maintain liaison with duly authorized representatives of the Government on labor surplus area matters, (ii) supervise compliance with the Utilization of Concerns in Labor Surplus Areas clause, and (iii) administer the Contractor's "Labor Surplus Area Subcontracting Program";

(2) Provide adequate and timely consideration of the potentialities of labor surplus area concerns in all "make-or-buy" decisions;

(3) Assure that labor surplus area concerns will have an equitable opportunity to compete for subcontracts, particularly by arranging solicitations, time for the preparation of bids, quantities, specifications, and delivery schedules so as to facilitate the participation of labor surplus area concerns;

(4) Maintain records showing procedures which have been adopted to comply with the policies set forth in this clause. Records maintained pursuant to this clause will be kept available for review by the Government until the expiration of 1 year after the award of this contract, or for such longer period as may be required by any other clause of this contract or by applicable law or regulations; and

(5) Include the Utilization of Concerns in Labor Surplus Areas clause in subcontracts which offer substantial labor surplus area subcontracting opportunities.

(b) A "labor surplus area concern" is a concern that (1) has been certified by the Secretary of Labor (hereafter referred to as a certified-eligible concern) regarding the employment of a proportionate number of disadvantaged individuals and has agreed to perform substantially in or near sections of concentrated unemployment or underemployment, in persistent or substantial labor surplus

areas, or in other areas of the United States or (2) is a noncertified concern which has agreed to perform a substantial proportion of a contract in persistent or substantial labor surplus areas. A certified-eligible concern shall be deemed to have performed a substantial proportion of a contract in or near sections of concentrated unemployment or underemployment, in persistent or substantial labor surplus areas, or in other areas if the costs that the concern will incur on account of manufacturing or production in or near such sections or in such areas (by itself, if a certified concern, or by certified concerns acting as first-tier subcontractors) amount to more than 25 percent of the contract price. A concern shall be deemed to have performed a substantial proportion of a contract in persistent of substantial surplus areas (by itself or its first-tier subcontractors) if the costs that the concern will incur on account of production or manufacturing in such areas amount to more than 50 percent of the contract price.

(c) The Contractor further agrees to insert, in any subcontract hereunder which may exceed $500,000 and which contains the Utilization of Concerns in Labor Surplus Areas clause, provisions which shall conform substantially to the language of this clause, including this paragraph (c), and to notify the Contracting Officer of the names of such subcontractors.

Clause 24

PRICING OF ADJUSTMENTS

When costs are a factor in any determination of a contract price adjustment pursuant to the "Changes" clause or any other provision of this contract, such costs shall be in accordance with the contract cost and profit criteria contained in Appendix A of this contract.

MODIFICATIONS TO GENERAL PROVISIONS, STANDARD FORM 32 (Supply)

Disabled Veterans and Veterans of the Vietnam Era

(This clause is applicable pursuant to 41 CFR 50-250 if this contract is for $10,000 or more.)

(a) The contractor will not discriminate against any employee or applicant for employment because he or she is a disabled veteran or veteran of the Vietnam era in regard to any position for which the employee or applicant for employment is qualified. The contractor agrees to take affirmative action to employ, advance in employment, and otherwise treat qualified disabled veterans and veterans of the Vietnam era without discrimination based upon their disability or veterans status in all employment practices such as the following: employment upgrading, demotion or transfer, recruitment, advertising, layoff or termination, rates of pay or other forms of compensation, and selection for training, including apprenticeship.

(b) The contractor agrees that all suitable employment openings of the contractor which exist at the time of the execution of this contract and those which occur during the performance of this contract, including those not generated by this contract and including those occurring at an establishment of the contractor other than the one wherein the contract is being performed but excluding those of independently operated corporate affiliates, shall be listed at an appropriate local office of the State employment service system wherein the opening occurs. The contractor further agrees to provide such reports to such local office regarding employment openings and hires as may be required.

State and local government agencies holding Federal contracts of $10,000 or more shall also list all their suitable openings with the appropriate office of the State employment service, but are not required to provide those reports set forth in paragraphs (d) and (e).

(c) Listing of employment openings with the employment service system pursuant to this clause shall be made at least concurrently with the use of any other recruitment source or effort and shall involve the normal obligations which attache to the placing of a bona fide job order, including the acceptance of referrals of veterans and nonveterans. The listing of employment openings does not require the hiring of any particular job applicant or from any particular group of job applicants, and nothing herein is intended to relieve the contractor from any requirements in Executive orders or regulations regarding nondiscrimination in employment.

(d) The reports required by paragraph (b) of this clause shall include, but not be limited to, periodic reports which shall be filed at least quarterly with the appropriate local office or, where the contractor has more than one hiring location in a State, with the central office of that State employment service. Such reports shall indicate for each hiring location (a) the number of individuals hired during the reporting period, (2) the number of nondisabled veterans of the Vietnam era hired, (3) the number of disabled veterans of the Vietnam era hired, and (4) the total number of disabled veterans hired. The reports should include covered veterans hired for on-the-job training under

38 U.S.C. 1787. The contractor shall submit a report within 30 days after the end of each reporting period wherein any performance is made on this contract identifying data for each hiring location. The contractor shall maintain at each hiring location copies of the reports submitted until the expiration of one year after final payment under the contract during which time these reports and related documentation shall be made available, upon request, for examination by any authorized representatives of the Contracting Officer or of the Secretary of Labor. Documentation would include personnel records respecting job openings, recruitment, and placement.

(e) Whenever the contractor becomes contractually bound to the listing provisions of this clause, it shall advise the employment service system in each State where it has establishments of the name and location of each hiring location in the State. As long as the contractor is contractually bound to these provisions and has so advised the State system, there is no need to advise the State system of subsequent contracts. The contractor may advise the State system when it is no longer bound by this contract clause.

(f) This clause does not apply to the listing of employment openings which occur and are filled outside the 50 States, the District of Columbia, Puerto Rico, Guam, and the Virgin Islands.

(g) The provisions of paragraphs (b), (c), (d), and (e) of this clause do not apply to openings which the contractor proposes to fill from within his own organization or to fill pursuant to a customary and traditional employer-union hiring arrangement. This exclusion does not apply to a particular opening once an employer decides to consider applicants outside of his own organization or employer-union arrangement for that opening.

(h) As used in this clause: (1) "All suitable employment openings" includes, but is not limited to, openings which occur in the following job categories: production and non-production; plant and office; laborers and mechanics; supervisory and nonsupervisory; technical; and executive, administrative, and professional openings that are compensated on a salary basis of less than $25,000 per year. This term includes full-time employment, temporary employment of more than 3 days' duration, and part-time employment. It does not include openings which the contractor proposes to fill from within his own organization or to fill pursuant to a customary and traditional employer-union hiring arrangement nor openings in an educational institution which are restricted to students of that institution. Under the most compelling circumstances an employment opening may not be suitable for listing, including such situations where the needs of the Government cannot reasonably be otherwise supplies, where listing would be contrary to national security, or where the requirement of listing would otherwise not be for the best interest of the Government.

(2) "Appropriate office of the State employment service system" means the local office of the Federal/State national system of public employment offices with assigned responsibility for serving the area where the employment

opening is to be filled, including the Distric of Columbia, Guam, Puerto Rico, and the Virgin Islands.

(3) "Openings which the contractor proposes to fill from within his own organization" means employment openings for which no consideration will be given to persons outside the contractor's organization (including affiliates, subsidiaries, and the parent companies) and includes any openings which the contractor proposes to fill from regularly established "recall" lists.

(4) "Openings which the contractor proposes to fill pursuant to a customary and traditional employer-union hiring arrangement" means employment openings which the contractor proposes to fill from union halls, which is part of the customary and traditional hiring relationship which exists between the contractor and representatives of his employees.

(i) The contractor agrees to comply with the rules, regulations, and relevant orders of the Secretary of Labor issued pursuant to the Act.

(j) In the event of the contractor's noncompliance with the requirements of this clause, actions for noncompliance may be taken in accordance with the rules, regulations, and relevant orders of the Secretary of Labor issued pursuant to the Act.

(k) The contractor agrees to post in conspicuous places available to employees and applicants for employment notices in a form to be prescribed by the Director, provided by or through the Contracting Officer. Such notice shall state the contractor's obligation under the law to take affirmative action to employ and advance in employment qualified disabled veterans and veterans of the Vietnam era for employment, and the rights of applicants and employees.

(l) The contractor will notify each labor union or representative of workers with which it has a collective bargaining agreement or other contract understanding that the contractor is bound by terms of the Vietnam Era Veteran's Readjustment Assistance Act and is committed to take affirmative action to employ and advance in employment qualified disabled veterans and veterans of the Vietnam era.

(m) The contractor will include the provisions of this clause in every subcontract or purchase order of $10,000 or more unless exempted by rules, regulations, or orders of the Secretary issued pursuant to the Act, so that such provisions will be binding upon each subcontractor or vendor. The contractor will take such action with respect to any subcontract or purchase order as the Director of the Office of Federal Contract Compliance Programs may direct to enforce such provisions, including action for noncompliance.

MINORITY BUSINESS ENTERPRISES SUBCONTRACTING PROGRAM

FPR 1-1.1310-2(b)

(This clause is applicable if this contract exceeds $500,000.00.)

(a) The Contractor agrees to establish and conduct a program which will enable minority business enterprises (as defined in the clause entitled "Utilization of Minority Business Enterprises") to be considered fairly as subcontractors and suppliers under this contract. In this connection, the Contractor shall:

(1) Designate a liaison officer who will administer the Contractor's minority business enterprises program.

(2) Provide adequate and timely consideration of the potentialities of known minority business enterprises in all "make-or-buy" decisions.

(3) Assure that known minority business enterprises will have an equitable opportunity to compete for subcontracts, particularly by arranging solicitations, time for the preparation of bids, quantities, specifications, and delivery schedules so as to facilitate the participation of minority business enterprises.

(4) Maintain records showing (i) procedures which have been adopted to comply with the policies set forth in this clause, including the establishment of a source list of minority business enterprises on the source list, and (iii) specific efforts to identify and award contracts to minority business enterprises.

(5) Include the Utilization of Minority Business Enterprises clause in subcontracts which offer substantial minority business enterprises subcontracting opportunities.

(6) Cooperate with the Contracting Officer in any studies and surveys of the Contractor's minority business enterprises procedures and practices that the Contracting Officer may from time to time conduct.

(7) Submit periodic reports of subcontracting to known minority business enterprises with respect to the records referred to in subparagraph (4), above, in such form and manner and at such time (not more often than quarterly) as the Contracting Officer may prescribe.

(b) The Contractor further agrees to insert, in any subcontract hereunder which may exceed $500,000, provisions which shall conform substantially to the language of this clause, including this paragraph (b), and to notify the Contracting Officer of the names of such subcontractors.

ALTERATION TO SF-32, General Provisions

UNSOLICITED SAMPLES, DESCRIPTIVE LITERATURE, OR BRAND NAME REFERENCES:

Where procurement is effected under specifications or purchase descriptions (other than "brand name or equal") and the Government does not specifically request bid samples, descriptive literature, or references to brand names, models, or part numbers as an integral part of the bid, bids which are accompanied by any of the foregoing will be rejected unless it is clear from the bid or accompanying papers that the samples, descriptive literature, or references to brand names, models, or part numbers are not intended to qualify the bid and that the bidder proposes to furnish items fully in accordance with the specifications or purchase descriptions. Where offers contain unsolicited material such as samples, descriptive literature, or references to brand names, models, or part numbers, the Government will not be responsible in any way for determining whether the items which are offered meet the Government's requirements set forth in the applicable specifications or purchase descriptions.

EXAMINATION OF RECORDS BY DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE:
(Applicable to negotiated contracts only.)

The provisions of the clause included herein, entitled "Examination of Records by the Comptroller General," are extended to provide equal rights to duly authorized representatives of the Secretary or of the Contracting Officer.

ALTERATIONS TO SF-32, GENERAL PROVISIONS (Supply Contract)

(See Federal Procurement Regulations, Subpart 1-11.4 Regarding Use.)

FEDERAL, STATE AND LOCAL TAXES

(a) Except as may be otherwise provided in this contract, the contract price includes all applicable Federal, State, and local taxes and duties.

(b) Nevertheless, with respect to any Federal excise tax or duty on the transactions or property covered by this contract, if a statute, court decision, written ruling, or regulation takes effect after the contract date, and–

(1) Results in the Contractor being required to pay or bear the burden of any such Federal excise tax or duty or increase in the rate thereof which would not otherwise have been payable on such transactions or property, the contract price shall be increased by the amount of such tax or duty or rate increase: *Provided,* That the Contractor if requested by the Contracting Officer, warrants in writing that no amount for such newly imposed Federal excise tax or duty or rate increase was included in the contract price as a contingency reserve or otherwise; or

(2) Results in the Contractor not being required to pay or bear the burden of, or in his obtaining a refund or drawback of, any such Federal excise tax or duty which would otherwise have been payable on such transactions or property or which was the basis of an increase in the contract price, the contract price shall be decreased by the amount of the relief, refund, or drawback, or that amount shall be paid to Government, as directed by the Contracting Officer. The contract price shall be similarly decreased if the Contractor, through his fault or negligence or his failure to follow instructions of the Contracting Officer, is required to pay or bear the burden of, or does not obtain a refund or drawback of, any such Federal excise tax or duty.

(c) No adjustment pursuant to paragraph (b) above will be made under this contract unless the aggregate amount thereof is or may reasonably be expected to be over $100.

(d) As used in paragraph (b) above, the term "contract date" means the date set for the bid opening, or if this is a negotiated contract, the date of this contract. As to additional supplies or services procured by modification to this contract, the term "contract date" means the date of such modification.

(e) Unless there does not exist any reasonable basis to sustain an exemption, the Government, upon request of the Contractor, without further liability, agrees, except as otherwise provided in this contract, to furnish evidence appropriate to establish exemption from any tax which the Contractor warrants in writing was excluded from the contract price. In addition, the Contracting Officer may furnish evidence to establish exemption from any tax that may, pursuant to this clause, give rise to either an increase or decrease in the contract price. Except as otherwise provided in this contract, evidence appropriate to establish exemption from duties will be furnished only at the direction of the Contracting Officer.

(f) The Contractor shall promptly notify the Contracting Officer of matters which will result in either an increase or decrease in the contract price, and shall take action with respect thereto as directed by the Contracting Officer.

ALTERATION TO SF-32, GENERAL PROVISIONS

EMPLOYMENT OF THE HANDICAPPED

(a) The contractor will not discriminate against any employee or applicant for employment because of physical or mental handicap in regard to any position for which the employee or applicant for employment is qualified. The contractor agrees to take affirmative action to employ, advance in employment and otherwise treat qualified handicapped individuals without discrimination based upon their physicial or mental handicap in all employment practices such as the following: employment, upgrading, demotion or transfer, recruitment, advertising, layoff or termination, rates of pay or other forms of compensation, and selection for training, including apprenticeship.

(b) The contractor agrees to comply with the rules, regulations, and relevant orders of the Secretary of Labor issued pursuant to the Act.

(c) In the event of the contractor's noncompliance with the requirements of this clause, actions for noncompliance may be taken in accordance with the rules, regulations and relevant orders of the Secretary of Labor issued pursuant to the Act.

(d) The contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices in a form to be prescribed by the Director, provided by or through the Contracting Officer. Such notices shall state the contractor's obligation under the law to take affirmative action to employ and advance in employment qualified handicapped employees and applicants for employment, and the rights of applicants and employees.

(e) The contractor will notify each labor union or representative of workers with which it has a collective bargaining agreement or other contract understanding, that the contractor is bound by the terms of section 503 of the Rehabilitation Act of 1973, and is committed to take affirmative action to employ and advance in employment physically and mentally handicapped individuals.

(f) The contractor will include the provisions of this clause in every subcontract or purchase order of $2,500 or more unless exempted by rules, regulations, or orders of the Secretary issued pursuant to section 503 of the Act, so that such provisions will be binding upon each subcontractor or vendor. The contractor will take such action with respect to any subcontract or purchase order as the Director of the Office of Federal Contract Compliance Programs may direct to enforce such provisions, including action for noncompliance.

Revised 6/8/76

TERMINATION FOR CONVENIENCE
OF THE GOVERNMENT

(a) The performance of work under this contract may be terminated by the Government in accordance with this clause in whole, or from time to time in part, whenever the Contracting Officer shall determine that such termination is in the best interest of the Government. Any such termination shall be effected by delivery to the Contractor of a Notice of Termination specifying the extent to which performance of work under the contract is terminated, and the dates upon which such termination becomes effective.

(b) After receipt of a Notice of Termination, and except as otherwise directed by the Contracting Officer, the Contractor shall:

(1) Stop work under the contract on the date and to the extent specified in the Notice of Termination;

(2) Place no further orders or subcontracts for materials, services, or facilities, except as may be necessary for completion of such portion of the work under the contract as is not terminated;

(3) Terminate all orders and subcontracts to the extent that they relate to the performance of work terminated by the Notice of Termination;

(4) Assign to the Government, in the manner, at the times, and to the extent directed by the Contracting Officer, all of the right, title, and interest of the Contractor under the orders and subcontracts so terminated, in which case the Government shall have the right, in its discretion, to settle or pay any or all claims arising out of the termination of such orders and subcontracts;

(5) Settle all outstanding liabilities and all claims arising out of such termination of orders and subcontracts, with the approval or ratification of the Contracting Officer, to the extent he may require, which approval or ratification shall be final for all the purposes of this clause;

(6) Transfer title to the Government and deliver in the manner, at the times, and to the extent, if any, directed by the Contracting Officer, (i) the fabricated or unfabricated parts, work in process, completed work, supplies, and other material produced as a part of, or acquired in connection with the performance of, the work terminated by the Notice of Termination, and (ii) the completed or partially completed plans, drawings, information and other property which, if the contract had been completed, would have been required to be furnished to the Government;

(7) Use his best efforts to sell, in the manner, at the times, to the extent, and at the price or prices directed or authorized by the Contracting Officer, any property of the types referred to in (6) above: Provided, however, that the Contractor (i) shall not be required to extend credit to any purchaser, and (ii) may acquire any such property under the conditions prescribed by and at a price or prices approved by the Contracting Officer: And provided further, that the proceeds of any such transfer or disposition shall be applied in reduction of any payments to be made by the Government to the Contractor under this contract or shall otherwise be credited to the price or cost of the work covered by this contract or paid in such other manner as the Contracting Officer may direct;

(8) Complete performance of such part of the work as shall not have been terminated by the Notice of Termination; and

(9) Take such action as may be necessary, or as the Contracting Officer may direct, for the protection and preservation of the property related to this contract which is in the possession of the Contractor and in which the Government has or may acquire an interest.

At any time after expiration of the plant clearance period, as defined in Subpart 1-8.1 of the Federal Procurement Regulations (41 CFR 1-8.1), as the definition may be amended from time to time, the Contractor may submit to the Contracting Officer a list, certified as to quantity and quality, of any or all items of termination inventory not previously disposed of, exclusive of items the disposition of which has been directed or authorized by the Contracting Officer, and may request the Government to remove such items or enter into a storage agreement covering them. Not later than fifteen (15) days thereafter, the Government will accept title to such items and remove them or enter into a storage agreement covering the same: Provided, that the list submitted shall be subject to verification by the Contracting Officer upon removal of the items or, if the items are stored, within forty-five (45) days from the date of submission of the list, and any necessary adjustment to correct the list as submitted shall be made prior to final settlement.

(c) After receipt of a Notice of Termination, the Contractor shall submit to the Contracting Officer his termination claim, in the form and with certification prescribed by the Contracting Officer. Such claim shall be submitted promptly but in no event later than one year from the effective date of termination, unless one or more extensions in writing are granted by the Contracting Officer upon request of the Contractor made in writing within such one-year period or authorized extensiton thereof. However, if the Contracting Officer determines that the facts justify such action, he may receive and act upon any such termination claim at any time after such one-year period or any extension thereof. Upon failure of the Contractor to submit his termination claim within the time allowed, the Contracting Officer may, subject to any review

required by the contracting agency's procedures in effect as of the date of execution of this contract, determine, on the basis of information available to him, the amount, if any, due to the Contractor by reason of the termination and shall thereupon pay to the Contractor the amount so determined.

(d) Subject to the provisions of paragraph (c), and subject to any review required by the contracting agency's procedures in effect as of the date of execution of this contract, the Contractor and the Contracting Officer may agree upon the whole or any part of the amount or amount to be paid to the Contractor by reason of the total or partial termination of work pursuant to this clause, which amount or amounts may include a reasonable allowance for profit on work done: Provided, that such agreed amount or amounts, exclusive of settlement costs, shall not exceed the total contract price as reduced by the amount of payments otherwise made and as further reduced by the contract price of work not terminated. The contract shall be amended accordingly, and the Contractor shall be paid the agreed amount. Nothing in paragraph (e) of this clause, prescribing the amount to be paid to the Contractor in the event of failure of the Contractor and the Contracting Officer to agree upon the whole amount to be paid to the Contractor by reason of the termination of work pursuant to this clause, shall be deemed to limit, restrict, or otherwise determine or affect the amount or amounts which may be agreed upon to be paid to the Contractor pursuant to this paragraph (d).

(e) In the event of the failure of the Contractor and the Contracting Officer to agree as provided in paragraph (d) upon the whole amount to be paid to the Contractor by reason of the termination of work pursuant to this clause, the Contracting Officer shall, subject to any review required by the contracting agency's procedures in effect as of the date of execution of this contract, determine, on the basis of information available to him, the amount, if any, due to the Contractor by reason of the termination and shall pay to the Contractor the amounts determined as follows:

(1) For completed supplies accepted by the Government (or sold or acquired as provided in paragraph (b)(7) above) and not theretofore paid for, a sum equivalent to the aggregate price for such supplies computed in accordance with the price or prices specified in the contract, appropriately adjusted for any saving of freight or other charges;

(2) The total of --

(i) The costs incurred in the performance of the work terminated, including initial costs and preparatory expense allocable thereto, but exclusive of any costs attributable to supplies paid or to be paid for under paragraph (e)(1) hereof;

(ii) The cost of settling and paying claims arising out of the termination of work under subcontracts or orders, as provided in paragraph (b)(5) above, which are properly chargeable to the terminated portion of the contract (exclusive of amounts paid or payable on account of supplies or materials delivered or services furnished by subcontractors or vendors prior to the effective date of the Notice of Termination, which amounts shall be included in the costs payable under (i) above); and

(iii) A sum, as a profit, equal to 2 percent of that part of the amout determined under (i) above which represents the cost of articles and materials not processed by the Contractor, plus a sum equal to 8 percent of the remainder of such amount, but the aggregate of such sums shall not exceed 6 percent of the whole of the amount determined under (i) above: Provided, however, that if it appears that the Contractor would have sustained a loss on the entire contract had it been completed, no profit shall be included or allowed under this subdivision (iii) and an appropriate adjustment shall be made reducing the amount of the settlement to reflect the indicated rate of loss; and

(3) The reasonable costs of settlement, including accounting, legal, clerical, and other expenses reasonably necessary for the preparation of settlement claims and supporting data with respect to the terminated portion of the contract and for the termination and settlement of subcontracts thereunder, together with reasonable storage, transportation, and other costs incurred in connection with the protection or disposition of property allocable to this contract.

The total sum to be paid to the Contractor under (1) and (2) of this paragraph (e) shall not exceed the total contract price as reduced by the amount of payments otherwise made and as further reduced by the contract price of work not terminated. Except for normal spoilage, and except to the extent that the Government shall have otherwise expressly assumed the risk of loss, there shall be excluded from the amounts payable to the Contractor as provided in (e)(1) and (2)(i) above, the fair value, as determined by the Contracting Officer, of property which is destroyed, lost, stolen, or damaged so as to become undeliverable to the Government, or to a buyer pursuant to paragraph (b)(7).

(f) Costs claimed, agreed to, or determined pursuant to paragraphs (c), (d), and (e) of this clause shall be in accordance with the contract cost principles and procedures in Part 1-15 of the Federal Procurement Regulations (41 CFR 1-15) in effect on the date of this contract.

(g) The Contractor shall have the right to appeal, under the clause of this contract entitled "Disputes," from any determination made by the Contracting Officer under paragraph (c) or (e) above, except that, if the Contractor has failed to submit his claim within the time provided in paragraph (c) above and has failed to request extension of such time, he shall have no such right of appeal. In any case where the Contracting Officer has made a determination of the amount due under paragraph (c) or (e) above, the Government shall pay to the Contractor the following: (1) if there is no right of appeal hereunder or if no timely appeal has been taken, the amount so determined by the Contracting Officer; or (2) if an appeal has been taken, the amount finally determined on such appeal.

(h) In arriving at the amount due the Contractor under this clause there shall be deducted (1) all unliquidated advance or other payments on account theretofore made to the Contractor, applicable to the terminated portion of this contract; (2) any claim which the Government may have against the Contractor in connection with this contract; and (3) the agreed price for, or the proceeds of sale of, any materials, supplies, or other things acquired by the Contractor or sold, pursuant to the provisions of this clause, and not otherwise recovered by or credited to the Government.

(i) If the termination hereunder be partial, prior to the settlement of the terminated portion of this contract, the Contractor may file with the Contracting Officer a request in writing for an equitable adjustment of the price or prices specified in the contract relating to the continued portion of the contract (the portion not terminated by the Notice of Termination), and such equitable adjustment as may be agreed upon shall be made in such price or prices.

(j) The Government may from time to time, under such terms and conditions as it may prescribe, make partial payments and payments on account against costs incurred by the Contractor in connection with the terminated portion of this contract whenever in the opinion of the Contracting Officer the aggregate of such payments shall be within the amount to which the Contractor will be entitled hereunder. If the total of such payments is in excess of the amount finally agreed or determined to be due under this clause, such excess shall be payable by the Contractor to the Government upon demand, together with interest computed at the rate of 6 percent per annum for the period from the date such excess payment is received by the Contractor to the date on which such excess is repaid to the Government: Provided, however, that no interest shall be charged with respect to any such excess payment attributable to a reduction in the Contractor's claim by reason of retention or other disposition of termination inventory until ten days after the date of such retention or disposition, or such later date as determined by the Contracting Officer by reason of the circumstances.

(k) Unless otherwise provided for in this contract, or by applicable statute, the Contractor, from the effective date of termination and for a period of three years after final settlement under this contract, shall

preserve and make available to the Government at all reasonable times at the office of the Contractor but without direct charge to the Government, all his books, records, documents, and other evidence bearing on the costs and expenses of the Contractor under this contract and relating to the work terminated hereunder, or, to the extent approved by the Contracting Officer, photographs, microphotographs, or other authentic reproductions thereof.

FPR 1-8.701

PRICE REDUCTION FOR DEFECTIVE COST OR PRICING DATA (FPR 1-3.814-1(a))

If any price, including profit or fee, negotiated in connection with this contract or any cost reimbursable under this contract was increased by any significant sums because:

(a) The Contractor furnished cost or pricing data which was not accurate, complete and current as certified in the Contractor's Certificate of Current Cost or Pricing Data;

(b) A subcontractor, pursuant to the clause of this contract entitled "Subcontractor Cost or Pricing Data" or "Subcontractor Cost or Pricing Data -Price Adjustments" or any subcontract clause therein required, furnished cost of pricing data which was not accurate, complete and current as certified in the subcontractor's Certificate of Current Cost or Pricing Data;

(c) A subcontractor or prospective subcontractor furnished cost of pricing data which was required to be accurate, complete and current and to be submitted to support a subcontract cost estimate furnished by the Contractor but which was not accurate, complete and current as of the date certified in the Contractor's Certificate of Current Cost or Pricing Data; or

(d) The Contractor or a subcontractor or prospective subcontractor furnished any data, not within (a), (b), or (c) above, which was not accurate as submitted; the price or cost shall be reduced accordingly and the contract shall be modified in writing as may be necessary to reflect such reduction. However, any reduction in the contract price due to defective subcontract data of a prospective subcontractor when the subcontract was not subsequently awarded to such subcontractor, will be limited to the amount (plus applicable overhead and profit markup) by which the actual subcontract, or actual cost to the Contractor if there was no subcontract, was less than the prospective subcontract cost estimate submitted by the Contractor: PROVIDED, The actual subcontract price was not affected by defective cost or pricing data.

(NOTE: Since the contract is subject to reduction under this clause by reason of defective cost or pricing data submitted in connection with certain subcontracts, it is expected that the Contractor may wish to include a clause in each such subcontract requiring the subcontractor to appropriately indemnify the Contractor. It is also expected that any subcontractor subject to such indemnification will generally require substantially similar indemnification for defective cost or pricing data required to be submitted by his lower tier subcontractors.)

SUBCONTRACTOR COST OR PRICING DATA (FPR 1-3.814-3)

(a) The Contractor shall require subcontractors hereunder to submit, actually or by specific indentification in writing, cost or pricing data under the following circumstances:

(1) Prior to the award of any subcontract the amount of which is expected to exceed $100,000 when entered into;

(2) Prior to the pricing of any subcontract modification which involves aggregate increases and/or decreases in costs plus applicable profits expected to exceed $100,000; except where the price is based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation.

(b) The Contractor shall require subcontractors to certify, in substantially the same form as that used in the certificate by the Prime Contractor to the Government, that to the best of their knowledge and belief, the cost and pricing data submited under (a) above is accurate, complete, and current as of the date of agreement on the negotiated price of the subcontract or subcontract change or modification.

(c) The Contractor shall insert the substance of this clause including this paragraph (c) in each subcontract hereunder which exceeds $100,000 when entered into except where the price thereof is based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation. In each such excepted subcontract hereunder in excess of $100,000, the Contractor shall insert the substances of the following clause:

SUBCONTRACTOR COST OR PRICING DATA -
PRICE ADJUSTMENTS

(a) Paragraphs (b) and (c) of this clause shall become operative only with respect to any modification made pursuant to one or more provisions of this contract which involves aggregate increases and/or decreases in costs plus applicable profits expected to exceed $100,000. The requirements of this clause shall be limited to such contract modifications.

(b) The Contractor shall require subcontractors hereunder to submit, actually or by specific identification in writing, cost or pricing data under the following circumstances.

(1) Prior to award of any subcontract, the amount of which is expected to exceed $100,000 when entered into;

(2) Prior to the pricing of any subcontract modification which involves aggregate increases and/or decreases in costs plus applicable profits expected to exceed $100,000; except where the price is based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation.

Subcontractor Cost or Pricing Data (Continued)

(c) The Contractor shall require subcontractors to certify, in substantially the same form as that used in the certificate by the Prime Contractor to the Government, that to the best of their knowledge and belief the cost and pricing data submitted under (b) above is accurate, complete, and current as of the date of agreement on the negotiated price of the subcontract or subcontract change or modification.

(d) The Contractor shall insert the substance of this clause including this paragraph (d) in each subcontract hereunder which exceeds $100,000 when entered into.

ALTERATIONS (Continued)

AUDIT (FPR 1-3.814-2)

(a) GENERAL. The Contracting Officer or his representatives shall have the audit and inspection rights described in the applicable paragraphs (b), (c), and (d) below.

(b) EXAMINATION OF COSTS: If this is a cost-reimbursement type, incentive, time and materials, labor hour, or price redeterminable contract, or any combination thereof, the Contractor shall maintain, and the Contracting Officer or his represetnatives shall have the right to examine books, records, documents, and other evidence and accounting procedures and practices, sufficient to reflect properly all direct and indirect costs of whatever nature claimed to have been incurred and anticipated to be incurred for the performance of this contract. Such right of examination shall include inspection at all reasonable times of the Contractor's plants, or such parts thereof, as may be engaged in the performance of this contract.

(c) COST OR PRICING DATA. If the Contractor submitted cost or pricing data in connection with the pricing of this contract or any change or modification thereto, unless such pricing was based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation, the Contracting Officer or his representatives who are employees of the United States Government shall have the right to examine all books, records, documents and other data of the Contractor related to the negotiation, pricing or performance of such contract, change or modification, for the purpose of evaluating the accuracy, completeness and currency of the cost or pricing data submitted. Additionally, in the case of pricing any change or modification exceeding $100,000 to formally advertised contracts, the Comptroller General of the United States or his representatives who are employees of the United States Government shall have such rights. The right of examination shall extend to all documents necessary to permit adequate evaluation of the cost or pricing data submitted, along with the computations and projections used therein.

(d) AVAILABILITY. The materials described in (b) and (c) above, shall be made available at the office of the Contractor, at all reasonable times, for inspection, audit or reproduction, until the expiration of 3 years from the date of final payment under this contract or such lesser time specified in Part 1-20 of the Federal Procurement Regulations (41 CFR Part 1-20) and for such longer period, if any, as is required by applicable statute, or by other clauses of this contract, or by (1) and (2) below:

(1) If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for a period of 3 years from the date of any resulting final settlement.

(2) Records which relate to appeals under the "Disputes" clause of this contract, or litigation or the settlement of claims arising out of the performance of this contract, shall be made available until such appeals, litigation, or claims have been disposed of.

(e) The Contractor shall insert a clause containing all the provisions of this clause, including this paragraph (e), in all subcontracts hereunder except altered as necessary for proper identification of the contracting parties and the Contracting Officer under the Government prime contract.

July 1974

ACCOUNTS, AUDITS, AND RECORDS

(a) The Contractor shall maintain books, records, documents, and other evidence, accounting procedures and practices sufficient to reflect properly all direct and indirect costs of whatever nature claimed to have been incurred for the performance of this contract. The foregoing constitutes "records" for the purpose of this clause.

(b) The Contractor's facility(ies) or such part thereof as may be engaged in the performance of this contract, and his records shall be subject at all reasonable time to inspection and audit by the Secretary or his authorized representatives.

(c) The Contractor shall preserve and make available his records (1) until the expiration of 3 years from the date of final payment under this contract, or the time periods for particular records specified in 41 CFR Part 1-20, whichever expires earlier, and (2) for such longer period, if any, as is required by applicable statute, or by other clauses of this contract, or by (i) or (ii) below:

(i) If this contract is completely or partially terminated, the records relating to the work terminated shall be preserved and made available for a period of 3 years from the date of any resulting final payment.

(ii) Records which relate to (A) appeals under the "Disputes" clause of this contract, (B) litigation or the settlement of claims arising out of the performance of this contract, or (C) costs and expenses of this contract to which exception has been taken by the Contracting Officer or any of his duly authorized representatives, shall be retained until such appeals, litigation, claims, or exceptions have been disposed of.

(d) The Contractor shall insert the substance of this clause, including this paragraph (d) in each subcontract hereunder with the exceptions of (1) purchase orders not exceeding $2,500 and (2) subcontracts or purchase orders for public utility services at rates established for uniform applicability to the general public. When so inserted, changes shall be made to designate the higher-tier subcontractor at this level involved in place of the Contractor; to add "of the Government prime contract," in place of "this contract" in (B) of subparagraph (c)(ii) above.

PREAWARD EQUAL OPPORTUNITY COMPLIANCE REVIEWS

Where the bid of the apparent low responsible bidder is in the amount of $1 million or more, the bidder and his known first-tier subcontractors which will be awarded subcontracts of $1 million or more will be subject to full, preaward equal opportunity compliance reviews before the award of the contract for the purpose of determining whether the bidder and his subcontractors are able to comply with the provisions of the Equal Opportunity clause.

ALTERATION TO SF-32, General Provisions

CLEAN AIR AND WATER CLAUSE

(Applicable only if the contract exceeds $100,000, or the contracting officer has determined that the orders under an indefinite quantity contract in any one year will exceed $100,000, or a facility to be used has been the subject of a conviction under the Clean Air Act (42 U.S.C. 1857C-8(C)(1)) or the Federal Water Pollution Control Act (33 U.S.C. 1319 (C)) and is listed by EPA, or the contract is not otherwise exempt.)

(A) The contractor agrees as follows:

(I) To comply with all the requirements of Section 114 of the Clean Air Act, as amended (42 U.S.C. 1857, et seq., as amended by Public Law 91-604 and Section 308 of the Federal Water Pollution Control Act (33 U.S.C. 1251, as amended by Public Law 92-500), respectively, relating to inspection, monitoring, entry, reports, and information, as well as other requirements specified in Section 114 and Section 308 of the Air Act and the Water Act, respectively, and all regulation and guidelines issued thereunder before the award of this contract.

(II) That no portion of the work required by this prime contract will be performed in a facility listed on the Environmental Protection Agency list of violating facilities on the date when this contract was awarded unless and until the EPA eliminates the name of such facility or facilities from listing.

(III) To use his best efforts to comply with Clean Air Standards and Clean Water Standards at the facilities in which the contract is being performed.

(IV) To insert the substance of the provisions of this clause in any nonexempt subcontract, including this paragraph (IV).

(B) The terms used in this clause have the following meanings:

(I) The term "Air Act" means the Clean Air Act, as amended (42 U.S.C. 1857 et seq., as amended by Public Law 91-604).

(II) The term "Water Act" means Federal Water Pollution Control Act, as amended (33 U.S.C. 1251 et seq., as amended by Public Law 92-500).

(III) The term "Clean Air Standards" means any enforceable rules, regulations, guidelines, standards, limitations, orders, controls, prohibitions, or other requirements which are contained in, issued under, or otherwise adopted pursuant to the Air Act or Executive Order 11738, an applicable implementation plan as described in Section 110(D) of the Clean Air Act (42 U.S.C. 1857C-5(D)), an approved implementation procedure or plan under Section 111(C) or Section 111(D), respectively, of the Air Act (42 U.S.C. 1857C-6(C) or (D)), or an approved implementation procedure under Section 112(D) of the Air Act (42 U.S.C. 1857C-7(D)).

ALTERATION TO SF-32, General Provisions

Clean Air and Water Clause **(Continued)**

(IV) The term "Clean Water Standards" means any enforceable limitation, control, condition, prohibition, standard, or other requirement which is promulgated pursuant to the Water Act or contained in a permit issued to a discharger by the Environmental Protection Agency or by a State under an approved program, as authorized by Section 402 of the Water Act (33 U.S.C. 1342), or by a local government to ensure compliance with pretreatment regulations as required by Section 307 of the Water Act (33 U.S.C. 1317).

(V) The term "compliance" means compliance with Clean Air or Water Standards. Compliance shall also mean compliance with a schedule or plan ordered or approved by a court of competent jurisdiction, The Environmental Protection Agency or an Air or Water Pollution Control Agency in accordance with the requirement of the Air Act or Water Act and regulations issued pursuant thereto.

(VI) The term "Facility" means any building, plant, installation, structure, mine, vessel or other floating craft, location, or site of operations, owned, leased, or supervised by a contractor, subcontractor, to be utilized in the performance of a contract or subcontract. Where a location or site of operations contains or includes more than one building, plant, installation, or structure, the entire location shall be deemed to be a facility except where the Director, Office of Federal Activities, Environmental Protection Agency, determines that independent facilities are colocated in one geographical area.

EQUAL OPPORTUNITY (July 1976)

(The following clause is applicable unless this contract is exempt under the rules, regulations, and relevant orders of the Secretary of Labor (41 CFR ch. 60).)

During the performance of this contract, the Contractor agrees as follows:

(a) The Contractor will not discriminate against any employee or applicant for employment because of race, color, religion, sex, or national origin. The Contractor will take affirmative action to ensure that applicants are employed, and that employees are treated during employment, without regard to their race, color, religion, sex, or national origin. Such action shall include, but not be limited to, the following: Employment, upgrading, demotion, or transfer; recruitment or recruitment advertising; layoff or termination; rates of pay or other forms of compensation; and selection for training, including apprenticeship.

The Contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices to be provided by the Contracting Officer setting forth the provisions of this Equal Opportunity clause.

(b) The Contractor will, in all solicitations or advertisements for employees placed by or on behalf of the Contractor, state that all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, or national origin.

(c) The Contractor will send to each labor union or representative of workers with which he has a collective bargaining agreement or other contract or understanding, a notice, to be provided by the agency Contracting Officer, advising the labor union or workers' representative of the Contractor's commitments under this Equal Opportunity clause, and shall post copies of the notice in conspicuous places available to employees and applicants for employment.

(d) The Contractor will comply with all provisions of Executive Order No. 11246 of September 24, 1965, and of the rules, regulations, and relevant orders of the Secretary of Labor.

(e) The Contractor will furnish all information and reports required by Executive Order No. 11246 of September 24, 1965, and by the rules, regulations, and orders of the Secretary of Labor, or pursuant thereto, and will permit access to his books, records, and accounts by the contracting agency and the Secretary of Labor for purposes of investigation to ascertain compliance with such rules, regulations, and orders.

(f) In the event of the Contractor's noncompliance with the Equal Opportunity clause of this contract or with any of the said rules, regulations, or orders, this contract may be canceled, terminated, or suspended, in whole or in part, and the Contractor may be declared ineligible for further Government contracts in accordance with procedures authorized in Executive Order No. 11246 of September 24, 1965, and such other sanctions may be imposed and remedies invoked as provided in Executive Order No. 11246 of September 24, 1965, or by rule, regulation, or order of the Secretary of Labor, or as otherwise provided by law.

(g) The Contractor will include the provisions of paragraphs (a) through (g) in every subcontract or purchase order unless exempted by rules, regulations, or orders of the Secretary of Labor issued pursuant to section 204 of Executive Order No. 11246 of September 24, 1965, so that such provisions will be binding upon each subcontractor or vendor. The Contractor will take such action with respect to any subcontract or purchase order as the contracting agency may direct as a means of enforcing such provisions, including sanctions for noncompliance: *Provided, however,* That in the event the Contractor becomes involved in, or is threatened with, litigation with a subcontractor or vendor as a result of such direction by the contracting agency, the Contractor may request the United States to enter into such litigation to protect the interests of the United States.

STANDARD FORM 30, JULY 1960
GENERAL SERVICES ADMINISTRATION
FPDC 1B5, (41 CFR) 1-16.101

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

PAGE 1

1. AMENDMENT/MODIFICATION NO.	2. EFFECTIVE DATE	3. REQUISITION/PURCHASE REQUEST NO.	4. PROJECT NO. (If applicable)
11	6-30-77		

5. ISSUED BY — CODE

Center for Disease Control
1600 Clifton Road, N.E.
Atlanta, GA 30305

6. ADMINISTERED BY (If other than Block 5) — CODE

Same as shown in Block 5.

ORIGINAL

7. CONTRACTOR AND ADDRESS — CODE — FACILITY CODE

Merrell-National Laboratories
Div. of Richardson-Merrell, Inc.
Amity Road
Cincinnati, Ohio 45215

8. ☐ AMENDMENT OF SOLICITATION NO. _____
DATED _____ (See Block 9)
☒ MODIFICATION OF CONTRACT/ORDER NO. Letter 200-76-0625
DATED 9-13-76 (See Block 11)

THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Block 12. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided such telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

ACCOUNTING AND APPROPRIATION DATA (If required)

THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) ☒ This Change Order is issued pursuant to: the authorization for Letter Contract by the Secretary, 9/1/76.
The Changes set forth in block 12 are made to the above numbered contract/order.

☐ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation data, etc.) set forth in block 12.

(c) ☐ This Supplemental Agreement is entered into pursuant to authority of _____
It modifies the above numbered contract as set forth in block 12.

DESCRIPTION OF AMENDMENT/MODIFICATION

The target date for definitization, set forth in Subparagraph B, Article III - DEFINITIZATION, as established by Modification No. 10, dated May 31, 1977, is further extended to August 15, 1977.

Except as provided herein, all terms and conditions of the document referenced in block 8, as heretofore changed, remain unchanged and in full force and effect.

☒ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT ☐ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN _____ COPIES TO ISSUING OFFICE

15A. NAME OF CONTRACTOR/OFFEROR

(Signature of person authorized to sign)

15B. NAME AND TITLE OF SIGNER (Type or print) — 15C. DATE SIGNED

16A. UNITED STATES OF AMERICA

BY _____
(Signature of Contracting Officer)

16B. NAME OF CONTRACTING OFFICER (Type or print): John L. Williams

16C. DATE SIGNED: 6-30-77

STANDARD FORM 30, Rev. 1 1968
GENERAL SERVICES ADMINISTRATION
FED. PROC. REG. (41 CFR) 1-16.101

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

PAGE 1 OF 1

1. AMENDMENT/MODIFICATION NO.	2. EFFECTIVE DATE	3. REQUISITION/PURCHASE REQUEST NO.	4. PROJECT NO. (If applicable)
10	5-31-77		

5. ISSUED BY CODE

PGO, Center for Disease Control
255 East Paces Ferry Road, N.E.
Atlanta, GA 30305

6. ADMINISTERED BY (If other than block 5) CODE

Same as shown in Block 5

7. CONTRACTOR NAME AND ADDRESS (Street, city, county, state, and ZIP Code) CODE FACILITY CODE

Merrell-National Laboratories
Div. of Richardson-Merrell, Inc.
Amity Road
Cincinnati, Ohio 45215

8.
☐ AMENDMENT OF SOLICITATION NO. _____
DATED _____ (See block 9)
☒ MODIFICATION OF CONTRACT/ORDER NO. Letter 200-76-0425
DATED 9/13/76 (See block 11)

9. THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in block 12. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation, or as amended, by one of the following methods:

(a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided such telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

10. ACCOUNTING AND APPROPRIATION DATA (If required)

No Change

11. THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) ☒ This Change Order is issued pursuant to: the authorization for Letter Contract by the Secretary, 9/1/76.
The Changes set forth in block 12 are made in the above numbered contract/order.

(b) ☐ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation date, etc.) set forth in block 12.

(c) ☐ This Supplemental Agreement is entered into pursuant to authority of _____
It modifies the above numbered contract as set forth in block 12.

12. DESCRIPTION OF AMENDMENT/MODIFICATION

The target date for definitization, set forth in Subparagraph B, Article III - DEFINITIZATION, as established by Modification No. 9, dated April 28, 1977, is further extended hereby to July 1, 1977.

Except as provided herein, all terms and conditions of the document referenced in block 8, as heretofore changed, remain unchanged and in full force and effect.

13. ☒ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT ☐ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN _____ COPIES TO ISSUING OFFICE

NAME OF CONTRACTOR/OFFEROR	17. UNITED STATES OF AMERICA
BY _____ (Signature of person authorized to sign)	BY _____ (Signature of Contracting Officer)
15. NAME AND TITLE OF SIGNER (Type or print)	16. DATE SIGNED
	18. NAME OF CONTRACTING OFFICER (Type or print): John L. Williams
	19. DATE SIGNED: 5-31-77

PSD PMSA, REG. (41 CFR) 1-16.101

1. AMENDMENT/MODIFICATION NO.	2. EFFECTIVE DATE	3. REQUISITION/PURCHASE REQ. NO.	4. PROJECT NO. (If applicable)
9	4-28-77		

5. ISSUED BY — CODE
PGO, Center for Disease Control
255 East Paces Ferry Road, N.E.
Atlanta, GA 30305

6. ADMINISTERED BY (If other than block 5) — CODE
Same as shown in Block 5

7. CONTRACTOR NAME AND ADDRESS (Street, city, county, state, and ZIP Code) — CODE — FACILITY CODE
Merrell-National Laboratories
Div. of Richardson-Merrell Company
Amity Road
Cincinnati, OH 45215

8.
☐ AMENDMENT OF SOLICITATION NO. _____
DATED _____ (See block 9)
☒ MODIFICATION OF CONTRACT/ORDER NO. Letter 200-76-0425
DATED 9/13/76 (See block 11)

9. THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS
☐ The above numbered solicitation is amended as set forth in block 12. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.
Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation, or as amended, by one of the following methods:
(a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

10. ACCOUNTING AND APPROPRIATION DATA (If required)

11. THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS
(a) ☒ This Change Order is issued pursuant to: The authorization for Letter Contract by the Secretary, 9/1/76.
The Changes set forth in block 12 are made in the above numbered contract/order.
(b) ☐ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation date, etc.) set forth in block 12.
(c) ☐ This Supplemental Agreement is entered into pursuant to authority of _____
It modifies the above numbered contract as set forth in block 12.

12. DESCRIPTION OF AMENDMENT/MODIFICATION

The target date for definitization, set forth in Subparagraph B, Article III - DEFINITIZATION, as established by Modification No. 8, dated 3/31/77, is further extended hereby to June 1, 1977.

Except as provided herein, all terms and conditions of the document referenced in Block 8, as heretofore changed, remain unchanged and in full force and effect.

13. ☒ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT ☐ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN _____ COPIES TO ISSUING OFFICE

14. NAME OF CONTRACTOR/OFFEROR
(Signature of person authorized to sign)

15. NAME AND TITLE OF SIGNER (Type or print) — 16. DATE SIGNED

17. UNITED STATES OF AMERICA
BY _____ (Signature of Contracting Officer)

18. NAME OF CONTRACTING OFFICER (Type or print)
John L. Williams

19. DATE SIGNED
4-28-77

30-101

U.S. GOVERNMENT PRINTING OFFICE: 1977 O-240-124

GENERAL SERVICES ADMINISTRATION
FED. PROC. REG. (41 CFR) 1-16.101

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. AMENDMENT/MODIFICATION NO.	2. EFFECTIVE DATE	3. REQUISITION/PURCHASE REQUEST NO.	4. PROJECT NO. (If applicable)
8	3/31/77		

5. ISSUED BY CODE
Center for Disease Control
255 East Paces Ferry Road, N.E.
Atlanta, GA 30305

6. ADMINISTERED BY (If other than Item 5) CODE
Same as shown in Block 5

7. CONTRACTOR NAME AND ADDRESS (Street, city, county, state, and ZIP Code) CODE FACILITY CODE
Merrell-National Laboratories
Div. of Richardson-Merrell Company
Amity Road
Cincinnati, OH 45215

8. [ ] AMENDMENT OF SOLICITATION NO. _____
DATED _____ (See Item 9)
[X] MODIFICATION OF CONTRACT/ORDER NO. LETTER 200-76-0425
DATED 9/13/76 (See Item 11)

9. THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS
[ ] The above numbered solicitation is amended as set forth in Item 12. The hour and date specified for receipt of Offers [ ] is extended, [ ] is not extended.
Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:
(a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

10. ACCOUNTING AND APPROPRIATION DATA (If required)

11. THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS
(a) [X] This Change Order is issued pursuant to: The authorization for Letter Contract by the Secretary, 9/1/76.
The Changes set forth in Block 12 are made to the above numbered contract/order.
(b) [ ] The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation data, etc.) set forth in Block 12.
(c) [ ] This Supplemental Agreement is entered into pursuant to authority of _____
It modifies the above numbered contract as set forth in Block 12.

12. DESCRIPTION OF AMENDMENT/MODIFICATION
The target date for definitization, set forth in Subparagraph B, Article III - DEFINITIZATION, as established by Modification No. 7, dated 3/1/77, is further extended hereby to May 1, 1977.

Except as provided herein, all terms and conditions of the document referenced in Block 8, as heretofore changed, remain unchanged and in full force and effect.

13. [X] CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT [ ] CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN _____ COPIES TO ISSUING OFFICE

14. NAME OF CONTRACTOR/OFFEROR		15. UNITED STATES OF AMERICA	
BY _____ (Signature of person authorized to sign)		BY John L. Williams (Signature of Contracting Officer)	
15. NAME AND TITLE OF SIGNER (Type or print)	16. DATE SIGNED	17. NAME OF CONTRACTING OFFICER (Type or print) Contracting Officer John L. Williams	18. DATE SIGNED 3-31-77

1. AMENDMENT/MODIFICATION NO. 7 | EFFECTIVE DATE 2-28-77 | 3. REQUISITION/PURCHASE REQUEST | 4. PROJECT NO. (If applicable)

5. ISSUED BY: Center for Disease Control, 255 East Paces Ferry Road N.E., Atlanta, GA 30305 | CODE

6. ADMINISTERED BY (If other than Block 5): Same as shown in Block 5. | CODE

ORIGINAL

7. CONTRACTOR NAME AND ADDRESS (Street, city, county, state, and ZIP Code): Merrell-National Laboratories, Div. of Richardson-Merrell Company, Amity Road, Cincinnati, Ohio 45215 | CODE | FACILITY CODE

8. ☐ AMENDMENT OF SOLICITATION NO. _____ DATED _____ (See Block 9)
☒ MODIFICATION OF CONTRACT/ORDER NO. 200-76-0425 Letter
DATED 9/13/76 (See Block 11)

9. THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Block 12. The hour and date specified for receipt of Offers ☐ is unchanged, ☐ is extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation, or as amended, by one of the following methods:

(a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided such telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

10. ACCOUNTING AND APPROPRIATION DATA (If required)

11. THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) ☒ This Change Order is issued pursuant to: the authorization for letter contracts by the Secretary-9/1/76.
The Changes set forth in block 12 are made to the above numbered contract/order.

(b) ☐ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation date, etc.) set forth in block 12.

(c) ☐ This Supplemental Agreement is entered into pursuant to authority of _____
It modifies the above numbered contract as set forth in block 12.

12. DESCRIPTION OF AMENDMENT/MODIFICATION

The target date for definitization, set forth in Subparagraph B, ARTICLE III-DEFINITIZATION, as established by Modification No. 5, dated 1/31/77, is further extended hereby to April 1, 1977.

Except as provided herein, all terms and conditions of the document referenced in Block 8, as heretofore changed, remain unchanged and in full force and effect.

13. ☒ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT ☐ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN _____ COPIES TO ISSUING OFFICE

14. NAME OF CONTRACTOR/OFFEROR
BY _____ (Signature of person authorized to sign)

15. NAME AND TITLE OF SIGNER (Type or print) | 16. DATE SIGNED

17. UNITED STATES OF AMERICA
BY _____ (Signature of Contracting Officer)

18. NAME OF CONTRACTING OFFICER (Type or print): John L. Williams | 19. DATE SIGNED: 2-28-77

Modification No. 6 | 2/10/77

ISSUED BY: CODE
HEW - PHS
Center for Disease Control
1655 East Paces Ferry Ave. N.E.
Atlanta, GA. 30305

6. ADMINISTERED BY (If other than Item 5) CODE
Same as shown in Block 5

CONTRACTOR NAME AND ADDRESS (Street, city, county, state, and ZIP code) CODE FACILITY CODE

Merrell-National Laboratories
Div. of Richardson-Merrell Company
Amity Road
Cincinnati, Ohio 45215

8. ☐ AMENDMENT OF SOLICITATION NO. _____ DATED _____ (See Block 9)

☒ MODIFICATION OF CONTRACT/ORDER NO. Letter 200-76-0425 DATED 9/13/76 (See Block 11)

THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Block 12. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

10. ACCOUNTING AND APPROPRIATION DATA (If required)

THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

11. ☒ This Change Order is issued pursuant to: Article 2, "Changes", of the General Provisions

The Changes set forth in Block 12 are made to the above numbered contract/order.

(B) ☐ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation data, etc.) set forth in Block 12.

(C) ☐ This Supplemental Agreement is entered into pursuant to authority of _____

(D) ☐ Modifies the above numbered contract as set forth in Block 12.

12. DESCRIPTION OF AMENDMENT/MODIFICATION

All processing on vaccine lots Nos. 2449 and 2450 is ordered stopped as of January 10, 1977, and vaccine material shall be maintained in bulk concentrate form with sufficient safety measures to be taken to preserve the material, pending further notification from the Government to resume processing.

This Modification confirms telephone notification to Contractor on January 10, 1977, and confirming telegram of January 11, 1977.

Except as provided herein, all terms and conditions of the document referenced in Block 8, as heretofore changed, remain unchanged and in full force and effect.

13. ☐ CONTRACTOR'S COPY IS NOT REQUIRED TO SIGN THIS DOCUMENT ☒ CONTRACTOR OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 4 COPIES TO ISSUING OFFICE

14. NAME OF CONTRACTOR/OFFEROR: Merrell-National Laboratories

BY: Richard D. Mauter (Signature of person authorized to sign)

15. NAME AND TITLE OF SIGNER (Type or print): Vice President & Counsel

15C. DATE SIGNED: 2/24/77

16. NAME OF CONTRACTING OFFICER (Type or print): John L. Williams

16B. UNITED STATES OF AMERICA

BY: John L. Williams (Signature of Contracting Officer)

16C. DATE SIGNED: 2/10/77

NO. PROC. REG. (41 CFR) 1-16.101

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT | 1 | 1

1. AMENDMENT/MODIFICATION NO.	2. EFFECTIVE DATE	3. REQUISITION/PURCHASE REQUEST NO.	4. PROJECT NO. (If applicable)
Modification No. 5	1/31/77		

5. ISSUED BY	CODE	6. ADMINISTERED BY (If other than block 5)	CODE
CDC, Center for Disease Control 255 East Paces Ferry Road, NE Atlanta, Georgia 30305		Same as shown in Block 5.	

ORIGINAL

7. CONTRACTOR NAME AND ADDRESS (Street, city, county, state, and ZIP Code)

CODE | FACILITY CODE

Merrell-National Laboratories
Division of Richardson-Merrell Company
Amity Road
Cincinnati, Ohio 45215

8. ☐ AMENDMENT OF SOLICITATION NO. _____
DATED _____ (See block 9)
☐ MODIFICATION OF CONTRACT/ORDER NO. Letter 200-76-0625
DATED _____ (See block 11)

9. THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in block 12. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation, or as amended, by one of the following methods:

(a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

10. ACCOUNTING AND APPROPRIATION DATA (If required)

11. THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) ☒ This Change Order is issued pursuant to: the Authorization for letter contracts by the Secretary, 9/1/76.
The Changes set forth in block 12 are made to the above numbered contract/order.

(b) ☐ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation data, etc.) set forth in block 12.

(c) ☐ This Supplemental Agreement is entered into pursuant to authority of _____
It modifies the above numbered contract as set forth in block 12.

12. DESCRIPTION OF AMENDMENT/MODIFICATION

The target date for contract definitization, set forth in Subparagraph B of Article XIII - DEFINITIZATION, as established by Modification No. 4, dated December 17, 1976, is further extended hereby to March 1, 1977.

This confirms verbal agreement between Contractor and Contracting Officer of 1/31/77.

Except as provided herein, all terms and conditions of the document referenced in block 8, as heretofore changed, remain unchanged and in full force and effect.

13. ☒ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT ☐ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN _____ COPIES TO ISSUING OFFICE

14. NAME OF CONTRACTOR/OFFEROR		17. UNITED STATES OF AMERICA	
BY _____ (Signature of person authorized to sign)		BY _____ (Signature of Contracting Officer)	
15. NAME AND TITLE OF SIGNER (Type or print)	16. DATE SIGNED	18. NAME OF CONTRACTING OFFICER (Type or print)	19. DATE SIGNED
		John L. Williams	1/31/77

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST NO.	5. PROJECT NO. (If applicable)
Modification No. 4	12/17/76		

6. ISSUED BY — CODE
PGO, Center for Disease Control
5 East Paces Ferry Rd., N.E.
Atlanta, Ga. 30305

7. ADMINISTERED BY (If other than Block 5) — CODE
Same as shown in Block 5.

ORIGINAL

8. CONTRACTOR NAME AND ADDRESS (Street, city, county, state, and ZIP code) — CODE — FACILITY CODE

Merrell-National Laboratories
Division of Richardson-Merrell Company
Amity Road
Cincinnati, Ohio 45215

9. ☐ AMENDMENT OF SOLICITATION NO. _____
DATED _____ (See block 9)

10. ☒ MODIFICATION OF CONTRACT/ORDER NO. Letter 200-76-0425
DATED 9/13/76 (See block 11)

THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in block 12. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation, or as amended, by one of the following methods:

(a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

ACCOUNTING AND APPROPRIATION DATA (If required)

THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) ☒ This Change Order is issued pursuant to: Authorization for Letter Contracts by the Secretary, 9/1/76
The Changes set forth in block 12 are made to the above numbered contract/order.

(b) ☐ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation data, etc.) set forth in block 12.

(c) ☐ This Supplemental Agreement is entered into pursuant to authority of _____
It modifies the above numbered contract as set forth in block 12.

DESCRIPTION OF AMENDMENT/MODIFICATION

The target date for contract definitization, set forth in Subparagraph B of Article XIII - DEFINITIZATION, as established by Modification No. 3 of December 2, 1976 is further extended hereby to January 1, 1977.

This confirms Contracting Officer's telegram of December 16, 1976.

Except as provided herein, all terms and conditions of the document referenced in block 8, as heretofore changed, remain unchanged and in full force and effect.

☒ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT ☐ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN _____ COPIES TO ISSUING OFFICE

14. NAME OF CONTRACTOR/OFFEROR (Signature of person authorized to sign)		17. UNITED STATES OF AMERICA BY (Signature of Contracting Officer)	
15. NAME AND TITLE OF SIGNER (Type or print)	16. DATE SIGNED	18. NAME OF CONTRACTING OFFICER (Type or print) John L. Williams	19. DATE SIGNED 12/17/76

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT | 1 | 1

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST NO.	5. PROJECT NO. (If applicable)
Modification No. 3	12/2/76		

6. ISSUED BY (If other than item 5) — CODE

Center for Disease Control
255 East Paces Ferry Road, N.E.
Atlanta, Georgia 30305

7. ADMINISTERED BY (If other than item 5) — CODE

Same as shown in Block 5

8. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, state and ZIP code) — CODE — FACILITY CODE

Merrell-National Laboratories
Division of Richardson-Merrell Company
Amity Road
Cincinnati, Ohio 45215

9. [ ] AMENDMENT OF SOLICITATION NO. _____
DATED _____ (See Item 9)

10. [X] MODIFICATION OF CONTRACT/ORDER NO. 200-76-0425
DATED 9/13/76 (See Item 11)

THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

[ ] The above numbered solicitation is amended as set forth in Item 13. The hour and date specified for receipt of Offers [ ] is extended, [ ] is not extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

ACCOUNTING AND APPROPRIATION DATA (If required)

THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) [X] This Change Order is issued pursuant to: Authorization for Letter Contracts by the Secretary, 9/1/76
The Changes set forth in block 13 are made in the above numbered contract/order.

[ ] The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation data, etc.) set forth in block 13.

(c) [ ] This Supplemental Agreement is entered into pursuant to authority of _____
It modifies the above numbered contract as set forth in block 13.

DESCRIPTION OF AMENDMENT/MODIFICATION

Subparagraph B of ARTICLE XIII - DEFINITIZATION of referenced contract is deleted hereby and the following is substituted therefor:

B. The schedules for definitization of this contract are set forth below:

Negotiation of price - On or before November 10, 1976.

Target date for definitization - On or before December 15, 1976.

This confirms verbal agreement reached in telecon of December 1, 1976, between Contractor's Vice President and Counsel, Frederic D. Lamb, and John L. Williams, Contracting Officer, Center for Disease Control.

Except as provided herein, all terms and conditions of the document referenced in block 8, as heretofore changed, remain unchanged and in full force and effect.

[ ] CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT — [ ] CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN _____ COPIES TO ISSUING OFFICE

15. NAME OF CONTRACTOR/OFFEROR

_____ (Signature of person authorized to sign)

16. NAME AND TITLE OF SIGNER (Type or print) — 16A. DATE SIGNED

17. UNITED STATES OF AMERICA

BY _____ (Signature of Contracting Officer)

18. NAME OF CONTRACTING OFFICER (Type or print)

David K. Rowe

19. DATE SIGNED

12/2/76

GENERAL SERVICES ADMINISTRATION FPR (41 CFR) 1-16.101

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1 | 2

1. AMENDMENT/MODIFICATION NO.	2. EFFECTIVE DATE	3. REQUISITION/PURCHASE REQUEST NO.	4. PROJECT NO. (If applicable)
Modification No. 2	10/29/76		

5. ISSUED BY — CODE

HEW, PHS
Center for Disease Control
255 East Paces Ferry Road, N. E.
Atlanta, GA 30305

6. ADMINISTERED BY (If other than Block 5) — CODE

Same as shown in Block 5.

7. CONTRACTOR — CODE — FACILITY CODE

(Street, city, county, State, and ZIP Code)

Merrell-National Laboratories
Division of Richardson-Merrell Inc.
Amity Road
Cincinnati, OH 45215

8.
☐ AMENDMENT OF SOLICITATION NO. _____

DATED _____ (See Block 9)

☒ MODIFICATION OF CONTRACT/ORDER NO. Letter Contract 200-76-0425

DATED _____ (See Block 11)

9. THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Block 12. The hour and date specified for receipt of Offers ☐ is extended. ☐ is not extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

10. ACCOUNTING AND APPROPRIATION DATA (If required)

11. THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) ☐ This Change Order is issued pursuant to: _____

The Changes set forth in block 12 are made to the above numbered contract/order.

(b) ☐ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation data, etc.) set forth in block 12.

(c) ☒ This Supplemental Agreement is entered into pursuant to authority of: 41 U.S.C. 252(c)(7)

It modifies the above numbered contract as set forth in block 12.

12. DESCRIPTION OF AMENDMENT/MODIFICATION

The purpose of this modification is to revise Article IX - Payment of the Letter Contract. Article IX of the Letter Contract is deleted in its entirety, and the following Article IX - Payment is substituted therefor:

ARTICLE IX - PAYMENT:

A. Payment shall be made within 30 days for all vaccine which has been accepted. Each invoice or voucher shall, as a minimum, identify the appropriate Delivery Order for which the delivery was made, the vaccine type and amount delivered, the unit price, the total price, and the vaccine lot number(s). All payment shall be on a provisional basis pending definitization of a contract. The following prices shall be used for provisional payments for vaccine:

	10-dose vials	50 dose vials
Bivalent Vaccine	$ 3.97	$19.11
Monovalent Vaccine	$ 1.85	$ 8.58

Except as provided herein, all terms and conditions of the document referenced in Block 8, as heretofore changed, remain unchanged and in full force and effect.

13. ☐ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT ☒ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 4 COPIES TO ISSUING OFFICE

14. NAME OF CONTRACTOR/OFFEROR

BY: Frederic D. Lamb
(Signature of person authorized to sign)

15. NAME AND TITLE OF SIGNER (Type or print)
Frederic D. Lamb
Vice President and Counsel

16. DATE SIGNED
10/1/76

17. UNITED STATES OF AMERICA

BY: Julia R. Williams
(Signature of Contracting Officer)

18. NAME OF CONTRACTING OFFICER (Type or print)
John L. Williams

19. DATE SIGNED
10/29/76

STANDARD FORM 36, JULY 1966 GENERAL SERVICES ADMINISTRATION FPR (41 CFR) 1-16.101	CONTINUATION SHEET	REF. NO. OF DOC. BEING CONT'D Modification No. 2 Letter Contract 200-76-0425	PAGE 2	OF 2

NAME OF OFFEROR OR CONTRACTOR

ouchers shall be submitted to the following address:

Center for Disease Control
Bureau of State Services
Immunization Division
1600 Clifton Road, N. E.
Atlanta, GA 30333

. Payment for self-insurance retention and Insurance Premium on Liability shall be made ithin 30 days of receipt of contractor's invoice for same. The vaccine prices do not in-lude the costs for self-insurance ($2,500,000) or premiums for liability insurance $2,166,250) which are solely attributable to the National Swine Flu Immunization Program f 1976, or the surplus lines tax for said liability insurance.

2. AMENDMENT/MODIFICATION NO. Modification No. 1	3. EFFECTIVE DATE 9/28/76	4. REQUISITION/PURCHASE REQUEST NO.	5. PROJECT NO. (If applicable)

6. ISSUED BY: Center for Disease Control, 255 East Paces Ferry Road, N. E., Atlanta, GA 30305 — CODE

7. ADMINISTERED BY (If other than Item 6): Same as shown in Block 5. — CODE

ORIGINAL

8. CONTRACTOR NAME AND ADDRESS (Street, city, county, state, and ZIP code): Merrell-National Laboratories, Division of Richardson-Merrell Company, Amity Road, Cincinnati, OH 45215 — CODE — FACILITY CODE

9. ☐ AMENDMENT OF SOLICITATION NO. _____ DATED _____ (See Block 9)

10. ☒ MODIFICATION OF CONTRACT/ORDER NO. Letter 200-76-0425 DATED 9/13/76 (See Block 11)

THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Block 12. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation, or as amended, by one of the following methods: (a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

11. ACCOUNTING AND APPROPRIATION DATA (If required)

75X0943 PHS (Influenza Immunization)
6-6140/6944 (26.11) INCREASE $2,700,000.00

THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) ☐ This Change Order is issued pursuant to: _____

The Changes set forth in Block 12 are made to the above numbered contract/order.

(b) ☐ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation data, etc.) set forth in Block 12.

(c) ☒ This Supplemental Agreement is entered into pursuant to authority of: 41 U.S.C. 252(c)(7)

D. modifies the above numbered contract as set forth in Block 12.

12. DESCRIPTION OF AMENDMENT/MODIFICATION

The following changes are made hereby to referenced contract:

1. ARTICLE III - QUANTITIES is modified to read as follows:
The number of doses, by vial size, to be furnished under the contract is:

Monovalent		Bivalent		
10-dose vials	22,300,000	10-dose vials	~~2,700,000~~	2,690,000
50-dose vials	32,700,000	50-dose vials	~~3,300,000~~	3,310,000
	55,000,000			6,000,000

Variation in Quantity: A variation in the total quantity supplied hereunder will be accepted, provided that such variation is not in excess of 15% of the contract quantity as specified above, and is available for delivery prior to the final delivery date (January 15, 1977).

2. The last sentence of Subparagraph B, Delivery Schedule, of ARTICLE IV - DISTRIBUTION, is changed to read, "All deliveries shall be completed on or before January 15, 1977.

13. Except as provided herein, all terms and conditions of the document referenced in Block 8, as heretofore changed, remain unchanged and in full force and effect.

☐ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT ☒ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 4 COPIES TO ISSUING OFFICE

14. NAME OF CONTRACTOR/OFFEROR (Signature of person authorized to sign)		17. UNITED STATES OF AMERICA (Signature of Contracting Officer)	
15. NAME AND TITLE OF SIGNER (Type or print)	16. DATE SIGNED	18. NAME OF CONTRACTING OFFICER (Type or print) John L. Williams	19. DATE SIGNED 9/28/76

STANDARD FORM 36 JULY 1966
GENERAL SERVICES ADMINISTRATION
FPR (41 CFR) 1-16.101

CONTINUATION SHEET

REF NO OF DOCUMENT BEING CONTINUED
Modification No. 1
Letter Contract 200-76-0425

PAGE 2 OF 2

NAME OF OFFEROR OR CONTRACTOR

3. The last sentence of Subparagraph A, ARTICLE XIV - LIMITATION ON CONTRACTOR'S PROFIT, is changed to read: "The Secretary of Health, Education, and Welfare has issued criteria for the determination of the costs of the contractor for the vaccine delivered under this contract and for the determination of a reasonable profit on the A/Victoria/75 vaccine, and criteria is as set forth in Attachment A."

4. The following sentence is added to Subparagraph B of ARTICLE XIV - LIMITATION ON CONTRACTOR'S PROFIT: "In the event the contractor is required to pay a claim by the Government pursuant to Section 317(k)(7) of the Public Health Service Act after the contractor has refunded the unexpended amount retained for self-insurance, such claims shall be deemed satisfied up to the amount of such refund."

5. ARTICLE XVI - LIMITATION OF GOVERNMENT'S LIABILITY is change to read as follows:

"The contractor is not authorized to make expenditures or to incur obligations, in performance of this contract, which exceeds $17,500,000.00. In the event of a termination of this contract, the Government's liability shall not exceed $17,500,000.00."

6. The AVAILABILITY SCHEDULE is deleted and the AVAILABILITY SCHEDULE attached hereto is substituted therefor.

7. The SCHEDULE A - COST AND PROFIT CRITERIA FOR THE PROCUREMENT OF SWINE FLU VACCINE is deleted and the revised AMENDMENT A - COST AND PROFIT CRITERIA FOR THE PROCUREMENT OF SWINE FLU VACCINE attached hereto is substituted therefor.

AVAILABILITY SCHEDULE

The quantities by package size listed below shall be available for delivery on the dates shown:

A. BIVALENT VACCINE - 200 CCA Units per dose

Total	10-Dose	50-Dose	Available
4,810,000	2,690,000	2,120,000	September 30, 1976
1,190,000		1,190,000	October 11, 1976
6,000,000	2,690,000	3,310,000	

B. MONOVALENT VACCINE - 200 CCA Units per dose

Total	10-Dose	50-Dose	Available
7,770,000	3,130,000	4,640,000	September 30, 1976
5,350,000	1,900,000	3,450,000	October 11, 1976
5,900,000	1,580,000	4,320,000	October 22, 1976
5,980,000	1,590,000	4,390,000	November 1, 1976
5,000,000	1,700,000	3,300,000	November 11, 1976
5,000,000	1,700,000	3,300,000	November 18, 1976
5,000,000	1,700,000	3,300,000	November 26, 1976
5,000,000	3,000,000	2,000,000	December 3, 1976
5,000,000	3,000,000	2,000,000	December 17, 1976
5,000,000	3,000,000	2,000,000	January 12, 1977
55,000,000	22,300,000	32,700,000	

The contractual commitments regarding quantities and/or shipping dates are conditioned upon the Bureau of Biologics reviewing, testing and releasing submitted lots of the vaccine under the following time schedule:

a. CCA release of the bulk vaccine within 7 days following receipt of the samples by the Bureau of Biologics for testing.

b. Release of the final container vaccine within 3 days following receipt by the Bureau of Biologics of the final protocol.

It is understood that if any lot is not accepted by BoB, the above schedule shall be adjusted accordingly.

COST AND PROFIT CRITERIA FOR THE
PROCUREMENT OF SWINE FLU VACCINE

Pursuant to §317(j)(3) of the Public Health Service Act (42 U.S.C. 247(b)), as amended by the National Swine Flu Immunization Program of 1976 (P.L. 94-380), I hereby prescribe the following criteria for renegotiation to eliminate any profit realized from procurement of swine flu vaccine under the Swine Flu Program.

1. "Profit realized" from any procurement shall be the amount by which the amount paid by the Government to the contractor in the procurement exceeds the costs to the contractor of performing the contract.

2. The contractor will be paid its costs in performing the contract as follows:

   a. All direct and indirect costs actually and reasonably incurred by the contractor resulting from its participation in the Government's procurement of vaccine for the Swine Flu Program shall be reimbursed by the Government. The amount of such costs shall be determined in accordance with reasonable methods of allocation, practices and procedures applied on a basis consistent with those applied by the contractor in preparing his proposal and reviewed by the Department's audit agency.

   b. Reimbursable costs shall include, but not be limited to:

      1) Costs resulting from the production of vaccine that fails, through no gross negligence of the contractor, to meet the specifications of the contract because it is refused certification by the Bureau of Biologics of the Food and Drug Administration.

      2) Costs incurred prior to execution of the contract in order to meet the reasonably anticipated delivery dates for the vaccine under the Program.

      3) Imputed interest on working capital, at rates determined by the Secretary of Treasury pursuant to P.L. 92-41, 85 Stat. 97.

      4) Actual and unrecoverable costs due to interruption of production or sale of other biologicals in order to devote staff and facilities to the production of vaccine for the Program.

3. Profit will only be allowed on A/Victoria/75 vaccine and shall be negotiated at arm's length based on the contractor's degree of risk, difficulty and complexity of performance, type of contract, and cooperation with the Government in meeting the needs of this health emergency.

4. Any insurance premium amount which is included in the price of any procurement of swine flu vaccine under the Program and which is refunded to the contractor under any retrospective, experience-rating plan or similar rating plan shall in turn be refunded to the Government.

STANDARD FORM 26, JULY 1966
GENERAL SERVICES ADMINISTRATION
FPR (41 CFR) 1-16.101

AWARD/CONTRACT

PAGE 1 OF 10

CONTRACT (Proc. Inst. Ident.) NO
Letter Contract
No. 200-76-0425

3. EFFECTIVE DATE

4. REQUISITION/PURCHASE REQUEST/PROJECT NO.

5. CERTIFIED FOR NATIONAL DEFENSE UNDER BDSA REG. 2 AND/OR DMS REG. 1 RATING

ISSUED BY CODE
CDC, PHS
Center for Disease Control
255 East Paces Ferry Road, N.E.
Atlanta, GA 30305

6. ADMINISTERED BY (If other than Item 5) CODE
Same as shown in Block 5.

7. DELIVERY
☐ FOR DESTINATION
☒ OTHER (See below) *

CONTRACTOR CODE / FACILITY CODE
NAME AND ADDRESS
(No., city, county, State, ZIP code)
Merrell-National Laboratories
Div. of Richardson-Merrell Company
Amity Road
Cincinnati, OH 45215

8. DISCOUNT FOR PROMPT PAYMENT
None: Net - 30 days
*Delivery shall be F.O.B. Destination within Consignee's Premises, to the points shown on Delivery Orders

10. SUBMIT INVOICES (4 copies unless otherwise specified) TO ADDRESS SHOWN IN BLOCK

SHIP TO/MARK FOR CODE
As directed on Delivery Orders.

12. PAYMENT WILL BE MADE BY CODE
Center for Disease Control
Financial Management Office
Atlanta, GA 30333

THIS PROCUREMENT WAS ☐ ADVERTISED, ☒ NEGOTIATED, PURSUANT TO: ☐ 10 U.S.C. 2304 (a)( ) ☒ 41 U.S.C. 253 (c)(7)

ACCOUNTING AND APPROPRIATION DATA
75X0943 PHS (Influenza Immunization)
6-6140/ 6944 4591 (26.11) $14,800,000.

13. ITEM NO.	14. SUPPLIES/SERVICES	17. QUANTITY	18. UNIT	19. UNIT PRICE	20. AMOUNT
1.	INFLUENZA VIRUS VACCINE, Monovalent, 200 CCA units, A/New Jersey/76 strain, and Bivalent, 200/200 CCA units, A/New Jersey/76-A/Victoria/3/75, to be supplied in accordance with the Scope of Work, Delivery Schedule, and terms set forth herein.				

TOTAL AMOUNT OF CONTRACT $

CONTRACTING OFFICER WILL COMPLETE BLOCK 22 OR 26 AS APPLICABLE

☒ CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 3 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)

22. NAME OF CONTRACTOR
[signature]
(Signature of person authorized to sign)

23. NAME AND TITLE OF SIGNER (Type or print)
[illegible]

24. DATE SIGNED
9/13/76

☐ 26. AWARD (Contractor is not required to sign this document.) Your offer on Solicitation Number ____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual document is necessary.

25. UNITED STATES OF AMERICA
BY John L. Williams
(Signature of Contracting Officer)

26. NAME OF CONTRACTING OFFICER (Type or print)
John L. Williams

27. DATE SIGNED
9/13/76

ICLE I - SCOPE OF CONTRACT:

contractor shall manufacture and distribute influenza vaccine in accordance with the cifications set forth below during the contract period to the points and in the quantis specified on Delivery Orders issued by the Center for Disease Control. The only obliions or responsibilities of the contractor in connection with the National Swine Flu unization Program of 1976 are contained in this contract. There are no warranties, exss or implied, imposed on the contractor except as stated in this contract.

ICLE II - SPECIFICATIONS:

Type of Vaccine:
The vaccine shall be Influenza Monovalent A/New Jersey/76 (Swine) and Bivalent A/New Jersey/76 (Swine) - A/Victoria/3/75 manufactured under a current establishment and product license as set forth below. Formulation standards, specifications and applicable tests of the vaccine shall be as set forth in the approved product license or as otherwise directed by the Food and Drug Administration.

Product Licensure:

The vaccine supplied under this contract shall be produced under U. S. Establishment License No. /e/ and Amendment to the product license for influenza vaccine issued by the Bureau of Biologics. If, during the contract period of performance, the product or establishment license is suspended or revoked for any reason, production of the vaccine shall be discontinued until such time as the license is renewed. In the event production is suspended for the above reason, the Government shall not be held liable for failure to procure the guaranteed minimum contained in this contract.

Shelf Life:

Delivered vaccine shall have an expiration date through August 1, 1977. The Government agrees to take all appropriate steps to see to it that all persons who are responsible for administering vaccine are notified that the vaccine must not be administered after August 1, 1977.

Containers:

Vaccine shall be contained in vials of 10-dose and 50-dose capacity, with 2ml overfill in the 50-dose vial and 0.9ml overfill in the 10-dose vial. Ten-dose vials shall have an internal neck size no smaller than about 7mm in diameter; 50-dose vials, about 13mm. Vials shall be supplied with stoppers made of nonpyrogenic, high-grade rubber. Cap size for the vials will match the diameter of the necks. Vaccine dosage will be 0.5ml.

Labeling:

Labeling of vials shall be in accordance with 21 CFR 610.60. In addition, the color of label for the monovalent vaccine shall be red with black or white markings, and the color of the bivalent vaccine shall be blue with black or white markings. Lot number all be specified on each vial label. Text of the labels shall be supplied by the overnment.

Caps:

Caps shall be metallic color.

Packaging:

For shipping purposes, vials shall be packaged as follows:

10-dose vials - 10 vials per package, nested.
50-dose vials - 20 vials per package, nested.

Each package shall be labeled in accordance with Paragraph S5.2.2.2 - Intermediate Containers of Federal Standard 123D. In addition to the requirements of the referenced Federal Standard, the following is required:

A. Labeling shall show applicable lot numbers.

B. A paste-on label shall be attached to each package. Label shall conform to the sample supplied with RFP.

C. Package inserts shall be placed in each intermediate package, a total of 10 inserts per package. Text of the package insert shall be supplied by the Government.

Preservation, packaging, and packing shall furnish a degree of protection to preclude damage to containers and/or contents thereof under normal shipping conditions, handling, etc., and shall conform to applicable carrier rules and regulations, including carriers handling overseas shipments.

Vaccine shall be shipped under refrigeration at a temperature between 2° and 15°C (34° to 60°F). Packing and packaging shall be such that this temperature is maintained during shipment and that shipments shall arrive at destination in undamaged condition.

Marking Provisions:

Shipping containers: Containers shall be marked in accordance with Federal Standard Number 123D, January 22, 1975, and shall contain as a minimum the following:

a. Quantity and Unit
b. Purchase Order Number
c. Item Name
d. Contractor Name and Address
e. Gross Weight
f. Lot Number(s)

RTICLE III - QUANTITIES:

ie number of doses, by vial sizes, to be furnished under the contract is:

Monovalent Vaccine		Bivalent Vaccine	
10-dose vials	13,600,000	10-dose vials	2,700,000
50-dose vials	26,400,000	50-dose vials	3,300,000
	40,000,000		6,000,000

Variation in Quantity: A variation in the total quantity supplied hereunder will be accepted, provided that such variation is not in excess of 15% of the contract quantity as specified above, and is available for delivery prior to the final delivery date (December 3, 1976). The contractor shall notify the Government of availability of additional quantitites as soon as this status becomes known to the contractor.

ARTICLE IV - DISTRIBUTION:

A. Delivery Points:

The contractor shall deliver the vaccine, F.O.B. Destination, Within Consignee's Premises, as directed on delivery orders, to approximately 200 points in the 50 states and Trust Territories.

B. Delivery Schedule:

Deliveries shall begin on or before October 1, 1976, with the total amount of bivalent and monovalent vaccine to be delivered in accordance with the attached Availability Schedule. All deliveries shall be completed on or before December 3, 1976.

C. Overseas Delivery Requirements:

Overseas shipping and delivery methods shall be utilized for delivery to those points located outside the Continental United States.

Time of Delivery:

Delivery shall be made at destination within 10 days after receipt of written or telephonic order, but subject to the conditions noted on page 10, "Availability Schedule."

E. Shipments shall be made in increments of 10,000 doses.

F. The contractor shall not be required to deliver any vaccine under this contract (1) until it has obtained insurance in an amount not less that $55 million covering potential liability to it arising out of its participation in the influenza immunization program; and (2) unless the criteria issued by the Secretary of Health, Education and Welfare include, as allowable costs, the items set forth in Schedule A attached hereto.

ARTICLE V - DELIVERY TERMS:

Delivery shall be made F.O.B. DESTINATION, WITHIN CONSIGNEE'S PREMISES, as defined below:

The term, "F.O.B. Destination, Within Consignee's Premises," to which this contract is subject, means:

(a) Delivery, free of expense to the Government to within the doors of the Consignee's premises specified in the contract or delivery instructions.

(b) That it shall be the responsibility of the contractor to do the following:

(1) Pack and mark in such manner as to afford adequate protection against normal transportation hazards and secure prompt delivery to the consignee, and comply with all packing and marking specifications of the contract;

(2) Properly prepare and distribute commercial bills of lading;

(3) Make delivery laid down within the doors of the consignee's premises specified in the contract or delivery instructions;

(4) Pay and bear all transportation and accessorial charges for such delivery laid down within the doors of the consignee's premises specified in the contract or delivery instructions;

(5) Be responsible for any loss or damage occurring before delivery is laid down within the doors of the consignee's premises specified in the contract or delivery instructions.

ARTICLE VI - RETURN OF VACCINE:

No requirement to accept unused vaccines at end of the contract period will be placed on contractor.

ARTICLE VII - METHOD OF ORDERING:

Vaccine shall be ordered by Delivery Orders, each of which will designate the vaccine ordered, quantity required, and destination. Orders may be placed by telephone and confirmed in writing.

ARTICLE VIII - INSPECTION AND ACCEPTANCE:

...ots of vaccine will be submitted by the contractor to the Bureau of Biologics for reviewing ...d testing. Following release of the lots, Bureau of Biologics will send a notification of approval to the project officer at the Center for Disease Control. Final inspection shall be made at consignee's locations. Final acceptance/rejection will be made by the Center for Disease Control. Defective or damaged material received at consignee's locations will be rejected in accordance with Article 5 of the General Provisions.

ARTICLE IX - PAYMENT:

Payment shall be made for all vaccine which has been delivered and accepted. Each invoice or voucher shall, as a minimum, identify the appropriate Delivery Order for which the delivery was made, the vaccine and amount delivered, the unit price, the total price, and the lot number(s). All payments shall be on a provisional basis pending definitization of a contract. Vouchers shall be submitted to the following address:

Center for Disease Control
Financial Management Office
255 East Paces Ferry Road, N. E.
Atlanta, GA - 30305

ARTICLE X - PROJECT OFFICER:

...e Center for Disease Control, Atlanta, Georgia, will designate an individual to perform as Project Officer during the period of performance of the contract. The Project Officer shall be responsible for guidance in regard to the technical aspect of the contract, provide a point for liaison between the manufacturer and other Government agencies (Federal, State, and local) and be the general focal point to address technical and logistical problems relating to the performance under this contract. The Project Officer shall not have the

thority to make any commitments or authorize any changes which affect the contract price, rms, or conditions; any such changes shall be referred to the Contracting Officer for tion.

TICLE XI - PROJECT DIRECTOR:

he Contractor shall designate an individual who will serve as the point of contact egarding the technical performance of the contract. This individual shall have the uthority necessary to commit the company and shall be assigned responsibilities con- ruent with requirements of the contract. The Government reserves the right to pprove the Project Director and any successor to that position.

TICLE XII - DELINEATION OF RESPONSIBILITIES OF THE GOVERNMENT AND THE CONTRACTOR:

The parties recognize that the Government has initiated, planned, and is arranging for the implementation of the influenza immunization program. Because of the need to have the vaccine tested, manufactured, and delivered within a relatively short period of time in order that the population may be inoculated in an attempt to prevent an influenza epidemic, the Government has assumed certain responsibilities as specified herein which would ordinarily devolve upon the contractor. It is the intention of the parties that the contractor will be responsible solely for the performance of its obligations under Paragraph C herein. It is the purpose of this Article to delineate the separate responsibilities of the Government and the contractor.

In the light of the circumstances described in Paragraph A hereof, the Government shall be responsible for:

(1) The adequacy of the standards and specifications for the vaccine required to be delivered under this contract, including their compliance with all applicable requirements of law and regulation.

(2) The safety and suitability of materials provided to the contractor by the Government under or in connection with this contract.

(3) The investigation and determination of the safe and effective dosages and adequate directions for the use of the vaccine.

(4) The investigation and determination of the risks and benefits of inoculation with the vaccine.

(5) The development of an adequate statement of information respecting the risks and benefits referred to in subparagraph (4).

(6) The taking of all appropriate steps to assure that each individual to be inoculated (or, where appropriate, a parent or guardian of such individual) is adequately informed of such risks and benefits.

(7) The content of the labeling of the vaccine, including its compliance with all applicable requirements of law and regulation.

(8) The taking of all appropriate steps to assure that each person responsible for administering the vaccine has adequate notice of the labeling of the vaccine, provided that nothing herein shall limit the responsibility which the manufacturer otherwise has to assure that labeling is included in and delivered with each ship-

(9) The arrangements for the implementation of the influenza immunization program, including the issuance of appropriate guidelines and information.

The contractor shall use due care and comply with all applicable laws and regulations in the manufacture and handling of the vaccine in accordance with the specifications herein.

RTICLE XIII - DEFINITIZATION:

. A fixed price, redeterminable type contract is contemplated. To accomplish this result, the contractor agrees to enter into negotiation promptly with the Contracting Officer as to a definitive price for the vaccine which shall be incorporated in a definitive contract.

. The schedules for definitization of this contract are set forth below:

Negotiation of price - On or before November 10, 1976.

Target date for definitization - on or before December 1, 1976.

. If agreement on a definitive contract to supersede this letter contract is not reached by the target date set forth in B, above, or any extension thereof by the Contracting Officer, the Contracting Officer may, with the approval of the Head of the Procurement Activity, determine a reasonable price subject to appeal by the contractor as provided in the clause "Disputes" of this contract. The contract shall be governed by:

(1) All clauses, terms, and conditions contained in this letter contract except which by their nature are applicable only to a letter contract.

(2) All clauses required by law as of the date of this letter contract.

(3) Such other clauses, terms, and conditions as may be mutually agreed upon.

RTICLE XIV - LIMITATION ON CONTRACTOR'S PROFIT:

. In accordance with the provisions of P.L. 94-380, the contract price for the vaccine delivered under the contract shall be subject to renegotiation to eliminate any profit realized by the contractor on the swine flu vaccine and to limit the profit realized by the contractor on the A/Victoria/75 vaccine to a reasonable profit. The Secretary of Health, Education, and Welfare will issue criteria for the determination of the costs of the contractor for the vaccine delivered under this contract and for the determination of a reasonable profit on the A/Victoria/75 vaccine.

. Any insurance premium amount of which is included in the price of the vaccine delivered under this contract and which is refunded to the contractor under any retrospective, experience-rating plan or similar rating plan shall be refunded to the Government not later than 30 days after receipt of the refund by the contractor. Any amount retained by the contractor for self-insurance retention which is included in the price of the vaccine delivered under this contract shall be segregated in a separate account in a federally insured commercial bank with assets in excess of $100,000,000. Said self-insurance retention shall be invested, to the extent possible, in Certificates of Deposit at the said bank's prevailing interest rate. Any interest earned on the Certificates of Deposit

shall be added to said self-insurance retention fund. Payments from the separate account shall be made only for self-insurance as provided herein and any amount, including interest, in the separate account not so expended on or before August 1, 1985, shall be refunded to the Government not later than August 31, 1985. It is the understanding of the parties that, since the contract shall be subject to renegotiation to eliminate any profit realized by the contractor on the swine flu vaccine and to limit the profit realized by the contractor on the A/Victoria/75 vaccine to a reasonable profit, the self-insurance retention fund and interest thereon shall not constitute income to the contractor.

C. For the purposes of this Article, the contractor shall maintain and make available to the Secretary or his authorized representatives the records specified by the Articles of this contract entitled "Accounts, Audits, and Records"; Examination of Records by Comptroller General (Clause 10 of the General Provisions, SF-32); and Examination of Records by Department of Health, Education, and Welfare (Alterations to SF-32).

D. In the event the Contracting Officer determines that the contractor has realized any profit on swine flu vaccine or has realized more than a reasonable profit on A/Victoria/75 vaccine, the contract price shall be adjusted in accordance with the requirements of Paragraph A of this Article. Failure of the parties to reach agreement on the renegotiation of the contract price shall be subject to Clause 12 of the General Provisions, entitled "Disputes." The contractor shall make any necessary refunds to the Government not later than thirty days after receipt of the Contracting Officer's final decision. However, if the contractor takes an appeal from the Contracting Officer's final decision, it may withhold the funds in question until said appeal is decided. In the event that the decision on appeal is that the Government is entitled to a refund, such refund shall be made within thirty days from the date of the decision, with accrued interest at the rate determined by the Secretary of the Treasury pursuant to Public Law 92-41, 85 Stat. 97 from the date of the contractor's receipt of the Contracting Officer's final decision.

ARTICLE XV - COOPERATION IN PROCESSING AND DEFENSE OF CLAIMS AND SUITS:

A. Pursuant to the provisions of provisions of P.L. 94-380, the contractor shall cooperate with the Government in the processing or defense of any claim or suit brought against the United States under the Federal Tort Claims Act based upon alleged acts or omissions of the contractor.

B. While any such claim is under consideration by the Department of Health, Education, and Welfare's Claims Officer, the contractor shall furnish information requested by the Claims Officer or his representatives as is reasonably necessary to enable the claim to be considered and determined.

C. Should any action be filed against the United States under the Federal Tort Claims Act based upon alleged acts or omissions of the contractor, the contractor shall render all reasonable cooperation to the Government in the defense of such action as may be requested by the Department of Justice or cognizant United States Attorney. Such cooperation shall include, where appropriate, making records and personnel of the contractor available for pretrial proceedings and for the trial of the action.

ARTICLE XVI - LIMITATION OF GOVERNMENT'S LIABILITY:

The contractor is not authorized to make expenditures or to incur obligations, in performance of this contract, which exceeds $14,800,000. In the event of a termination of this contract, the Government's liability shall not exceed $14,800,000.

ARTICLE XVII- GENERAL PROVISIONS AND ALTERATIONS:

The General Provisions (SF-32), April 1975 edition are hereby incorporated in this contract, and are altered as follows:

1. Clause 21a, Small Business Subcontracting Program, is applicable if this contract exceeds $500,000.00.

2. Clause 22a, Labor Surplus Area Subcontracting Program, is applicable if this contract exceeds $500,000.00

3. The attached clauses, listed below, are added to and made a part of the General Provisions:

A. Listing of Employment Openings
B. Minority Business Enterprises Subcontracting Program
C. Unsolicited Samples, Descriptive Literature, or Brand Name Reference
D. Examination of Records by Department of Health, Education, and Welfare
E. Federal, State, and Local Taxes, HEW-328
F. Employment of the Handicapped
G. Termination for Convenience
H. Price Reduction for Defective Cost or Pricing Data
I. Subcontracting Cost or Pricing Data
J. Audit
K. Accounts, Audits, and Records
L. Disclosure Statement - Cost Accounting Practices and Certification
M. Cost Accounting Standards
N. Cost Accounting Standards - Exemption for Contracts of $500,000.00 or Less - Certifications
O. Preaward Equal Opportunity Compliance Reviews
P. Clean Air and Water
Q. Equal Opportunity Clause

GENERAL SERVICES ADMINISTRATION | CONTINUATION SHEET | Letter Contract No. 200-76-0425 | 10 | 1

NAME OF OFFEROR OR CONTRACTOR: MERRELL-NATIONAL LABORATORIES

AVAILABILITY SCHEDULE

The quantities by package size listed below shall be available for delivery on the dates shown:

1. BIVALENT VACCINE - 200 CCA Units per dose

Total	10 Dose	50 Dose	Available to Ship
6,000,000	2,700,000	3,300,000	Oct. 1, 1976
Excess, if any			Oct. 1, 1976

2. Monovalent Vaccine - 200 CCA Units per Dose

Total	10 Dose	50 Dose	
5,000,000	1,700,000	3,300,000	Oct. 1, 1976
5,000,000	1,700,000	3,300,000	Oct. 8, 1976
5,000,000	1,700,000	3,300,000	Oct. 18, 1976
5,000,000	1,700,000	3,300,000	Oct. 26, 1976
5,000,000	1,700,000	3,300,000	Nov. 3, 1976
5,000,000	1,700,000	3,300,000	Nov. 11, 1976
5,000,000	1,700,000	3,300,000	Nov. 18, 1976
5,000,000	1,700,000	3,300,000	Nov. 26, 1976
Excess, if any			Dec. 3, 1976
	13,600,000	26,400,000 = 40,000,000	

The contractual commitments regarding quantities and/or shipping dates are conditioned upon the Bureau of Biologics reviewing, testing and releasing submitted lots of the vaccine under the following time schedule:

a. CCA release of the bulk vaccine within 7 days following receipt of the samples by the Bureau of Biologics for testing.

b. Release of the final container vaccine within 3 days following receipt by the Bureau of Biologics of the final protocol.

It is understood that if any lot is not accepted by BOB the above schedule shall be adjusted accordingly.

SCHEDULE A

COST AND PROFIT CRITERIA FOR THE
PROCUREMENT OF SWINE FLU VACCINE

Pursuant to §317(j)(3) of the Public Health Service Act (42 U.S.C. 247(b)), as amended by the National Swine Flu Immunization Program of 1976 (P.L. 94-380), I hereby prescribe the following criteria for renegotiation to eliminate any profit realized from procurement of swine flu vaccine under the Swine Flu Program.

1. "Profit realized" from any procurement shall be the amount by which the amount paid by the Government to the contractor in the procurement exceeds the costs to the contractor of performing the contract.

2. The contractor will be paid its costs in performing the contract as follows:

a) All direct and indirect costs actually and reasonably incurred by the contractor resulting from its participation in the Government's procurement of vaccine for the Swine Flu Program shall be reimbursed by the Government. The amount of such costs shall be determined in accordance with reasonable methods of allocation, practices and procedures applied on a basis consistent with those applied by the contractor in preparing his proposal and reviewed by the Department's audit agency.

b) Reimbursable costs shall include, but not be limited to:

1) Costs resulting from the production of vaccine that fails, through no gross negligence of the contractor, to meet the specifications of the contract because it is refused certification by the Bureau of Biologics of the Food and Drug Administration.

2) Costs incurred prior to execution of the contract in order to meet the reasonably anticipated delivery dates for the vaccine under the Program.

3) Imputed interest on working capital, at rates determined by the Secretary of Treasure pursuant to P.L. 92-41, 85 Stat. 97.

4) Actual and unrecoverable costs due to interruption of production or sale of other biologicals in order to devote staff and facilities to the production of vaccine for the Program.

3. Profit will only be allowed on A/Victoria/75 vaccine and shall be negotiated at arm's length based on the contractor's degree of risk, difficulty and complexity of performance, type of contract, and cooperation with the Government in meeting the needs of this health emergency.

GENERAL PROVISIONS

(Supply Contract)

1. DEFINITIONS

As used throughout this contract, the following terms shall have the meaning set forth below:

(a) The term "head of the agency" or "Secretary" as used herein means the Secretary, the Under Secretary, any Assistant Secretary, or any other head or assistant head of the executive or military department or other Federal agency; and the term "his duly authorized representative" means any person or persons or board (other than the Contracting Officer) authorized to act for the head of the agency or the Secretary.

(b) The term "Contracting Officer" means the person executing this contract on behalf of the Government, and any other officer or civilian employee who is a properly designated Contracting Officer; and the term includes, except as otherwise provided in this contract, the authorized representative of a Contracting Officer acting within the limits of his authority.

(c) Except as otherwise provided in this contract, the term "subcontracts" includes purchase orders under this contract.

2. CHANGES

The Contracting Officer may at any time, by a written order, and without notice to the sureties, make changes, within the general scope of this contract, in any one or more of the following: (i) Drawings, designs, or specifications, where the supplies to be furnished are to be specially manufactured for the Government in accordance therewith; (ii) method of shipment or packing; and (iii) place of delivery. If any such change causes an increase or decrease in the cost of, or the time required for, the performance of any part of the work under this contract, whether changed or not changed by any such order, an equitable adjustment shall be made in the contract price or delivery schedule, or both, and the contract shall be modified in writing accordingly. Any claim by the Contractor for adjustment under this clause must be asserted within 30 days from the date of receipt by the Contractor of the notification of change: *Provided, however*, That the Contracting Officer, if he decides that the facts justify such action, may receive and act upon any such claim asserted at any time prior to final payment under this contract. Where the cost of property made obsolete or excess as a result of a change is included in the Contractor's claim for adjustment, the Contracting Officer shall have the right to prescribe the manner of disposition of such property. Failure to agree to any adjustment shall be a dispute concerning a question of fact within the meaning of the clause of this contract entitled "Disputes." However, nothing in this clause shall excuse the Contractor from proceeding with the contract as changed.

3. EXTRAS

Except as otherwise provided in this contract, no payment for extras shall be made unless such extras and the price therefor have been authorized in writing by the Contracting Officer.

4. VARIATION IN QUANTITY

No variation in the quantity of any item called for by this contract will be accepted unless such variation has been caused by conditions of loading, shipping, or packing, or allowances in manufacturing processes, and then only to the extent, if any, specified elsewhere in this contract.

5. INSPECTION

(a) All supplies (which term throughout this clause includes without limitation raw materials, components, intermediate assemblies, and end products) shall be subject to inspection and test by the Government, to the extent practicable at all times and places including the period of manufacture, and in any event prior to acceptance.

(b) In case any supplies or lots of supplies are defective in material or workmanship or otherwise not in conformity with the requirements of this contract, the Government shall have the right either to reject them (with or without instructions as to their disposition) or to require their correction. Supplies or lots of supplies which have been rejected or required to be corrected shall be removed or, if permitted or required by the Contracting Officer, corrected in place by and at the expense of the Contractor promptly after notice, and shall not thereafter be tendered for acceptance unless the former rejection or requirement of correction is disclosed. If the Contractor fails promptly to remove such supplies or lots of supplies which are required to be removed, or promptly to replace or correct such supplies or lots of supplies, the Government either (i) may by contract or otherwise replace or correct such supplies and charge to the Contractor the cost occasioned the Government thereby, or (ii) may terminate this contract for default as provided in the clause of this contract entitled "Default." Unless the Contractor corrects or replaces such supplies within the delivery schedule, the Contracting Officer may require the delivery of such supplies at a reduction in price which is equitable under the circumstances. Failure to agree to such reduction of price shall be a dispute concerning a question of fact within the meaning of the clause of this contract entitled "Disputes."

(c) If any inspection or test is made by the Government on the premises of the Contractor or a subcontractor, the Contractor without additional charge shall provide all reasonable facilities and assistance for the safety and convenience of the Government inspectors in the performance of their duties. If Government inspection or test is made at a point other than the premises of the Contractor or a subcontractor, it shall be at the expense of the Government except as otherwise provided in this contract: *Provided*, That in case of rejection the Government shall not be liable for any reduction in value of samples used in connection with such inspection or test. All inspections and tests by the Government shall be performed in such a manner as not to unduly delay the work. The Government reserves the right to charge to the Contractor any additional cost of Government inspection and test when supplies are not ready at the time such inspection and test is requested by the Contractor or when reinspection or retest is necessitated by prior rejection. Acceptance or rejection of the supplies shall be made as promptly as practicable after delivery, except as otherwise provided in this contract; but failure to inspect and accept or reject supplies shall neither relieve the Contractor from responsibility for such supplies as are not in accordance with the contract requirements nor impose liability on the Government therefor.

(d) The inspection and test by the Government of any supplies or lots thereof does not relieve the Contractor from any responsibility regarding defects or other failures to meet the contract requirements which may be discovered prior to acceptance. Except as otherwise provided in this contract, acceptance shall be conclusive except as regards latent defects, fraud, or such gross mistakes as amount to fraud.

(e) The Contractor shall provide and maintain an inspection system acceptable to the Government covering the supplies hereunder. Records of all inspection work by the Contractor shall be kept complete and available to the Government during

the performance of this contract and for such longer period as may be specified elsewhere in this contract.

6. RESPONSIBILITY FOR SUPPLIES

Except as otherwise provided in this contract, (i) the Contractor shall be responsible for the supplies covered by this contract until they are delivered at the designated delivery point, regardless of the point of inspection; (ii) after delivery to the Government at the designated point and prior to acceptance by the Government or rejection and giving notice thereof by the Government, the Government shall be responsible for the loss or destruction of or damage to the supplies only if such loss, destruction, or damage results from the negligence of officers, agents, or employees of the Government acting within the scope of their employment; and (iii) the Contractor shall bear all risks as to rejected supplies after notice of rejection, except that the Government shall be responsible for the loss, or destruction of, or damage to the supplies only if such loss, destruction or damage results from the gross negligence of officers, agents, or employees of the Government acting within the scope of their employment.

7. PAYMENTS

The Contractor shall be paid, upon the submission of proper invoices or vouchers, the prices stipulated herein for supplies delivered and accepted or services rendered and accepted, less deductions, if any, as herein provided. Unless otherwise specified, payment will be made on partial deliveries accepted by the Government when the amount due on such deliveries so warrants; or, when requested by the Contractor, payment for accepted partial deliveries shall be made whenever such payment would equal or exceed either $1,000 or 50 percent of the total amount of this contract.

8. ASSIGNMENT OF CLAIMS

(a) Pursuant to the provisions of the Assignment of Claims Act of 1940, as amended (31 U.S.C. 203, 41 U.S.C. 15), if this contract provides for payments aggregating $1,000 or more, claims for moneys due or to become due the Contractor from the Government under this contract may be assigned to a bank, trust company, or other financing institution, including any Federal lending agency, and may thereafter be further assigned and reassigned to any such institution. Any such assignment or reassignment shall cover all amounts payable under this contract and not already paid, and shall not be made to more than one party, except that any such assignment or reassignment may be made to one party as agent or trustee for two or more parties participating in such financing. Unless otherwise provided in this contract, payments to an assignee of any moneys due or to become due under this contract shall not, to the extent provided in said Act, as amended, be subject to reduction or setoff. (The preceding sentence applies only if this contract is made in time of war or national emergency as defined in said Act and is with the Department of Defense, the General Services Administration, the Energy Research and Development Administration, the National Aeronautics and Space Administration, the Federal Aviation Administration, or any other department or agency of the United States designated by the President pursuant to Clause 4 of the proviso of section 1 of the Assignment of Claims Act of 1940, as amended by the Act of May 15, 1951, 65 Stat. 41.)

(b) In no event shall copies of this contract or of any plans, specifications, or other similar documents relating to work under this contract, if marked "Top Secret," "Secret," or "Confidential," be furnished to any assignee of any claim arising under this contract or to any other person not entitled to receive the same. However, a copy of any part or all of this contract so marked may be furnished, or any information contained therein may be disclosed, to such assignee upon the prior written authorization of the Contracting Officer.

9. ADDITIONAL BOND SECURITY

If any surety upon any bond furnished in connection with this contract becomes unacceptable to the Government or if any such surety fails to furnish reports as to his financial condition from time to time as requested by the Government, the Contractor shall promptly furnish such additional security as may be required from time to time to protect the interests of the Government and of persons supplying labor or materials in the prosecution of the work contemplated by this contract.

10. EXAMINATION OF RECORDS BY COMPTROLLER GENERAL

(a) This clause is applicable if the amount of this contract exceeds $10,000 and was entered into by means of negotiation, including small business restricted advertising, but is not applicable if this contract was entered into by means of formal advertising.

(b) The Contractor agrees that the Comptroller General of the United States or any of his duly authorized representatives shall, until the expiration of 3 years after final payment under this contract or such lesser time specified in either Appendix M of the Armed Services Procurement Regulation or the Federal Procurement Regulations Part 1–20, as appropriate, have access to and the right to examine any directly pertinent books, documents, papers, and records of the Contractor involving transactions related to this contract.

(c) The Contractor further agrees to include in all his subcontracts hereunder a provision to the effect that the subcontractor agrees that the Comptroller General of the United States or any of his duly authorized representatives shall, until the expiration of 3 years after final payment under the subcontract or such lesser time specified in either Appendix M of the Armed Services Procurement Regulation or the Federal Procurement Regulations Part 1–20, as appropriate, have access to and the right to examine any directly pertinent books, documents, papers, and records of such subcontractor, involving transactions related to the subcontract. The term "subcontract" as used in this clause excludes (1) purchase orders not exceeding $10,000 and (2) subcontracts or purchase orders for public utility services at rates established for uniform applicability to the general public.

(d) The periods of access and examination described in (b) and (c), above, for records which relate to (1) appeals under the "Disputes" clause of this contract, (2) litigation or the settlement of claims arising out of the performance of this contract, or (3) costs and expenses of this contract as to which exception has been taken by the Comptroller General or any of his duly authorized representatives, shall continue until such appeals, litigation, claims, or exceptions have been disposed of.

11. DEFAULT

(a) The Government may, subject to the provisions of paragraph (c) below, by written notice of default to the Contractor, terminate the whole or any part of this contract in any one of the following circumstances:

(i) If the Contractor fails to make delivery of the supplies or to perform the services within the time specified herein or any extension thereof; or

(ii) If the Contractor fails to perform any of the other provisions of this contract, or so fails to make progress as to endanger performance of this contract in accordance with its terms, and in either of these two circumstances does not cure such failure within a period of 10 days (or such longer period as the Contracting Officer may authorize in writing) after receipt of notice from the Contracting Officer specifying such failure.

(b) In the event the Government terminates this contract in whole or in part as provided in paragraph (a) of this clause, the Government may procure, upon such terms and in such manner as the Contracting Officer may deem appropriate, supplies or services similar to those so terminated, and the Contractor shall be liable to the Government for any excess costs for such similar supplies or services: *Provided*, That the Contractor shall continue the performance of this contract to the extent not terminated under the provisions of this clause.

(c) Except with respect to defaults of subcontractors, the

Contractor shall not be liable for any excess costs if the failure to perform the contract arises out of causes beyond the control and without the fault or negligence of the Contractor. Such causes may include, but are not restricted to, acts of God or of the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, freight embargoes, and unusually severe weather; but in every case the failure to perform must be beyond the control and without the fault or negligence of the Contractor. If the failure to perform is caused by the default of a subcontractor, and if such default arises out of causes beyond the control of both the Contractor and subcontractor, and without the fault or negligence of either of them, the Contractor shall not be liable for any excess costs for failure to perform, unless the supplies or services to be furnished by the subcontractor were obtainable from other sources in sufficient time to permit the Contractor to meet the required delivery schedule.

(d) If this contract is terminated as provided in paragraph (a) of this clause, the Government, in addition to any other rights provided in this clause, may require the Contractor to transfer title and deliver to the Government, in the manner and to the extent directed by the Contracting Officer, (i) any completed supplies, and (ii) such partially completed supplies and materials, parts, tools, dies, jigs, fixtures, plans, drawings, information, and contract rights (hereinafter called "manufacturing materials") as the Contractor has specifically produced or specifically acquired for the performance of such part of this contract as has been terminated; and the Contractor shall, upon direction of the Contracting Officer, protect and preserve property in possession of the Contractor in which the Government has an interest. Payment for completed supplies delivered to and accepted by the Government shall be at the contract price. Payment for manufacturing materials delivered to and accepted by the Government and for the protection and preservation of property shall be in an amount agreed upon by the Contractor and Contracting Officer; failure to agree to such amount shall be a dispute concerning a question of fact within the meaning of the clause of this contract entitled "Disputes." The Government may withhold from amounts otherwise due the Contractor for such completed supplies or manufacturing materials such sum as the Contracting Officer determines to be necessary to protect the Government against loss because of outstanding liens or claims of former lien holders.

(e) If, after notice of termination of this contract under the provisions of this clause, it is determined for any reason that the Contractor was not in default under the provisions of this clause, or that the default was excusable under the provisions of this clause, the rights and obligations of the parties shall, if the contract contains a clause providing for termination for convenience of the Government, be the same as if the notice of termination had been issued pursuant to such clause. If, after notice of termination of this contract under the provisions of this clause, it is determined for any reason that the Contractor was not in default under the provisions of this clause, and if this contract does not contain a clause providing for termination for convenience of the Government, the contract shall be equitably adjusted to compensate for such termination and the contract modified accordingly; failure to agree to any such adjustment shall be a dispute concerning a question of fact within the meaning of the clause of this contract entitled "Disputes."

(f) The rights and remedies of the Government provided in this clause shall not be exclusive and are in addition to any other rights and remedies provided by law or under this contract.

(g) As used in paragraph (c) of this clause, the terms "subcontractor" and "subcontractors" mean subcontractor(s) at any tier.

12. DISPUTES

(a) Except as otherwise provided in this contract, any dispute concerning a question of fact arising under this contract which is not disposed of by agreement shall be decided by the Contracting Officer, who shall reduce his decision to writing and mail or otherwise furnish a copy thereof to the Contractor. The decision of the Contracting Officer shall be final and conclusive unless, within 30 days from the date of receipt of such copy, the Contractor mails or otherwise furnishes to the Contracting Officer a written appeal addressed to the Secretary. The decision of the Secretary or his duly authorized representative for the determination of such appeals shall be final and conclusive unless determined by a court of competent jurisdiction to have been fraudulent, or capricious, or arbitrary, or so grossly erroneous as necessarily to imply bad faith, or not supported by substantial evidence. In connection with any appeal proceeding under this clause, the Contractor shall be afforded an opportunity to be heard and to offer evidence in support of its appeal. Pending final decision of a dispute hereunder, the Contractor shall proceed diligently with the performance of the contract and in accordance with the Contracting Officer's decision.

(b) This "Disputes" clause does not preclude consideration of law questions in connection with decisions provided for in paragraph (a) above: *Provided*, That nothing in this contract shall be construed as making final the decision of any administrative official, representative, or board on a question of law.

13. NOTICE AND ASSISTANCE REGARDING PATENT AND COPYRIGHT INFRINGEMENT

The provisions of this clause shall be applicable only if the amount of this contract exceeds $10,000.

(a) The Contractor shall report to the Contracting Officer, promptly and in reasonable written detail, each notice or claim of patent or copyright infringement based on the performance of this contract of which the Contractor has knowledge.

(b) In the event of any claim or suit against the Government on account of any alleged patent or copyright infringement arising out of the performance of this contract or out of the use of any supplies furnished or work or services performed hereunder, the Contractor shall furnish to the Government, when requested by the Contracting Officer, all evidence and information in possession of the Contractor pertaining to such suit or claim. Such evidence and information shall be furnished at the expense of the Government except where the Contractor has agreed to indemnify the Government.

14. BUY AMERICAN ACT

(a) In acquiring end products, the Buy American Act (41 U.S. Code 10 a–d) provides that the Government give preference to domestic source end products. For the purpose of this clause:

(i) "Components" means those articles, materials, and supplies, which are directly incorporated in the end products;

(ii) "End products" means those articles, materials, and supplies, which are to be acquired under this contract for public use; and

(iii) A "domestic source end product" means (A) an unmanufactured end product which has been mined or produced in the United States and (B) an end product manufactured in the United States if the cost of the components thereof which are mined, produced, or manufactured in the United States exceeds 50 percent of the cost of all its components. For the purposes of this (a) (iii) (B), components of foreign origin of the same type or kind as the products referred to in (b) (ii) or (iii) of this clause shall be treated as components mined, produced, or manufactured in the United States.

(b) The Contractor agrees that there will be delivered under this contract only domestic source end products, except end products:

(i) Which are for use outside the United States;

(ii) Which the Government determines are not mined, produced, or manufactured in the United States in sufficient and reasonably available commercial quantities and of a satisfactory quality;

(iii) As to which the Secretary determines the domestic preference to be inconsistent with the public interest; or

(iv) As to which the Secretary determines the cost to the Government to be unreasonable.

(The foregoing requirements are administered in accordance with Executive Order No. 10582, dated December 17, 1954.)

15. CONVICT LABOR

In connection with the performance of work under this contract, the Contractor agrees not to employ any person undergoing sentence of imprisonment at hard labor except as provided by Public Law 89-176, September 10, 1965 (18 U.S.C. 4082(c)(2)) and Executive Order 11755, December 29, 1973.

16. CONTRACT WORK HOURS AND SAFETY STANDARDS ACT—OVERTIME COMPENSATION

This contract, to the extent that it is of a character specified in the Contract Work Hours and Safety Standards Act (40 U.S.C. 327-333), is subject to the following provisions and to all other applicable provisions and exceptions of such Act and the regulations of the Secretary of Labor thereunder.

(a) Overtime requirements. No Contractor or subcontractor contracting for any part of the contract work which may require or involve the employment of laborers, mechanics, apprentices, trainees, watchmen, and guards shall require or permit any laborer, mechanic, apprentice, trainee, watchman, or guard in any workweek in which he is employed on such work to work in excess of eight hours in any calendar day or in excess of forty hours in such workweek on work subject to the provisions of the Contract Work Hours and Safety Standards Act unless such laborer, mechanic, apprentice, trainee, watchman, or guard receives compensation at a rate not less than one and one-half times his basic rate of pay for all such hours worked in excess of eight hours in any calendar day or in excess of forty hours in such workweek, whichever is the greater number of overtime hours.

(b) Violation; liability for unpaid wages; liquidated damages. In the event of any violation of the provisions of paragraph (a), the Contractor and any subcontractor responsible therefor shall be liable to any affected employee for his unpaid wages. In addition, such Contractor and subcontractor shall be liable to the United States for liquidated damages. Such liquidated damages shall be computed with respect to each individual laborer, mechanic, apprentice, trainee, watchman, or guard employed in violation of the provisions of paragraph (a) in the sum of $10 for each calendar day on which such employee was required or permitted to be employed on such work in excess of eight hours or in excess of his standard workweek of forty hours without payment of the overtime wages required by paragraph (a).

(c) Withholding for unpaid wages and liquidated damages. The Contracting Officer may withhold from the Government Prime Contractor, from any moneys payable on account of work performed by the Contractor or subcontractor, such sums as may administratively be determined to be necessary to satisfy any liabilities of such Contractor or subcontractor for unpaid wages and liquidated damages as provided in the provisions of paragraph (b).

(d) Subcontracts. The Contractor shall insert paragraphs (a) through (d) of this clause in all subcontracts, and shall require their inclusion in all subcontracts of any tier.

(e) Records. The Contractor shall maintain payroll records containing the information specified in 29 CFR 516.2(a). Such records shall be preserved for three years from the completion of the contract.

17. WALSH-HEALEY PUBLIC CONTRACTS ACT

If this contract is for the manufacture or furnishing of materials, supplies, articles, or equipment in an amount which exceeds or may exceed $10,000 and is otherwise subject to the Walsh-Healey Public Contracts Act, as amended (41 U.S. Code 35–45), there are hereby incorporated by reference all representations and stipulations required by said Act and regulations issued thereunder by the Secretary of Labor, such representations and stipulations being subject to all applicable rulings and interpretations of the Secretary of Labor which are now or may hereafter be in effect.

18. EQUAL OPPORTUNITY

(The following clause is applicable unless this contract is exempt under the rules, regulations, and relevant orders of the Secretary of Labor (41 CFR, ch. 60).)

During the performance of this contract, the Contractor agrees as follows:

(a) The Contractor will not discriminate against any employee or applicant for employment because of race, color, religion, sex, or national origin. The Contractor will take affirmative action to ensure that applicants are employed, and that employees are treated during employment, without regard to their race, color, religion, sex, or national origin. Such action shall include, but not be limited to, the following: Employment, upgrading, demotion, or transfer; recruitment or recruitment advertising; layoff or termination; rates of pay or other forms of compensation; and selection for training, including apprenticeship. The Contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices to be provided by the Contracting Officer setting forth the provisions of this Equal Opportunity clause.

(b) The Contractor will, in all solicitations or advertisements for employees placed by or on behalf of the Contractor, state that all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, or national origin.

(c) The Contractor will send to each labor union or representative of workers with which he has a collective bargaining agreement or other contract or understanding, a notice, to be provided by the agency Contracting Officer, advising the labor union or workers' representative of the Contractor's commitments under this Equal Opportunity clause, and shall post copies of the notice in conspicuous places available to employees and applicants for employment.

(d) The Contractor will comply with all provisions of Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, and of the rules, regulations, and relevant orders of the Secretary of Labor.

(e) The Contractor will furnish all information and reports required by Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, and by the rules, regulations, and orders of the Secretary of Labor, or pursuant thereto, and will permit access to his books, records, and accounts by the contracting agency and the Secretary of Labor for purposes of investigation to ascertain compliance with such rules, regulations, and orders.

(f) In the event of the Contractor's noncompliance with the Equal Opportunity clause of this contract or with any of the said rules, regulations, or orders, this contract may be canceled, terminated, or suspended, in whole or in part, and the Contractor may be declared ineligible for further Government contracts in accordance with procedures authorized in Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, and such other sanctions may be imposed and remedies invoked as provided in Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, or by rule, regulation, or order of the Secretary of Labor, or as otherwise provided by law.

(g) The Contractor will include the provisions of paragraphs (a) through (g) in every subcontract or purchase order unless exempted by rules, regulations, or orders of the Secretary of Labor issued pursuant to section 204 of Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, so that such provisions will be binding upon each subcontractor or vendor. The Contractor will take such action with respect to any subcontract or purchase order as the contracting agency may direct as a means of enforcing such provisions, including sanctions for noncompliance: *Provided, however*, That in the event the Contractor becomes involved in,

or is threatened with, litigation with a subcontractor or vendor as a result of such direction by the contracting agency, the Contractor may request the United States to enter into such litigation to protect the interests of the United States.

19. OFFICIALS NOT TO BENEFIT

No member of or delegate to Congress, or resident Commissioner, shall be admitted to any share or part of this contract, or to any benefit that may arise therefrom; but this provision shall not be construed to extend to this contract if made with a corporation for its general benefit.

20. COVENANT AGAINST CONTINGENT FEES

The Contractor warrants that no person or selling agency has been employed or retained to solicit or secure this contract upon an agreement or understanding for a commission, percentage, brokerage, or contingent fee, excepting bona fide employees or bona fide established commercial or selling agencies maintained by the Contractor for the purpose of securing business. For breach or violation of this warranty the Government shall have the right to annul this contract without liability or in its discretion to deduct from the contract price or consideration, or otherwise recover, the full amount of such commission, percentage, brokerage, or contingent fee.

21. UTILIZATION OF SMALL BUSINESS CONCERNS

(a) It is the policy of the Government as declared by the Congress that a fair proportion of the purchases and contracts for supplies and services for the Government be placed with small business concerns.

(b) The Contractor agrees to accomplish the maximum amount of subcontracting to small business concerns that the Contractor finds to be consistent with the efficient performance of this contract.

22. UTILIZATION OF LABOR SURPLUS AREA CONCERNS

(a) It is the policy of the Government to award contracts to labor surplus area concerns that (1) have been certified by the Secretary of Labor (hereafter referred to as certified-eligible concerns with first or second preferences) regarding the employment of a proportionate number of disadvantaged individuals and have agreed to perform substantially (i) in or near sections of concentrated unemployment or underemployment or in persistent or substantial labor surplus areas or (ii) in other areas of the United States, respectively, or (2) are noncertified concerns which have agreed to perform substantially in persistent or substantial labor surplus areas, where this can be done consistent with the efficient performance of the contract and at prices no higher than are obtainable elsewhere. The Contractor agrees to use his best efforts to place his subcontracts in accordance with this policy.

(b) In complying with paragraph (a) of this clause and with paragraph (b) of the clause of this contract entitled "Utilization of Small Business Concerns" the Contractor in placing his subcontracts shall observe the following order of preference: (1) Certified-eligible concerns with a first preference which are also small business concerns; (2) other certified-eligible concerns with a first preference; (3) certified-eligible concerns with a second preference which are also small business concerns; (4) other certified-eligible concerns with a second preference; (5) persistent or substantial labor surplus area concerns which are also small business concerns; (6) other persistent or substantial labor surplus area concerns; and (7) small business concerns which are not labor surplus area concerns.

23. UTILIZATION OF MINORITY BUSINESS ENTERPRISES

(a) It is the policy of the Government that minority business enterprises shall have the maximum practicable opportunity to participate in the performance of Government contracts.

(b) The Contractor agrees to use his best efforts to carry out this policy in the award of his subcontracts to the fullest extent consistent with the efficient performance of this contract. As used in this contract, the term "minority business enterprise" means a business, at least 50 percent of which is owned by minority group members or, in case of publicly-owned businesses, at least 51 percent of the stock of which is owned by minority group members. For the purposes of this definition, minority group members are Negroes, Spanish-speaking American persons, American-Orientals, American-Indians, American-Eskimos, and American Aleuts. Contractors may rely on written representations by subcontractors regarding their status as minority business enterprises in lieu of an independent investigation.

24. PRICING OF ADJUSTMENTS

When costs are a factor in any determination of a contract price adjustment pursuant to the Changes clause or any other provision of this contract, such costs shall be in accordance with the contract cost principles and procedures in Part 1–15 of the Federal Procurement Regulations (41 CFR 1–15) or Section XV of the Armed Services Procurement Regulation, as applicable, which are in effect on the date of this contract.

25. PAYMENT OF INTEREST ON CONTRACTORS' CLAIMS

(a) If an appeal is filed by the Contractor from a final decision of the Contracting Officer under the Disputes clause of this contract, denying a claim arising under the contract, simple interest on the amount of the claim finally determined owed by the Government shall be payable to the Contractor. Such interest shall be at the rate determined by the Secretary of the Treasury pursuant to Public Law 92-41, 85 Stat. 97, from the date the Contractor furnishes to the Contracting Officer his written appeal under the Disputes clause of this contract, to the date of (1) a final judgment by a court of competent jurisdiction, or (2) mailing to the Contractor of a supplemental agreement for execution either confirming completed negotiations between the parties or carrying out a decision of a board of contract appeals.

(b) Notwithstanding (a), above, (1) interest shall be applied only from the date payment was due, if such date is later than the filing of appeal, and (2) interest shall not be paid for any period of time that the Contracting Officer determines the Contractor has unduly delayed in pursuing his remedies before a board of contract appeals or a court of competent jurisdiction.

Clause 21(a) SMALL BUSINESS SUBCONTRACTING PROGRAM

FPR 1-1.710-3(b)

(a) The Contractor agrees to establish and conduct a small business subcontracting program which will enable small business concerns to be considered fairly as subcontractors and suppliers under this contract. In this connection, the Contractor shall:

(1) Designate a liaison officer who will (i) maintain liaison with the Government on small business matters, (ii) supervise compliance with the Utilization of Small Business Concerns clause, and (iii) administer the Contractor's "Small Business Subcontracting Program."

(2) Provide adequate and timely consideration of the potentialities of small business concerns in all "make-or-buy" decisions.

(3) Assure that small business concerns will have an equitable opportunity to compete for subcontracts, particularly by arranging solicitations, time for the preparation of bids, quantities, specifications, and delivery schedules so as to facilitate the participation of small business concerns. Where the Contractor's lists of potential small business subcontractors are excessively long, reasonable effort shall be made to give all such small business concerns an opportunity to compete over a period of time.

(4) Maintain records showing (i) whether each prospective subcontractor is a small business concern, (ii) procedures which have been adopted to comply with the policies set forth in this clause, and (iii) with respect to the letting of any subcontract (including purchase orders) exceeding $10,000, information substantially as follows:

(A) Whether the award went to large or small business.

(B) Whether less than three or more than two small business firms were solicited.

(C) The reason for nonsolicitation of small business if such was the case.

(D) The reason for small business failure to receive the award if such was the case when small business was solicited.

The records maintained in accordance with (iii) above may be in such form as the Contractor may determine, and the information shall be summarized quarterly and submitted by the purchasing department of each individual plant or division to the Contractor's cognizant small business liaison officer. Such quarterly summaries will be considered to be management records only and need not be submitted routinely to the Government; however, records maintained pursuant to this clause will be kept available for review by the Government until the expiration of 1 year after the award of this contract, or for such longer period as may be required by any other clause of this contract or by applicable law or regulation.

(5) Notify the Contracting Officer before soliciting bids or quotations on any subcontract (including purchase orders) in excess of $10,000 if (i) no small business concern is to be solicited, and (ii) the Contracting Officer's consent to the subcontract (or ratification) is required by a "Subcontracts" clause in this contract. Such notice will state the Contractor's reasons for non-solicitation of small business concerns, and will be given as early in the procurement cycle as possible so that the Contracting Officer may give SBA timely notice to permit SBA a reasonable period to suggest potentially qualified small business concerns through the Contracting Officer. In no case will the procurement action be held up when to do so would, in the Contractor's judgment, delay performance under the contract.

(6) Include the Utilization of Small Business Concerns clause in subcontracts which offer substantial small business subcontracting opportunities.

(7) Cooperate with the Contracting Officer in any studies and surveys of the Contractor's subcontracting procedures and practices that the Contracting Officer may from time to time conduct.

(8) Submit quarterly reports of subcontracting to small business concerns on either Optional Form 61, Small Business Subcontracting Program Quarterly Report of Participating Large Company on Subcontract Committments to Small Business Concerns, or such other form as may be specified in the contract. Except as otherwise provided in this contract, the reporting requirements of this subparagraph (8) do not apply to small business contractors, small business subcontractors, educational and nonprofit institutions, and contractors or subcontractors for standard commercial items.

(b) A "small business concern" is a concern that meets the pertinent criteria established by the Small Business Administration and set forth in § 1-701 of the Federal Procurement Regulations.

(c) The Contractor agrees that, in the event he fails to comply with his contractual obligations concerning the small business subcontracting program, this contract may be terminated, in whole or in part, for default.

(d) The Contractor further agrees to insert, in any subcontract hereunder which may exceed $500,000 and which contains the Utilization of Small Business Concerns clause, provisions which shall conform substantially to the language of this clause, including this paragraph (d), and to notify the Contracting Officer of the names of such subcontractors.

Clause 22a

LABOR SURPLUS AREA SUBCONTRACTING PROGRAM

FPR 1-1.805-3(b)

(This clause is applicable if this contract exceeds $500,000.00)

(a) The Contractor agrees to establish and conduct a program which will encourage labor surplus area concerns to compete for subcontracts within their capabilities. In this connection, the Contractor shall:

(1) Designate a liaison officer who will (i) maintain liaison with duly authorized representatives of the Government on labor surplus area matters, (ii) supervise compliance with the Utilization of Concerns in Labor Surplus Areas clause, and (iii) administer the Contractor's "Labor Surplus Area Subcontracting Program";

(2) Provide adequate and timely consideration of the potentialities of labor surplus area concerns in all "make-or-buy" decisions;

(3) Assure that labor surplus area concerns will have an equitable opportunity to compete for subcontracts, particularly by arranging solicitations, time for the preparation of bids, quantities, specifications, and delivery schedules so as to facilitate the participation of labor surplus area concerns;

(4) Maintain records showing procedures which have been adopted to comply with the policies set forth in this clause. Records maintained pursuant to this clause will be kept available for review by the Government until the expiration of 1 year after the award of this contract, or for such longer period as may be required by any other clause of this contract or by applicable law or regulations; and

(5) Include the Utilization of Concerns in Labor Surplus Areas clause in subcontracts which offer substantial labor surplus area subcontracting opportunities.

(b) A "labor surplus area concern" is a concern that (1) has been certified by the Secretary of Labor (hereafter referred to as a certified-eligible concern) regarding the employment of a proportionate number of disadvantaged individuals and has agreed to perform substantially in or near sections of concentrated unemployment or underemployment, in persistent or substantial labor surplus

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areas, or in other areas of the United States or (2) is a noncertified concern which has agreed to perform a substantial proportion of a contract in persistent or substantial labor surplus areas. A certified-eligible concern shall be deemed to have performed a substantial proportion of a contract in or near sections of concentrated unemployment or underemployment, in persistent or substantial labor surplus areas, or in other areas if the costs that the concern will incur on account of manufacturing or production in or near such sections or in such areas (by itself, if a certified concern, or by certified concerns acting as first-tier subcontractors) amount to more than 25 percent of the contract price. A concern shall be deemed to have performed a substantial proportion of a contract in persistent of substantial surplus areas (by itself or its first-tier subcontractors) if the costs that the concern will incur on account of production or manufacturing in such areas amount to more than 50 percent of the contract price.

(c) The Contractor further agrees to insert, in any subcontract hereunder which may exceed $500,000 and which contains the Utilization of Concerns in Labor Surplus Areas clause, provisions which shall conform substantially to the language of this clause, including this paragraph (c), and to notify the Contracting Officer of the names of such subcontractors.

Clause 24

PRICING OF ADJUSTMENTS

When costs are a factor in any determination of a contract price adjustment pursuant to the "Changes" clause or any other provision of this contract, such costs shall be in accordance with the contract cost and profit criteria contained in Appendix A of this contract.

MODIFICATIONS TO GENERAL PROVISIONS, STANDARD FORM 32 (Supply)

Disabled Veterans and Veterans of the Vietnam Era

(This clause is applicable pursuant to 41 CFR 50-250 if this contract is for $10,000 or more.)

(a) The contractor will not discriminate against any employee or applicant for employment because he or she is a disabled veteran or veteran of the Vietnam era in regard to any position for which the employee or applicant for employment is qualified. The contractor agrees to take affirmative action to employ, advance in employment, and otherwise treat qualified disabled veterans and veterans of the Vietnam era without discrimination based upon their disability or veterans status in all employment practices such as the following: employment upgrading, demotion or transfer, recruitment, advertising, layoff or termination, rates of pay or other forms of compensation, and selection for training, including apprenticeship.

(b) The contractor agrees that all suitable employment openings of the contractor which exist at the time of the execution of this contract and those which occur during the performance of this contract, including those not generated by this contract and including those occurring at an establishment of the contractor other than the one wherein the contract is being performed but excluding those of independently operated corporate affiliates, shall be listed at an appropriate local office of the State employment service system wherein the opening occurs. The contractor further agrees to provide such reports to such local office regarding employment openings and hires as may be required.

State and local government agencies holding Federal contracts of $10,000 or more shall also list all their suitable openings with the appropriate office of the State employment service, but are not required to provide those reports set forth in paragraphs (d) and (e).

(c) Listing of employment openings with the employment service system pursuant to this clause shall be made at least concurrently with the use of any other recruitment source or effort and shall involve the normal obligations which attache to the placing of a bona fide job order, including the acceptance of referrals of veterans and nonveterans. The listing of employment openings does not require the hiring of any particular job applicant or from any particular group of job applicants, and nothing herein is intended to relieve the contractor from any requirements in Executive orders or regulations regarding nondiscrimination in employment.

(d) The reports required by paragraph (b) of this clause shall include, but not be limited to, periodic reports which shall be filed at least quarterly with the appropriate local office or, where the contractor has more than one hiring location in a State, with the central office of that State employment service. Such reports shall indicate for each hiring location (a) the number of individuals hired during the reporting period, (2) the number of nondisabled veterans of the Vietnam era hired, (3) the number of disabled veterans of the Vietnam era hired, and (4) the total number of disabled veterans hired. The reports should include covered veterans hired for on-the-job training under

38 U.S.C. 1787. The contractor shall submit a report within 30 days after the end of each reporting period wherein any performance is made on this contract identifying data for each hiring location. The contractor shall maintain at each hiring location copies of the reports submitted until the expiration of one year after final payment under the contract during which time these reports and related documentation shall be made available, upon request, for examination by any authorized representatives of the Contracting Officer or of the Secretary of Labor. Documentation would include personnel records respecting job openings, recruitment, and placement.

(e) Whenever the contractor becomes contractually bound to the listing provisions of this clause, it shall advise the employment service system in each State where it has establishments of the name and location of each hiring location in the State. As long as the contractor is contractually bound to these provisions and has so advised the State system, there is no need to advise the State system of subsequent contracts. The contractor may advise the State system when it is no longer bound by this contract clause.

(f) This clause does not apply to the listing of employment openings which occur and are filled outside the 50 States, the District of Columbia, Puerto Rico, Guam, and the Virgin Islands.

(g) The provisions of paragraphs (b), (c), (d), and (e) of this clause do not apply to openings which the contractor proposes to fill from within his own organization or to fill pursuant to a customary and traditional employer-union hiring arrangement. This exclusion does not apply to a particular opening once an employer decides to consider applicants outside of his own organization or employer-union arrangement for that opening.

(h) As used in this clause: (1) "All suitable employment openings" includes, but is not limited to, openings which occur in the following job categories: production and non-production; plant and office; laborers and mechanics; supervisory and nonsupervisory; technical; and executive, administrative, and professional openings that are compensated on a salary basis of less than $25,000 per year. This term includes full-time employment, temporary employment of more than 3 days' duration, and part-time employment. It does not include openings which the contractor proposes to fill from within his own organization or to fill pursuant to a customary and traditional employer-union hiring arrangement nor openings in an educational institution which are restricted to students of that institution. Under the most compelling circumstances an employment opening may not be suitable for listing, including such situations where the needs of the Government cannot reasonably be otherwise supplies, where listing would be contrary to national security, or where the requirement of listing would otherwise not be for the best interest of the Government.

(2) "Appropriate office of the State employment service system" means the local office of the Federal/State national system of public employment offices with assigned responsibility for serving the area where the employment

opening is to be filled, including the Distric of Columbia, Guam, Puerto Rico, and the Virgin Islands.

(3) "Openings which the contractor proposes to fill from within his own organization" means employment openings for which no consideration will be given to persons outside the contractor's organization (including affiliates, subsidiaries, and the parent companies) and includes any openings which the contractor proposes to fill from regularly established "recall" lists.

(4) "Openings which the contractor proposes to fill pursuant to a customary and traditional employer-union hiring arrangement" means employment openings which the contractor proposes to fill from union halls, which is part of the customary and traditional hiring relationship which exists between the contractor and representatives of his employees.

(i) The contractor agrees to comply with the rules, regulations, and relevant orders of the Secretary of Labor issued pursuant to the Act.

(j) In the event of the contractor's noncompliance with the requirements of this clause, actions for noncompliance may be taken in accordance with the rules, regulations, and relevant orders of the Secretary of Labor issued pursuant to the Act.

(k) The contractor agrees to post in conspicuous places available to employees and applicants for employment notices in a form to be prescribed by the Director, provided by or through the Contracting Officer. Such notice shall state the contractor's obligation under the law to take affirmative action to employ and advance in employment qualified disabled veterans and veterans of the Vietnam era for employment, and the rights of applicants and employees.

(l) The contractor will notify each labor union or representative of workers with which it has a collective bargaining agreement or other contract understanding that the contractor is bound by terms of the Vietnam Era Veteran's Readjustment Assistance Act and is committed to take affirmative action to employ and advance in employment qualified disabled veterans and veterans of the Vietnam era.

(m) The contractor will include the provisions of this clause in every subcontract or purchase order of $10,000 or more unless exempted by rules, regulations, or orders of the Secretary issued pursuant to the Act, so that such provisions will be binding upon each subcontractor or vendor. The contractor will take such action with respect to any subcontract or purchase order as the Director of the Office of Federal Contract Compliance Programs may direct to enforce such provisions, including action for noncompliance.

MINORITY BUSINESS ENTERPRISES SUBCONTRACTING PROGRAM

FPR 1-1.1310-2(b)

(This clause is applicable if this contract exceeds $500,000.00.)

(a) The Contractor agrees to establish and conduct a program which will enable minority business enterprises (as defined in the clause entitled "Utilization of Minority Business Enterprises") to be considered fairly as subcontractors and suppliers under this contract. In this connection, the Contractor shall:

(1) Designate a liaison officer who will administer the Contractor's minority business enterprises program.

(2) Provide adequate and timely consideration of the potentialities of known minority business enterprises in all "make-or-buy" decisions.

(3) Assure that known minority business enterprises will have an equitable opportunity to compete for subcontracts, particularly by arranging solicitations, time for the preparation of bids, quantities, specifications, and delivery schedules so as to facilitate the participation of minority business enterprises.

(4) Maintain records showing (i) procedures which have been adopted to comply with the policies set forth in this clause, including the establishment of a source list of minority business enterprises on the source list, and (iii) specific efforts to identify and award contracts to minority business enterprises.

(5) Include the Utilization of Minority Business Enterprises clause in subcontracts which offer substantial minority business enterprises subcontracting opportunities.

(6) Cooperate with the Contracting Officer in any studies and surveys of the Contractor's minority business enterprises procedures and practices that the Contracting Officer may from time to time conduct.

(7) Submit periodic reports of subcontracting to known minority business enterprises with respect to the records referred to in subparagraph (4), above, in such form and manner and at such time (not more often than quarterly) as the Contracting Officer may prescribe.

(b) The Contractor further agrees to insert, in any subcontract hereunder which may exceed $500,000, provisions which shall conform substantially to the language of this clause, including this paragraph (b), and to notify the Contracting Officer of the names of such subcontractors.

ALTERATION TO SF-32, General Provisions

UNSOLICITED SAMPLES, DESCRIPTIVE LITERATURE, OR BRAND NAME REFERENCES:

Where procurement is effected under specifications or purchase descriptions (other than "brand name or equal") and the Government does not specifically request bid samples, descriptive literature, or references to brand names, models, or part numbers as an integral part of the bid, bids which are accompanied by any of the foregoing will be rejected unless it is clear from the bid or accompanying papers that the samples, descriptive literature, or references to brand names, models, or part numbers are not intended to qualify the bid and that the bidder proposes to furnish items fully in accordance with the specifications or purchase descriptions. Where offers contain unsolicited material such as samples, descriptive literature, or references to brand names, models, or part numbers, the Government will not be responsible in any way for determining whether the items which are offered meet the Government's requirements set forth in the applicable specifications or purchase descriptions.

EXAMINATION OF RECORDS BY DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE:
(Applicable to negotiated contracts only.)

The provisions of the clause included herein, entitled "Examination of Records by the Comptroller General," are extended to provide equal rights to duly authorized representatives of the Secretary or of the Contracting Officer.

ALTERATIONS TO SF-32, GENERAL PROVISIONS (Supply Contract)

(See Federal Procurement Regulations, Subpart 1-11.4 Regarding Use.)

FEDERAL, STATE AND LOCAL TAXES

(a) Except as may be otherwise provided in this contract, the contract price includes all applicable Federal, State, and local taxes and duties.

(b) Nevertheless, with respect to any Federal excise tax or duty on the transactions or property covered by this contract, if a statute, court decision, written ruling, or regulation takes effect after the contract date, and–

(1) Results in the Contractor being required to pay or bear the burden of any such Federal excise tax or duty or increase in the rate thereof which would not otherwise have been payable on such transactions or property, the contract price shall be increased by the amount of such tax or duty or rate increase: *Provided*, That the Contractor if requested by the Contracting Officer, warrants in writing that no amount for such newly imposed Federal excise tax or duty or rate increase was included in the contract price as a contingency reserve or otherwise; or

(2) Results in the Contractor not being required to pay or bear the burden of, or in his obtaining a refund or drawback of, any such Federal excise tax or duty which would otherwise have been payable on such transactions or property or which was the basis of an increase in the contract price, the contract price shall be decreased by the amount of the relief, refund, or drawback, or that amount shall be paid to Government, as directed by the Contracting Officer. The contract price shall be similarly decreased if the Contractor, through his fault or negligence or his failure to follow instructions of the Contracting Officer, is required to pay or bear the burden of, or does not obtain a refund or drawback of, any such Federal excise tax or duty.

(c) No adjustment pursuant to paragraph (b) above will be made under this contract unless the aggregate amount thereof is or may reasonably be expected to be over $100.

(d) As used in paragraph (b) above, the term "contract date" means the date set for the bid opening, or if this is a negotiated contract, the date of this contract. As to additional supplies or services procured by modification to this contract, the term "contract date" means the date of such modification.

(e) Unless there does not exist any reasonable basis to sustain an exemption, the Government, upon request of the Contractor, without further liability, agrees, except as otherwise provided in this contract, to furnish evidence appropriate to establish exemption from any tax which the Contractor warrants in writing was excluded from the contract price. In addition, the Contracting Officer may furnish evidence to establish exemption from any tax that may, pursuant to this clause, give rise to either an increase or decrease in the contract price. Except as otherwise provided in this contract, evidence appropriate to establish exemption from duties will be furnished only at the direction of the Contracting Officer.

(f) The Contractor shall promptly notify the Contracting Officer of matters which will result in either an increase or decrease in the contract price, and shall take action with respect thereto as directed by the Contracting Officer.

ALTERATION TO SF-32, GENERAL PROVISIONS

EMPLOYMENT OF THE HANDICAPPED

(a) The contractor will not discriminate against any employee or applicant for employment because of physical or mental handicap in regard to any position for which the employee or applicant for employment is qualified. The contractor agrees to take affirmative action to employ, advance in employment and otherwise treat qualified handicapped individuals without discrimination based upon their physicial or mental handicap in all employment practices such as the following: employment, upgrading, demotion or transfer, recruitment, advertising, layoff or termination, rates of pay or other forms of compensation, and selection for training, including apprenticeship.

(b) The contractor agrees to comply with the rules, regulations, and relevant orders of the Secretary of Labor issued pursuant to the Act.

(c) In the event of the contractor's noncompliance with the requirements of this clause, actions for noncompliance may be taken in accordance with the rules, regulations and relevant orders of the Secretary of Labor issued pursuant to the Act.

(d) The contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices in a form to be prescribed by the Director, provided by or through the Contracting Officer. Such notices shall state the contractor's obligation under the law to take affirmative action to employ and advance in employment qualified handicapped employees and applicants for employment, and the rights of applicants and employees.

(e) The contractor will notify each labor union or representative of workers with which it has a collective bargaining agreement or other contract understanding, that the contractor is bound by the terms of section 503 of the Rehabilitation Act of 1973, and is committed to take affirmative action to employ and advance in employment physically and mentally handicapped individuals.

(f) The contractor will include the provisions of this clause in every subcontract or purchase order of $2,500 or more unless exempted by rules, regulations, or orders of the Secretary issued pursuant to section 503 of the Act, so that such provisions will be binding upon each subcontractor or vendor. The contractor will take such action with respect to any subcontract or purchase order as the Director of the Office of Federal Contract Compliance Programs may direct to enforce such provisions, including action for noncompliance.

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TERMINATION FOR CONVENIENCE
OF THE GOVERNMENT

(a) The performance of work under this contract may be terminated by the Government in accordance with this clause in whole, or from time to time in part, whenever the Contracting Officer shall determine that such termination is in the best interest of the Government. Any such termination shall be effected by delivery to the Contractor of a Notice of Termination specifying the extent to which performance of work under the contract is terminated, and the dates upon which such termination becomes effective.

(b) After receipt of a Notice of Termination, and except as otherwise directed by the Contracting Officer, the Contractor shall:

(1) Stop work under the contract on the date and to the extent specified in the Notice of Termination;

(2) Place no further orders or subcontracts for materials, services, or facilities, except as may be necessary for completion of such portion of the work under the contract as is not terminated;

(3) Terminate all orders and subcontracts to the extent that they relate to the performance of work terminated by the Notice of Termination;

(4) Assign to the Government, in the manner, at the times, and to the extent directed by the Contracting Officer, all of the right, title, and interest of the Contractor under the orders and subcontracts so terminated, in which case the Government shall have the right, in its discretion, to settle or pay any or all claims arising out of the termination of such orders and subcontracts;

(5) Settle all outstanding liabilities and all claims arising out of such termination of orders and subcontracts, with the approval or ratification of the Contracting Officer, to the extent he may require, which approval or ratification shall be final for all the purposes of this clause;

(6) Transfer title to the Government and deliver in the manner, at the times, and to the extent, if any, directed by the Contracting Officer, (i) the fabricated or unfabricated parts, work in process, completed work, supplies, and other material produced as a part of, or acquired in connection with the performance of, the work terminated by the Notice of Termination, and (ii) the completed or partially completed plans, drawings, information and other property which, if the contract had been completed, would have been required to be furnished to the Government;

(7) Use his best efforts to sell, in the manner, at the times, to the extent, and at the price or prices directed or authorized by the Contracting Officer, any property of the types referred to in (6) above: Provided, however, that the Contractor (i) shall not be required to extend credit to any purchaser, and (ii) may acquire any such property under the conditions prescribed by and at a price or prices approved by the Contracting Officer: And provided further, that the proceeds of any such transfer or disposition shall be applied in reduction of any payments to be made by the Government to the Contractor under this contract or shall otherwise be credited to the price or cost of the work covered by this contract or paid in such other manner as the Contracting Officer may direct;

(8) Complete performance of such part of the work as shall not have been terminated by the Notice of Termination; and

(9) Take such action as may be necessary, or as the Contracting Officer may direct, for the protection and preservation of the property related to this contract which is in the possession of the Contractor and in which the Government has or may acquire an interest.

At any time after expiration of the plant clearance period, as defined in Subpart 1-8.1 of the Federal Procurement Regulations (41 CFR 1-8.1), as the definition may be amended from time to time, the Contractor may submit to the Contracting Officer a list, certified as to quantity and quality, of any or all items of termination inventory not previously disposed of, exclusive of items the disposition of which has been directed or authorized by the Contracting Officer, and may request the Government to remove such items or enter into a storage agreement covering them. Not later than fifteen (15) days thereafter, the Government will accept title to such items and remove them or enter into a storage agreement covering the same: Provided, that the list submitted shall be subject to verification by the Contracting Officer upon removal of the items or, if the items are stored, within forty-five (45) days from the date of submission of the list, and any necessary adjustment to correct the list as submitted shall be made prior to final settlement.

(c) After receipt of a Notice of Termination, the Contractor shall submit to the Contracting Officer his termination claim, in the form and with certification prescribed by the Contracting Officer. Such claim shall be submitted promptly but in no event later than one year from the effective date of termination, unless one or more extensions in writing are granted by the Contracting Officer upon request of the Contractor made in writing within such one-year period or authorized extensiton thereof. However, if the Contracting Officer determines that the facts justify such action, he may receive and act upon any such termination claim at any time after such one-year period or any extension thereof. Upon failure of the Contractor to submit his termination claim within the time allowed, the Contracting Officer may, subject to any review

required by the contracting agency's procedures in effect as of the date of execution of this contract, determine, on the basis of information available to him, the amount, if any, due to the Contractor by reason of the termination and shall thereupon pay to the Contractor the amount so determined.

(d) Subject to the provisions of paragraph (c), and subject to any review required by the contracting agency's procedures in effect as of the date of execution of this contract, the Contractor and the Contracting Officer may agree upon the whole or any part of the amount or amount to be paid to the Contractor by reason of the total or partial termination of work pursuant to this clause, which amount or amounts may include a reasonable allowance for profit on work done: Provided, that such agreed amount or amounts, exclusive of settlement costs, shall not exceed the total contract price as reduced by the amount of payments otherwise made and as further reduced by the contract price of work not terminated. The contract shall be amended accordingly, and the Contractor shall be paid the agreed amount. Nothing in paragraph (e) of this clause, prescribing the amount to be paid to the Contractor in the event of failure of the Contractor and the Contracting Officer to agree upon the whole amount to be paid to the Contractor by reason of the termination of work pursuant to this clause, shall be deemed to limit, restrict, or otherwise determine or affect the amount or amounts which may be agreed upon to be paid to the Contractor pursuant to this paragraph (d).

(e) In the event of the failure of the Contractor and the Contracting Officer to agree as provided in paragraph (d) upon the whole amount to be paid to the Contractor by reason of the termination of work pursuant to this clause, the Contracting Officer shall, subject to any review required by the contracting agency's procedures in effect as of the date of execution of this contract, determine, on the basis of information available to him, the amount, if any, due to the Contractor by reason of the termination and shall pay to the Contractor the amounts determined as follows:

(1) For completed supplies accepted by the Government (or sold or acquired as provided in paragraph (b)(7) above) and not theretofore paid for, a sum equivalent to the aggregate price for such supplies computed in accordance with the price or prices specified in the contract, appropriately adjusted for any saving of freight or other charges;

(2) The total of --

(i) The costs incurred in the performance of the work terminated, including initial costs and preparatory expense allocable thereto, but exclusive of any costs attributable to supplies paid or to be paid for under paragraph (e)(1) hereof;

(ii) The cost of settling and paying claims arising out of the termination of work under subcontracts or orders, as provided in paragraph (b)(5) above, which are properly chargeable to the terminated portion of the contract (exclusive of amounts paid or payable on account of supplies or materials delivered or services furnished by subcontractors or vendors prior to the effective date of the Notice of Termination, which amounts shall be included in the costs payable under (i) above); and

(iii) A sum, as a profit, equal to 2 percent of that part of the amout determined under (i) above which represents the cost of articles and materials not processed by the Contractor, plus a sum equal to 8 percent of the remainder of such amount, but the aggregate of such sums shall not exceed 6 percent of the whole of the amount determined under (i) above: Provided, however, that if it appears that the Contractor would have sustained a loss on the entire contract had it been completed, no profit shall be included or allowed under this subdivision (iii) and an appropriate adjustment shall be made reducing the amount of the settlement to reflect the indicated rate of loss; and

(3) The reasonable costs of settlement, including accounting, legal, clerical, and other expenses reasonably necessary for the preparation of settlement claims and supporting data with respect to the terminated portion of the contract and for the termination and settlement of subcontracts thereunder, together with reasonable storage, transportation, and other costs incurred in connection with the protection or disposition of property allocable to this contract.

The total sum to be paid to the Contractor under (1) and (2) of this paragraph (e) shall not exceed the total contract price as reduced by the amount of payments otherwise made and as further reduced by the contract price of work not terminated. Except for normal spoilage, and except to the extent that the Government shall have otherwise expressly assumed the risk of loss, there shall be excluded from the amounts payable to the Contractor as provided in (e)(1) and (2)(i) above, the fair value, as determined by the Contracting Officer, of property which is destroyed, lost, stolen, or damaged so as to become undeliverable to the Government, or to a buyer pursuant to paragraph (b)(7).

(f) Costs claimed, agreed to, or determined pursuant to paragraphs (c), (d), and (e) of this clause shall be in accordance with the contract cost principles and procedures in Part 1-15 of the Federal Procurement Regulations (41 CFR 1-15) in effect on the date of this contract.

(g) The Contractor shall have the right to appeal, under the clause of this contract entitled "Disputes," from any determination made by the Contracting Officer under paragraph (c) or (e) above, except that, if the Contractor has failed to submit his claim within the time provided in paragraph (c) above and has failed to request extension of such time, he shall have no such right of appeal. In any case where the Contracting Officer has made a determination of the amount due under paragraph (c) or (e) above, the Government shall pay to the Contractor the following: (1) if there is no right of appeal hereunder or if no timely appeal has been taken, the amount so determined by the Contracting Officer; or (2) if an appeal has been taken, the amount finally determined on such appeal.

(h) In arriving at the amount due the Contractor under this clause there shall be deducted (1) all unliquidated advance or other payments on account theretofore made to the Contractor, applicable to the terminated portion of this contract; (2) any claim which the Government may have against the Contractor in connection with this contract; and (3) the agreed price for, or the proceeds of sale of, any materials, supplies, or other things acquired by the Contractor or sold, pursuant to the provisions of this clause, and not otherwise recovered by or credited to the Government.

(i) If the termination hereunder be partial, prior to the settlement of the terminated portion of this contract, the Contractor may file with the Contracting Officer a request in writing for an equitable adjustment of the price or prices specified in the contract relating to the continued portion of the contract (the portion not terminated by the Notice of Termination), and such equitable adjustment as may be agreed upon shall be made in such price or prices.

(j) The Government may from time to time, under such terms and conditions as it may prescribe, make partial payments and payments on account against costs incurred by the Contractor in connection with the terminated portion of this contract whenever in the opinion of the Contracting Officer the aggregate of such payments shall be within the amount to which the Contractor will be entitled hereunder. If the total of such payments is in excess of the amount finally agreed or determined to be due under this clause, such excess shall be payable by the Contractor to the Government upon demand, together with interest computed at the rate of 6 percent per annum for the period from the date such excess payment is received by the Contractor to the date on which such excess is repaid to the Government: Provided, however, that no interest shall be charged with respect to any such excess payment attributable to a reduction in the Contractor's claim by reason of retention or other disposition of termination inventory until ten days after the date of such retention or disposition, or such later date as determined by the Contracting Officer by reason of the circumstances.

(k) Unless otherwise provided for in this contract, or by applicable statute, the Contractor, from the effective date of termination and for a period of three years after final settlement under this contract, shall

preserve and make available to the Government at all reasonable times at the office of the Contractor but without direct charge to the Government, all his books, records, documents, and other evidence bearing on the costs and expenses of the Contractor under this contract and relating to the work terminated hereunder, or, to the extent approved by the Contracting Officer, photographs, microphotographs, or other authentic reproductions thereof.

FPR 1-8.701

PRICE REDUCTION FOR DEFECTIVE COST OR PRICING DATA (FPR 1-3.814-1(a))

If any price, including profit or fee, negotiated in connection with this contract or any cost reimbursable under this contract was increased by any significant sums because:

(a) The Contractor furnished cost or pricing data which was not accurate, complete and current as certified in the Contractor's Certificate of Current Cost or Pricing Data;

(b) A subcontractor, pursuant to the clause of this contract entitled "Subcontractor Cost or Pricing Data" or "Subcontractor Cost or Pricing Data -Price Adjustments" or any subcontract clause therein required, furnished cost of pricing data which was not accurate, complete and current as certified in the subcontractor's Certificate of Current Cost or Pricing Data;

(c) A subcontractor or prospective subcontractor furnished cost of pricing data which was required to be accurate, complete and current and to be submitted to support a subcontract cost estimate furnished by the Contractor but which was not accurate, complete and current as of the date certified in the Contractor's Certificate of Current Cost or Pricing Data; or

(d) The Contractor or a subcontractor or prospective subcontractor furnished any data, not within (a), (b), or (c) above, which was not accurate as submitted; the price or cost shall be reduced accordingly and the contract shall be modified in writing as may be necessary to reflect such reduction. However, any reduction in the contract price due to defective subcontract data of a prospective subcontractor when the subcontract was not subsequently awarded to such subcontractor, will be limited to the amount (plus applicable overhead and profit markup) by which the actual subcontract, or actual cost to the Contractor if there was no subcontract was less than the prospective subcontract cost estimate submitted by the Contractor: PROVIDED, The actual subcontract price was not affected by defective cost or pricing data.

(NOTE: Since the contract is subject to reduction under this clause by reason of defective cost or pricing data submitted in connection with certain subcontracts, it is expected that the Contractor may wish to include a clause in each such subcontract requiring the subcontractor to appropriately indemnify the Contractor. It is also expected that any subcontractor subject to such indemnification will generally require substantially similar indemnification for defective cost or pricing data required to be submitted by his lower tier subcontractors.)

SUBCONTRACTOR COST OR PRICING DATA (FPR 1-3.814-3)

(a) The Contractor shall require subcontractors hereunder to submit, actually or by specific indentification in writing, cost or pricing data under the following circumstances:

(1) Prior to the award of any subcontract the amount of which is expected to exceed $100,000 when entered into;

(2) Prior to the pricing of any subcontract modification which involves aggregate increases and/or decreases in costs plus applicable profits expected to exceed $100,000; except where the price is based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation.

(b) The Contractor shall require subcontractors to certify, in substantially the same form as that used in the certificate by the Prime Contractor to the Government, that to the best of their knowledge and belief, the cost and pricing data submited under (a) above is accurate, complete, and current as of the date of agreement on the negotiated price of the subcontract or subcontract change or modification.

(c) The Contractor shall insert the substance of this clause including this paragraph (c) in each subcontract hereunder which exceeds $100,000 when entered into except where the price thereof is based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation. In each such excepted subcontract hereunder in excess of $100,000, the Contractor shall insert the substances of the following clause:

SUBCONTRACTOR COST OR PRICING DATA -
PRICE ADJUSTMENTS

(a) Paragraphs (b) and (c) of this clause shall become operative only with respect to any modification made pursuant to one or more provisions of this contract which involves aggregate increases and/or decreases in costs plus applicable profits expected to exceed $100,000. The requirements of this clause shall be limited to such contract modifications.

(b) The Contractor shall require subcontractors hereunder to submit, actually or by specific identification in writing, cost or pricing data under the following circumstances.

(1) Prior to award of any subcontract, the amount of which is expected to exceed $100,000 when entered into;

(2) Prior to the pricing of any subcontract modification which involves aggregate increases and/or decreases in costs plus applicable profits expected to exceed $100,000; except where the price is based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation.

(c) The Contractor shall require subcontractors to certify, in substantially the same form as that used in the certificate by the Prime Contractor to the Government, that to the best of their knowledge and belief the cost and pricing data submitted under (b) above is accurate, complete, and current as of the date of agreement on the negotiated price of the subcontract or subcontract change or modification.

(d) The Contractor shall insert the substance of this clause including this paragraph (d) in each subcontract hereunder which exceeds $100,000 when entered into.

ALTERATIONS (Continued)

AUDIT (FPR 1-3.814-2)

(a) GENERAL. The Contracting Officer or his representatives shall have the audit and inspection rights described in the applicable paragraphs (b), (c), and (d) below.

(b) EXAMINATION OF COSTS: If this is a cost-reimbursement type, incentive, time and materials, labor hour, or price redeterminable contract, or any combination thereof, the Contractor shall maintain, and the Contracting Officer or his represetnatives shall have the right to examine books, records, documents, and other evidence and accounting procedures and practices, sufficient to reflect properly all direct and indirect costs of whatever nature claimed to have been incurred and anticipated to be incurred for the performance of this contract. Such right of examination shall include inspection at all reasonable times of the Contractor's plants, or such parts thereof, as may be engaged in the performance of this contract.

(c) COST OR PRICING DATA. If the Contractor submitted cost or pricing data in connection with the pricing of this contract or any change or modification thereto, unless such pricing was based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation, the Contracting Officer or his representatives who are employees of the United States Government shall have the right to examine all books, records, documents and other data of the Contractor related to the negotiation, pricing or performance of such contract, change or modification, for the purpose of evaluating the accuracy, completeness and currency of the cost or pricing data submitted. Additionally, in the case of pricing any change or modification exceeding $100,000 to formally advertised contracts, the Comptroller General of the United States or his representatives who are employees of the United States Government shall have such rights. The right of examination shall extend to all documents necessary to permit adequate evaluation of the cost or pricing data submitted, along with the computations and projections used therein.

(d) AVAILABILITY. The materials described in (b) and (c) above, shall be made available at the office of the Contractor, at all reasonable times, for inspection, audit or reproduction, until the expiration of 3 years from the date of final payment under this contract or such lesser time specified in Part 1-20 of the Federal Procurement Regulations (41 CFR Part 1-20) and for such longer period, if any, as is required by applicable statute, or by other clauses of this contract, or by (1) and (2) below:

(1) If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for a period of 3 years from the date of any resulting final settlement.

(2) Records which relate to appeals under the "Disputes" clause of this contract, or litigation or the settlement of claims arising out of the performance of this contract, shall be made available until such appeals, litigation, or claims have been disposed of.

(e) The Contractor shall insert a clause containing all the provisions of this clause, including this paragraph (e), in all subcontracts hereunder except altered as necessary for proper identification of the contracting parties and the Contracting Officer under the Government prime contract.

July 1974

ACCOUNTS, AUDITS, AND RECORDS

(a) The Contractor shall maintain books, records, documents, and other evidence, accounting procedures and practices sufficient to reflect properly all direct and indirect costs of whatever nature claimed to have been incurred for the performance of this contract. The foregoing constitutes "records" for the purpose of this clause.

(b) The Contractor's facility(ies) or such part thereof as may be engaged in the performance of this contract, and his records shall be subject at all reasonable time to inspection and audit by the Secretary or his authorized representatives.

(c) The Contractor shall preserve and make available his records (1) until the expiration of 3 years from the date of final payment under this contract, or the time periods for particular records specified in 41 CFR Part 1-20, whichever expires earlier, and (2) for such longer period, if any, as is required by applicable statute, or by other clauses of this contract, or by (i) or (ii) below:

(i) If this contract is completely or partially terminated, the records relating to the work terminated shall be preserved and made available for a period of 3 years from the date of any resulting final payment.

(ii) Records which relate to (A) appeals under the "Disputes" clause of this contract, (B) litigation or the settlement of claims arising out of the performance of this contract, or (C) costs and expenses of this contract to which exception has been taken by the Contracting Officer or any of his duly authorized representatives, shall be retained until such appeals, litigation, claims, or exceptions have been disposed of.

(d) The Contractor shall insert the substance of this clause, including this paragraph (d) in each subcontract hereunder with the exceptions of (1) purchase orders not exceeding $2,500 and (2) subcontracts or purchase orders for public utility services at rates established for uniform applicability to the general public. When so inserted, changes shall be made to designate the higher-tier subcontractor at this level involved in place of the Contractor; to add "of the Government prime contract," in place of "this contract" in (B) of subparagraph (c)(ii) above.

PREAWARD EQUAL OPPORTUNITY
COMPLIANCE REVIEWS

Where the bid of the apparent low responsible bidder is in the amount of $1 million or more, the bidder and his known first-tier subcontractors which will be awarded subcontracts of $1 million or more will be subject to full, preaward equal opportunity compliance reviews before the award of the contract for the purpose of determining whether the bidder and his subcontractors are able to comply with the provisions of the Equal Opportunity clause.

ALTERATION TO SF-32, General Provisions

CLEAN AIR AND WATER CLAUSE

(Applicable only if the contract exceeds $100,000, or the contracting officer has determined that the orders under an indefinite quantity contract in any one year will exceed $100,000, or a facility to be used has been the subject of a conviction under the Clean Air Act (42 U.S.C. 1857C-8(C)(1)) or the Federal Water Pollution Control Act (33 U.S.C. 1319 (C)) and is listed by EPA, or the contract is not otherwise exempt.)

(A) The contractor agrees as follows:

(I) To comply with all the requirements of Section 114 of the Clean Air Act, as amended (42 U.S.C. 1857, et seq., as amended by Public Law 91-604 and Section 308 of the Federal Water Pollution Control Act (33 U.S.C. 1251, as amended by Public Law 92-500), respectively, relating to inspection, monitoring, entry, reports, and information, as well as other requirements specified in Section 114 and Section 308 of the Air Act and the Water Act, respectively, and all regulation and guidelines issued thereunder before the award of this contract.

(II) That no portion of the work required by this prime contract will be performed in a facility listed on the Environmental Protection Agency list of violating facilities on the date when this contract was awarded unless and until the EPA eliminates the name of such facility or facilities from listing.

(III) To use his best efforts to comply with Clean Air Standards and Clean Water Standards at the facilities in which the contract is being performed.

(IV) To insert the substance of the provisions of this clause in any nonexempt subcontract, including this paragraph (IV).

(B) The terms used in this clause have the following meanings:

(I) The term "Air Act" means the Clean Air Act, as amended (42 U.S.C. 1857 et seq., as amended by Public Law 91-604).

(II) The term "Water Act" means Federal Water Pollution Control Act, as amended (33 U.S.C. 1251 et seq., as amended by Public Law 92-500).

(III) The term "Clean Air Standards" means any enforceable rules, regulations, guidelines, standards, limitations, orders, controls, prohibitions, or other requirements which are contained in, issued under, or otherwise adopted pursuant to the Air Act or Executive Order 11738, an applicable implementation plan as described in Section 110(D) of the Clean Air Act (42 U.S.C. 1857C-5(D)), an approved implementation procedure or plan under Section 111(C) or Section 111(D), respectively, of the Air Act (42 U.S.C. 1857C-6(C) or (D)), or an approved implementation procedure under Section 112(D) of the Air Act (42 U.S.C. 1857C-7(D)).

ALTERATION TO SF-32, General Provisions

Clean Air and Water Clause **(Continued)**

(IV) The term "Clean Water Standards" means any enforceable limitation, control, condition, prohibition, standard, or other requirement which is promulgated pursuant to the Water Act or contained in a permit issued to a discharger by the Environmental Protection Agency or by a State under an approved program, as authorized by Section 402 of the Water Act (33 U.S.C. 1342), or by a local government to ensure compliance with pretreatment regulations as required by Section 307 of the Water Act (33 U.S.C. 1317).

(V) The term "compliance" means compliance with Clean Air or Water Standards. Compliance shall also mean compliance with a schedule or plan ordered or approved by a court of competent jurisdiction, The Environmental Protection Agency or an Air or Water Pollution Control Agency in accordance with the requirement of the Air Act or Water Act and regulations issued pursuant thereto.

(VI) The term "Facility" means any building, plant, installation, structure, mine, vessel or other floating craft, location, or site of operations, owned, leased, or supervised by a contractor, subcontractor, to be utilized in the performance of a contract or subcontract. Where a location or site of operations contains or includes more than one building, plant, installation, or structure, the entire location shall be deemed to be a facility except where the Director, Office of Federal Activities, Environmental Protection Agency, determines that independent facilities are colocated in one geographical area.

EQUAL OPPORTUNITY (July 1976)

(The following clause is applicable unless this contract is exempt under the rules, regulations, and relevant orders of the Secretary of Labor (41 CFR ch. 60).)

During the performance of this contract, the Contractor agrees as follows:

(a) The Contractor will not discriminate against any employee or applicant for employment because of race, color, religion, sex, or national origin. The Contractor will take affirmative action to ensure that applicants are employed, and that employees are treated during employment, without regard to their race, color, religion, sex, or national origin. Such action shall include, but not be limited to, the following: Employment, upgrading, demotion, or transfer; recruitment or recruitment advertising; layoff or termination; rates of pay or other forms of compensation; and selection for training, including apprenticeship.

The Contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices to be provided by the Contracting Officer setting forth the provisions of this Equal Opportunity clause.

(b) The Contractor will, in all solicitations or advertisements for employees placed by or on behalf of the Contractor, state that all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, or national origin.

(c) The Contractor will send to each labor union or representative of workers with which he has a collective bargaining agreement or other contract or understanding, a notice, to be provided by the agency Contracting Officer, advising the labor union or workers' representative of the Contractor's commitments under this Equal Opportunity clause, and shall post copies of the notice in conspicuous places available to employees and applicants for employment.

(d) The Contractor will comply with all provisions of Executive Order No. 11246 of September 24, 1965, and of the rules, regulations, and relevant orders of the Secretary of Labor.

(e) The Contractor will furnish all information and reports required by Executive Order No. 11246 of September 24, 1965, and by the rules, regulations, and orders of the Secretary of Labor, or pursuant thereto, and will permit access to his books, records, and accounts by the contracting agency and the Secretary of Labor for purposes of investigation to ascertain compliance with such rules, regulations, and orders.

(f) In the event of the Contractor's noncompliance with the Equal Opportunity clause of this contract or with any of the said rules, regulations, or orders, this contract may be canceled, terminated, or suspended, in whole or in part, and the Contractor may be declared ineligible for further Government contracts in accordance with procedures authorized in Executive Order No. 11246 of September 24, 1965, and such other sanctions may be imposed and remedies invoked as provided in Executive Order No. 11246 of September 24, 1965, or by rule, regulation, or order of the Secretary of Labor, or as otherwise provided by law.

(g) The Contractor will include the provisions of paragraphs (a) through (g) in every subcontract or purchase order unless exempted by rules, regulations, or orders of the Secretary of Labor issued pursuant to section 204 of Executive Order No. 11246 of September 24, 1965, so that such provisions will be binding upon each subcontractor or vendor. The Contractor will take such action with respect to any subcontract or purchase order as the contracting agency may direct as a means of enforcing such provisions, including sanctions for noncompliance: *Provided, however,* That in the event the Contractor becomes involved in, or is threatened with, litigation with a subcontractor or vendor as a result of such direction by the contracting agency, the Contractor may request the United States to enter into such litigation to protect the interests of the United States.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

AMENDMENT/MODIFICATION NO.	EFFECTIVE DATE	3. REQUISITION/PURCHASE REQUEST NO.	4. PROJECT NO. (If applicable)
8	7-5-77		

5. ISSUED BY: CODE

nter for Disease Control
55 East Paces Ferry Road, N.E.
Atlanta, GA 30305

6. ADMINISTERED BY (If other than Block 5): CODE

Same as shown in Block 5/

ORIGINAL

7. CONTRACTOR NAME AND ADDRESS (street, city, county, state, and ZIP code): CODE / FACILITY CODE

Parke, Davis & Company
Joseph Campau at the River
Detroit, Michigan 48232

8. ☐ AMENDMENT OF SOLICITATION NO. _____ DATED _____ (See Item 9)

☒ MODIFICATION OF CONTRACT/ORDER NO. Letter 200-76-0426 DATED 9/22/76 (See Item 11)

THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 12. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided such telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

ACCOUNTING AND APPROPRIATION DATA (If required)

THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) ☒ This Change Order is issued pursuant to: the authorization for Letter Contract by the Secretary, 9/1/76.

The Changes set forth in Block 12 are made in the above numbered contract/order.

☐ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation data, etc.) set forth in Block 12.

(c) ☐ This Supplemental Agreement is entered into pursuant to authority of _____

It modifies the above numbered contract as set forth in Block 12.

DESCRIPTION OF AMENDMENT/MODIFICATION

The target date for definitization of the contract as established by Modification No. 7, dated May 13, 1977, is further extended hereby to August 15, 1977.

Except as provided herein, all terms and conditions of the document referenced in Block 8, as heretofore changed, remain unchanged and in full force and effect.

☒ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT ☐ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN _____ COPIES TO ISSUING OFFICE

15A. NAME OF CONTRACTOR/OFFEROR

(Signature of person authorized to sign)

15B. NAME AND TITLE OF SIGNER (Type or print) | 15C. DATE SIGNED

16A. UNITED STATES OF AMERICA

BY John L. Williams
(Signature of Contracting Officer)

16B. NAME OF CONTRACTING OFFICER (Type or print): John L. Williams

16C. DATE SIGNED: 7-5-77

AMENDMENT/MODIFICATION NO.	2. EFFECTIVE DATE	3. REQUISITION/PURCHASE REQUEST NO.	4. PROJECT NO. (If applicable)
7	5/13/77		

ISSUED BY — CODE

Center for Disease Control
255 East Paces Ferry Road, NE
Atlanta, GA 30305

6. ADMINISTERED BY (If other than block 5) — CODE

Same as shown in Block 5.

ORIGINAL

CONTRACTOR NAME AND ADDRESS (street, city, county, state, and ZIP code) — CODE — FACILITY CODE

Parke, Davis & Company
Joseph Campau at The River
Detroit, Michigan 48232

8. ☐ AMENDMENT OF SOLICITATION NO. _____
DATED _____ (See block 9)
☐ MODIFICATION OF CONTRACT/ORDER NO. Letter 200-76-0426
DATED _____ (See block 11)

THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in block 12. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation, or as amended, by one of the following methods:

(a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

ACCOUNTING AND APPROPRIATION DATA (If required)

THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) ☐ This Change Order is issued pursuant to: _____
The Changes set forth in block 12 are made in the above numbered contract/order.

(b) ☒ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation data, etc.) set forth in block 12.

(c) ☐ This Supplemental Agreement is entered into pursuant to authority of _____
It modifies the above numbered contract as set forth in block 12.

DESCRIPTION OF AMENDMENT/MODIFICATION

The target date for definitization of the contract, as established by Modification No. 6, dated April 12, 1977, is further extended hereby to July 15, 1977.

Except as provided herein, all terms and conditions of the document referenced in block 8, as heretofore changed, remain unchanged and in full force and effect.

☒ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT ☐ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN _____ COPIES TO ISSUING OFFICE

15. NAME OF CONTRACTOR/OFFEROR

(Signature of person authorized to sign)

15. NAME AND TITLE OF SIGNER (Type or print) — 16. DATE SIGNED

17. UNITED STATES OF AMERICA
BY _____
(Signature of Contracting Officer)

18. NAME OF CONTRACTING OFFICER (Type or print)
John L. Williams

STANDARD FORM 30, MAY 1986
GENERAL SERVICES ADMINISTRATION
FED. PROC. REG. (41 CFR) 1-16.101

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

PAGE 1 OF 1

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	3. REQUISITION/PURCHASE REQUEST NO.	4. PROJECT NO. (If applicable)
6	4-12-77		

5. ISSUED BY / CODE
PCO, Center for Disease Control
255 East Paces Ferry Rd. N.E.
Atlanta, GA 30305

6. ADMINISTERED BY (If other than block 5) / CODE
Same as shown in Block 5.

7. CONTRACTOR NAME AND ADDRESS (Street, city, county, state, and ZIP Code) / CODE / FACILITY CODE

Parke, Davis & Company
Joseph Campau at the River
Detroit, Michigan 48232

8.
☐ AMENDMENT OF SOLICITATION NO. _____
DATED _____ (See block 9)
☒ MODIFICATION OF CONTRACT/ORDER NO. Letter 200-76-0426
DATED 9/22/76 (See block 11)

9. THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in block 12. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation, or as amended, by one of the following methods:

(a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted, or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

10. ACCOUNTING AND APPROPRIATION DATA (If required)

11. THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) ☐ This Change Order is issued pursuant to _____
The Changes set forth in block 12 are made in the above numbered contract/order.

(b) ☒ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation date, etc.) set forth in block 12.

(c) ☐ This Supplemental Agreement is entered into pursuant to authority of _____

D modifies the above numbered contract as set forth in block 12.

12. DESCRIPTION OF AMENDMENT/MODIFICATION

The target date for definitization of the Contract, as set forth in ARTICLE III. B. of Modification No. 5, dated March 14, 1977, is further extended to May 15, 1977.

Except as provided herein, all terms and conditions of the document referenced in block 9, as heretofore changed, remain unchanged and in full force and effect.

13. ☐ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT ☐ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN _____ COPIES TO ISSUING OFFICE

14. NAME OF CONTRACTOR/OFFEROR
(Signature of person authorized to sign)

15. NAME AND TITLE OF SIGNER (Type or print) / 16. DATE SIGNED

17. UNITED STATES OF AMERICA
BY John L. Williams
(Signature of Contracting Officer)

18. NAME OF CONTRACTING OFFICER (Type or print)
John L. Williams

19. DATE SIGNED
4-12-77

STANDARD FORM 30, JULY 1965
GENERAL SERVICES ADMINISTRATION
FED. PROC. REG. (41 CFR) 1-16.101

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

PAGE 1 OF 1

1. AMENDMENT/MODIFICATION NO.	2. EFFECTIVE DATE	3. REQUISITION/PURCHASE REQUEST NO.	4. PROJECT NO. (If applicable)
5	3/14/77		

5. ISSUED BY (CODE)
PGO, Center for Disease Control
255 East Paces Ferry Rd., N.E.
Atlanta, Ga. 30305

6. ADMINISTERED BY (If other than block 5) (CODE)
Same as shown in Block 5

ORIGINAL

7. CONTRACTOR NAME AND ADDRESS (CODE) (FACILITY CODE)
Parke, Davis & Company
Joseph Campau at the River
Detroit, Michigan 48232
(Street, city, county, state, and ZIP Code)

8. ☐ AMENDMENT OF SOLICITATION NO. _____
DATED _____ (See block 9)
☒ MODIFICATION OF CONTRACT/ORDER NO. 200-76-0496 Letter
DATED 9/22/76 (See block 11)

9. THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS
☐ The above numbered solicitation is amended as set forth in block 12. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.
Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation, or as amended, by one of the following methods:
(a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided such telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

10. ACCOUNTING AND APPROPRIATION DATA (If required)

11. THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS
(a) ☐ This Change Order is issued pursuant to _____
The Changes set forth in block 12 are made to the above numbered contract/order.
(b) ☒ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation date, etc.) set forth in block 12.
(c) ☐ This Supplemental Agreement is entered into pursuant to authority of _____
It modifies the above numbered contract as set forth in block 12.

12. DESCRIPTION OF AMENDMENT/MODIFICATION

The Target Date for definitization of the Contract, as set forth in ARTICLE III. B. of Modification No. 4, is further extended hereby to April 15, 1977.

Except as provided herein, all terms and conditions of the document referenced in block 8, as heretofore changed, remain unchanged and in full force and effect.

☐ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT ☐ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN _____ COPIES TO ISSUING OFFICE

14. NAME OF CONTRACTOR/OFFEROR	17. UNITED STATES OF AMERICA
BY _____ (Signature of person authorized to sign)	BY _____ (Signature of Contracting Officer)
15. NAME AND TITLE OF SIGNER (Type or print)	16. DATE SIGNED
	18. NAME OF CONTRACTING OFFICER (Type or print) John L. Williams
	19. DATE SIGNED 3/14/77

STANDARD FORM 30, JULY 1966
GENERAL SERVICES ADMINISTRATION
P.R. PROC. REG. (41 CFR) 1-16.101

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

PAGE 1 OF 1

AMENDMENT/MODIFICATION NO.	2. EFFECTIVE DATE	3. REQUISITION/PURCHASE REQUEST NO.	4. PROJECT NO. (If applicable)
Modification No. 4	2-14-77		

5. ISSUED BY — CODE

Center for Disease Control
255 East Paces Ferry Road, N.E.
Atlanta, Ga. 30305

6. ADMINISTERED BY (If other than block 5) — CODE

Same as shown in Block 5

7. CONTRACTOR NAME AND ADDRESS (number, street, city, county, state, and ZIP code) — CODE — FACILITY CODE

Parke, Davis & Company
Joseph Campau at the River
Detroit, Michigan 48232

8.
☐ AMENDMENT OF SOLICITATION NO. _____
DATED _____ (See block 9)
☒ MODIFICATION OF CONTRACT/ORDER NO. Letter 200-76-0426
DATED 9/22/76 (See block 11)

THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in block 12. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

ACCOUNTING AND APPROPRIATION DATA (If required)

THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) ☐ This Change Order is issued pursuant to _____
The Changes set forth in block 12 are made to the above numbered contract/order.

(b) ☒ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation data, etc.) set forth in block 12.

(c) ☐ This Supplemental Agreement is entered into pursuant to authority of _____
It modifies the above numbered contract as set forth in block 12.

DESCRIPTION OF AMENDMENT/MODIFICATION

The target date for definitization of the Contract as set forth in Article III.B. of Modification No. 3 is further extended to March 15, 1977.

Except as provided herein, all terms and conditions of the document referenced in block 8, as heretofore changed, remain unchanged and in full force and effect.

☐ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT ☐ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN _____ COPIES TO ISSUING OFFICE

15. NAME OF CONTRACTOR/OFFEROR		17. UNITED STATES OF AMERICA	
_____ (Signature of person authorized to sign)		BY John L. Williams (Signature of Contracting Officer)	
16. NAME AND TITLE OF SIGNER (Type or print)	16. DATE SIGNED	18. NAME OF CONTRACTING OFFICER (Type or print) John L. Williams	19. DATE SIGNED 2/14/77

GENERAL SERVICES ADMINISTRATION
FED. PROC. REG. (41 CFR) 1-16.101

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1

1. AMENDMENT/MODIFICATION NO.	2. EFFECTIVE DATE	3. REQUISITION/PURCHASE REQ. NO.	4. PROJECT NO. (If applicable)
Modification No. 3	12-30-76		

5. ISSUED BY CODE

PGO, Center for Disease Control
255 East Paces Ferry Rd., N.E.
Atlanta, Ga. 30305

6. ADMINISTERED BY (If other than Block 5) CODE

Same as shown in Block 5

7. CONTRACTOR NAME AND ADDRESS (Street, city, county, state, and ZIP Code) CODE FACILITY CODE

Parke, Davis and Company
Joseph Campau at The River
Detroit, Michigan 48232

8.
☐ AMENDMENT OF SOLICITATION NO. _____
DATED _____ (See Block 9)
☒ MODIFICATION OF CONTRACT/ORDER NO. Letter 200-76-0426
DATED 9/22/76 (See Block 11)

9. THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in block 12. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation, or as amended, by one of the following methods:

(a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided such telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

10. ACCOUNTING AND APPROPRIATION DATA (If required)

11. THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) ☐ This Change Order is issued pursuant to _____
The Changes set forth in block 12 are made to the above numbered contract/order.

(b) ☐ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation data, etc.) set forth in block 12.

(c) ☒ This Supplemental Agreement is entered into pursuant to authority of ~~41 USC 252 (c)(7)~~
It modifies the above numbered contract as set forth in block 12.

12. DESCRIPTION OF AMENDMENT/MODIFICATION

1. ARTICLE III - QUANTITIES is cancelled hereby in its entirety and the following is substituted therefor:

ARTICLE III - QUANTITIES:

The number of doses, by vial sizes, to be furnished under the contract is:

Bivalent Vaccine		Monovalent Vaccine	
10-dose vials	25,400,000 doses	10-dose vials	2,800,000 doses
50-dose vials	2,300,000 doses	50-dose vials	2,200,000 doses
Total	27,700,000 doses	Total	5,000,000 doses

Variation in Quantity: A variation in the total quantity supplied hereunder will be accepted, provided that such variation is not in excess of 15% of the contract quantity as specified above, and is available for delivery prior to the final delivery date (January 15, 1977). The Contractor shall notify the Government of availability of additional quantities as soon as this status becomes known to the contractor.

2. ARTICLE VI - RETURN OF VACCINE is cancelled hereby in its entirety and the following is substituted therefor:

(Continued)

13. Except as provided herein, all terms and conditions of the document referenced in block 9, as heretofore changed, remain unchanged and in full force and effect.

☐ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT ☐ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN _____ COPIES TO ISSUING OFFICE

14. NAME OF CONTRACTOR/OFFEROR		17. UNITED STATES OF AMERICA	
BY Robert R. Adams (Signature of person authorized to sign)		BY John L. Williams (Signature of Contracting Officer)	
15. NAME AND TITLE OF SIGNER (Type or print)	16. DATE SIGNED	18. NAME OF CONTRACTING OFFICER (Type or print)	19. DATE SIGNED
Robert R. Adams Director, Legal Division	12-30-76	John L. Williams	12-30-76

STANDARD FORM 30, JULY 1966
GENERAL SERVICES ADMINISTRATION
FED. PROC. REG. (41 CFR) 1-16.101

CONTINUATION SHEET

REF. NO. OF DOC. BEING CONT'D.
Modification No. 3
Letter Contract 200-76-0424

PAGE 2 OF

NAME OF OFFEROR OR CONTRACTOR

ITEM NO.	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT

2. (Continued)

ARTICLE VI - RETURN OF VACCINE:

No requirement to accept unused vaccines is placed on the contractor.

3. The amended ARTICLE IX - PAYMENT is deleted hereby and the following is substituted therefor:

ARTICLE IX - PAYMENT:

A. Payment shall be made within 30 days of the contractor's invoice for all vaccine which has been accepted. Each invoice or voucher shall, as a minimum, identify the appropriate Delivery Order for which the delivery was made, the vaccine type and amount delivered, the unit price, the total price, and the vaccine lot number(s). All payments shall be on a provisional basis pending definitization of a contract. The following prices shall be used for provisional payments for vaccine:

	10-dose vial	50-dose vial
For the first 26,700,000 doses		
Bivalent	$4.34	$ 19.01
For any additional Bivalent	$0.17	$ 0.38
Monovalent	$1.51	$ 9.43

Vouchers shall be submitted to the following address:

Center for Disease Control
Bureau of State Services
Immunization Division
1600 Clifton Road, N.E.
Atlanta, GA. 30333

B. Payment for self-insurance retention and Insurance Premium on Liability shall be made within 30 days of receipt of contractor's invoice for same. The vaccine prices do not include the cost for self-insurance ($2,500,000) or premiums for liability insurance and applicable taxes ($2,176,648.03) which are solely attributable to the National Swine Flu Immunization Program of 1976.

C. The prices of Bivalent Vaccine shall include a $.0194 per dose profit on the A/Victoria/75 Vaccine component which is considered to be a reasonable profit pursuant to P. L. 94-380.

4. ARTICLE XI - PROJECT DIRECTOR is deleted hereby in its entirety and the following is substituted therefor:

ARTICLE XI- PROJECT DIRECTOR:

The Contractor shall designate an individual who will serve as the point of contact regarding the technical performance of the contract. This individual shall have the authority necessary to commit the company in any aspect of this contract. The Government reserves the right to approve the Project Director and any successor to that position.

5. Subparagraph B of ARTICLE XIII - DEFINITIZATION as set forth in Modification No. 2 of December 29, 1976, is deleted hereby in its entirety and the following is substituted therefor:

STANDARD FORM 36, JULY 1966
GENERAL SERVICES ADMINISTRATION
FED. PROC. REG. (41 CFR) 1-16.101

CONTINUATION SHEET

Modification No. 3
Under Contract 200-76-0426 3

NAME OF OFFEROR OR CONTRACTOR

ITEM NO.	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT

ARTICLE XIII - DEFINITIZATION:

B. The Schedules for definitization of this contract are set forth below:

Negotiation of price and other terms and conditions - On or before January 30, 1977

Target date for definitization - On or before February 15, 1977.

6. Subparagraph B of ARTICLE XIV - LIMITATION ON CONTRACTOR'S PROFIT is deleted hereby in its entirety and the following is substituted hereby:

ARTICLE XIV - LIMITATION ON CONTRACTOR'S PROFIT:

B.

1) The cost of the premium for the liability insurance which is solely attributa to this Program is not included in the vaccine price. (See Article IXB; Payment. In the event that the insurance premium for liability insurance, or any part thereof, is refunded to the contractor under any retrospective, experience-rating plan, it shall be refunded to the Government not later than thirty (30) days after receipt by the contractor.

2) Any money provided to the contractor by the Government for a self-insurance retention fund ("Fund") (see Article IX B; Payment) shall be segregated in a separate account in a federally insured commercial bank with assets in excess of $100,000,000. Said Fund shall be invested in an interest bearing arrangement or arrangements, e.g., Certificates of Deposit, at the bank's prevailing interest rates. In the event any payment by the contractor is required to be made from the invested principal of the Fund prior to the stated maturity date or dates of such invested principal, the total proceeds of such liquidated investment or investments shall be deemed to apply first to principal and second to interest. To the extent such total proceeds are less than the original invested principal, the difference shall be charged against all other accrued interest due the Government. Payments shall be made only from the principal of said account and only for self-insurance losses and related expenditures of the contractor as follows:

a) All sums which the United States shall have the right to recover from the contractor as damages under section 317(k)(7) of the Public Health Service Act (42 U.S.C. 247(b)), and any costs of litigation or attorney fees incurred by the contractor and attributable thereto; and

b) All payments made by the contractor for expenses (other than office expenses or expenses for salaries of employees of the contractor) incurred in the investigation, negotiation, settlement, or defense of any claim or suit pursuant to section 317 (K) (7) of the Public Health Service Act (42 U.S.C. 247(b)) or in the investigation of a case reasonably likely to result in such claim or suit.

Such losses and related expenditures are more particularly described in the insurance policy between the contractor and its respective insurers. Any interest earned on the Fund shall be reinvested with the balance of the principal remaining in the Fund. Any amount provided the contractor by the Government for the Fund, which is not expended by August 1, 1985, including accrued interest to such date, shall be returned to the Government not later than August 31, 1985.

STANDARD FORM 36, JULY 1966 GENERAL SERVICES ADMINISTRATION FED. PROC. REG. (41 CFR) 1-16.101	CONTINUATION SHEET	REF. NO. OF DOC. BEING CONT'D: Modification No. 3 Letter Contract 200-76-0426	PAGE 4 OF

NAME OF OFFEROR OR CONTRACTOR

ITEM NO.	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
	B.. (Continued) 3) In the event the contractor is required to pay a claim by the Government pursuant to Section 317(k)(7) of the Public Health Service Act (42 U.S.C.247(b)) after the contractor has returned the unexpended amount provided for self-insurance, including accrued interest, such claim shall be deemed satisfied up to the amount of principal returned to the Government. Therefore, the total of the payments made from the Fund by the contractor and the credits provided to the contractor by the Government, after the unexpended principal and accrued interest have been returned to the Government, shall not exceed $2,500,000. 4) It is the understanding of the parties to this contract that since the Fund may only be expended for the reasons stated in B.2 above, and since the unexpended principal of the Fund, including accrued interest, shall be returned to the Government under the circumstances set forth above, they do not constitute income to the contractor.				
7.	The AVAILABILITY SCHEDULE is deleted hereby in its entirety and the attached AVAILABILITY SCHEDULE is substituted therefor:				

AVAILABILITY SCHEDULE

Bivalent vaccine - each 0.5 ml. dose contains
200 CCA units of A/New Jersey/76 (Swine)
and 200 CCA units of A/Victoria/3/75

Availability Date	Doses *	Packaged In
9-28-76	10.3	10-dose vials
9-28-76	11.6	50-dose vials
9-28-76	10.3	10-dose vials
9-29-76	10.	10-dose vials
9-29-76	10.7	50-dose vials
9-30-76	10.	10-dose vials
10-11-76	10.	10-dose vials
10-12-76	10.	10-dose vials
10-13-76	10.	10-dose vials
10-19-76	10.	10-dose vials
10-25-76	10.	10-dose vials
10-26-76	10.	10-dose vials
10-27-76	10.	10-dose vials
11-1-76	10.	10-dose vials
11-2-76	10.	10-dose vials
11-3-76	10.	10-dose vials
11-8-76	10.	10-dose vials
11-9-76	10.	10-dose vials
11-15-76	10.	10-dose vials
11-16-76	10.	10-dose vials
11-17-76	10.	10-dose vials
11-22-76	10.	10-dose vials
11-23-76	10.	10-dose vials
11-29-76	10.	10-dose vials
11-30-76	10.	10-dose vials
12-6-76	10.	10-dose vials
12-7-76	10.	10-dose vials
12-13-76	4.	10-dose vials

* expressed in units of 100,000

Modification No. 3
Letter Contract 200-76-0426

AVAILABILITY SCHEDULE

Monovalent vaccine - each 0.5 ml. dose contains 200 CCA units of A/New Jersey/76 (Swine)

Availability Date	Doses*	Packaged In:
12-13-76	10.0	10-dose vials
12-20-76	18.0	10-dose vials
11-17-76	11.0	50-dose vials
12-2-76	11.0	50-dose vials

*express in units of 100,000

GENERAL SERVICES ADMINISTRATION FPR (41 CFR) 1-16.103 — AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. AMENDMENT/MODIFICATION NO.	2. EFFECTIVE DATE	3. REQUISITION/PURCHASE REQUEST NO.	4. PROJECT NO. (If applicable)
Modification No. 2	DEC 2 9 1976		

5. ISSUED BY — CODE
CDC, Center for Disease Control
255 East Paces Ferry Rd, N.E.
Atlanta, Ga. 30305

6. ADMINISTERED BY (If other than Block 5) — CODE
Same as shown in Block 5.

7. CONTRACTOR NAME AND ADDRESS (Street, city, county, state, and ZIP code) — CODE — FACILITY CODE
Parke, Davis and Company
Joseph Campau at The River
Detroit, Michigan 48232

8. ☐ AMENDMENT OF SOLICITATION NO. _____ DATED _____ (See Block 9)
☒ MODIFICATION OF CONTRACT/ORDER NO. Letter 200-76-0426 DATED 9/22/76 (See Block 11)

THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Block 12. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

9. ACCOUNTING AND APPROPRIATION DATA (If required)

THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) ☐ This Change Order is issued pursuant to _____
The Changes set forth in block 12 are made to the above numbered contract/order.

(b) ☐ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation data, etc.) set forth in block 12.

(c) ☒ This Supplemental Agreement is entered into pursuant to authority of 41 USC 252(c)(7)
It modifies the above numbered contract as set forth in block 12.

10. DESCRIPTION OF AMENDMENT/MODIFICATION

Subparagraph B of ARTICLE XIII - DEFINITIZATION is deleted in its entirety and the following is substituted therefor:

B. The Schedules for definitization of this contract are set forth below:
Negotiation of price and other terms and conditions - On or before November 10, 1976.
Target date for definitization - On or before January 1, 1977.

The price of $1.51 per 10-dose vial for Monovalent Vaccine is added hereby to ARTICLE IX - PAYMENT as set forth in Modification No. 1 of November 5, 1976.

Except as provided herein, all terms and conditions of the document referenced in Block 8, as heretofore changed, remain unchanged and in full force and effect.

11. ☐ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT ☒ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 4 COPIES TO ISSUING OFFICE

12A. NAME OF CONTRACTOR/OFFEROR PARKE, DAVIS & COMPANY
Robert R. Adams
(Signature of person authorized to sign)

12B. UNITED STATES OF AMERICA
John L. Williams
(Signature of Contracting Officer)

12C. NAME AND TITLE OF SIGNER (Type or print)
Robert R. Adams
Director, Legal Division

12D. DATE SIGNED
12/28/76

13B. NAME OF CONTRACTING OFFICER (Type or print)
John L. Williams

13C. DATE SIGNED
DEC 29 197

1	2
Modification No. 1	11/5/76

Center for Disease Control
255 East Paces Ferry Road, N. E.
Atlanta, GA 30305

Same as shown in Block 5.

Parke, Davis & Company
Joseph Campau at the River
Detroit, MI 48232

☐ AMENDMENT OF SOLICITATION NO. _____
DATED _____ (See Block 9)

☒ MODIFICATION OF CONTRACT/ORDER NO. Letter 200-76-0426
DATED 9/22/76 (See Block 11)

THIS ITEM APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Block 12. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation, or as amended, by one of the following methods:

(a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

ACCOUNTING AND APPROPRIATION DATA (If required)

THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) ☐ This Change Order is issued pursuant to: _____
The Changes set forth in block 12 are made in the above numbered contract/order.

(b) ☐ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation data, etc.) set forth in block 12.

(c) ☒ This Supplemental Agreement is entered into pursuant to authority of 41 U.S.C. 252(c)(7)

It modifies the above numbered contract as set forth in block 12.

DESCRIPTION OF AMENDMENT/MODIFICATION

The following change is made to referenced contract:

ARTICLE IX - PAYMENT is deleted in its entirety, and the following ARTICLE IX - PAYMENT is substituted therefor:

ARTICLE IX - PAYMENT:

A. Payment shall be made within 30 days of contractor's invoice for all vaccine which has been accepted. Each invoice or voucher shall, as a minimum, identify the appropriate Delivery Order for which the delivery was made, the vaccine type and amount delivered, the unit price, the total price, and the vaccine lot number(s). All payments shall be on a provisional basis pending definitization of a contract. The following prices shall be used for provisional payments for vaccine:

	10-dose vial	50-dose vial
For the first 26,700,000 doses		
Bivalent	4.34	19.01
For any additional Bivalent	0.17	0.38
Monovalent		9.43

Except as provided herein, all terms and conditions of the document referenced in block 8, as heretofore changed, remain unchanged and in full force and effect.

☐ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT ☒ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 4 COPIES TO ISSUING OFFICE

15A. NAME OF CONTRACTOR/OFFEROR: PARKE, DAVIS & COMPANY
Robert R. Adams
(Signature of person authorized to sign)

15B. NAME AND TITLE OF SIGNER (Type or print): Robert R. Adams, Director, Legal Division
15C. DATE SIGNED: 10-14-76

16A. UNITED STATES OF AMERICA
BY John L. Williams
(Signature of Contracting Officer)

16B. NAME OF CONTRACTING OFFICER (Type or print): John L. Williams
16C. DATE SIGNED: 11/5/76

	CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED Modification No. 1 Letter Contract 200-76-042	PAGE 2	OF 2

Vouchers shall be submitted to the following address:

Center for Disease Control
Bureau of State Services
Immunization Division
1600 Clifton Road, N. E.
Atlanta, GA 30333

B. Payment for self-insurance retention and Insurance Premium on Liability shall be made within 30 days of receipt of Contractor's invoice for same. The vaccine prices do not include the cost for self-insurance ($2,500,000) or premiums for liability insurance ($2,162,500) which are solely attributable to the National Swine Flu Immunization Program of 1976.

STANDARD FORM 26, JULY 1964
GENERAL SERVICES ADMINISTRATION
FPR (41 CFR) 1-16.101

AWARD/CONTRACT

PAGE 1 OF 10

1. CONTRACT (Proc. Inst. Ident.) NO.
Letter Contract
No. 200-76-0426

2. EFFECTIVE DATE

3. REQUISITION/PURCHASE REQUEST/PROJECT NO.

4. CERTIFIED FOR NATIONAL DEFENSE UNDER DMS REG. 1 AND/OR DMS REG. 1, RATING:

5. ISSUED BY CODE
HEW, PHS
Center for Disease Control
55 East Paces Ferry Road, N.E.
Atlanta, GA 30305

6. ADMINISTERED BY (If other than block 5) CODE
Same as shown in block 5.

7. DELIVERY
☐ FOB DESTINATION
☒ OTHER (See Delivery S

8. CONTRACTOR NAME AND ADDRESS (Street, city, county, State, and ZIP code) CODE FACILITY CODE
Parke, Davis & Company
Joseph Campau at the River
Detroit, MI 48232

9. DISCOUNT FOR PROMPT PAYMENT
NONE; Prices are net - FOB
Delivery shall be F.O.B. Destination within Continental United States, Premises, to the points stated on Delivery Orders

10. SUBMIT INVOICES (4 copies unless otherwise specified) TO ADDRESS SHOWN IN BLOCK

11. SHIP TO/MARK FOR CODE
As directed on Delivery Orders.

12. PAYMENT WILL BE MADE BY CODE
Center for Disease Control
Financial Management Office
Atlanta, GA 30333

13. THIS PROCUREMENT WAS ☐ ADVERTISED, ☒ NEGOTIATED, PURSUANT TO: ☐ 10 U.S.C. 2304 (a) ( ) ☒ 41 U.S.C. 252 (a) (3)

14. ACCOUNTING AND APPROPRIATION DATA
75X0943 PHS (Influenza Immunization)
6-6140/ 6944 4591 (26.11) $19,000,000.00

15. ITEM NO.	16. SUPPLIES/SERVICES	17. QUANTITY	18. UNIT	19. UNIT PRICE	20. AMOUNT
1.	INFLUENZA VIRUS VACCINE, Monovalent, 200 CCA units, A/New Jersey/76 strain, and Bivalent, 200/200 CCA units, A/New Jersey/76-A/Victoria/3/75, to be supplied in accordance with the Scope of Work, Delivery Schedule, and terms set forth herein.				

21. TOTAL AMOUNT OF CONTRACT $

CONTRACTING OFFICER WILL COMPLETE BLOCK 22 OR 26 AS APPLICABLE

22. ☒ CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 3 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)

23. NAME OF CONTRACTOR Parke, Davis & Company
Robert R. Adams
(Signature of person authorized to sign)

24. NAME AND TITLE OF SIGNER (Type or print)
Robert R. Adams
Director, Legal Division

25. DATE SIGNED
Sept 22, 1976

26. ☐ AWARD (Contractor is not required to sign this document.) Your offer on Solicitation Number _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual document is necessary.

27. UNITED STATES OF AMERICA
BY David K. Rowe
(Signature of Contracting Officer)

28. NAME OF CONTRACTING OFFICER (Type or print)
David K. Rowe

29. DATE SIGNED
9/22/1976

-100

ARTICLE I - SCOPE OF CONTRACT:

The contractor shall manufacture and distribute influenza vaccine in accordance with the specifications set forth below during the contract period to the points and in the quantities specified on Delivery Orders issued by the Center for Disease Control. The only obligations or responsibilities of the Contractor in connection with the National Swine Flu Immunization Program of 1976 are contained in this contract. There are no warranties, expressed or implied, imposed on on the contractor except as stated in this contract.

ARTICLE II - SPECIFICATIONS:

A. Type of Vaccine:
The vaccine shall be Influenza Monovalent A/New Jersey/76 (Swine) and/or Bivalent A/New Jersey/76 (Swine) - A/Victoria/3/75 manufactured under a current establishment and product license as set forth below. Formulation standards, specifications and applicable tests of the vaccine shall be as set forth in the approved product license or as otherwise directed by the Food and Drug Administration.

B. Product Licensure:

The vaccine supplied under this contract shall be produced under U. S. Establishment License No. 1 and Amendment to the product license for influenza vaccine issued by the Bureau of Biologics. If, during the contract period of performance, the product or establishment license is suspended or revoked for any reason, production of the vaccine shall be discontinued until such time as the license is renewed. In the event production is suspended for the above reason, the Government shall not be held liable for failure to procure the guaranteed minimum contained in this contract.

C. Shelf Life:

Delivered vaccine shall have an expiration date through August 1, 1977. The Government agrees to take all appropriate steps to see to it that all persons who are responsible for administering vaccine are notified that the vaccine must not be administered after August 1, 1977.

D. Containers:

Vaccine shall be contained in vials of 10-dose and 50-dose capacity, with 2ml overfill in the 50-dose vial and 0.9ml overfill in the 10-dose vial. Ten-dose vials shall have an internal neck size no smaller than about 7mm in diameter; 50-dose vials, about 13mm OD. Vials shall be supplied with stoppers made of nonpyrogenic, high-grade rubber. Cap size for the vials will match the diameter of the necks. Vaccine dosage will be 0.5 ml.

E. Labeling:

Labeling of vials shall be in accordance with 21 CFR 610.60. In addition, the color of label for the monovalent vaccine shall be red with black or white markings, and the color of the bivalent vaccine shall be blue with black or white markings. Lot number shall be specified on each vial label. Text of the labels shall be supplied by the Government.

F. Caps:
Caps shall be the same color as the vial labels - red caps on monovalent vials and blue caps on bivalent vials.

G. Packaging:

For shipping purposes, vials shall be in intermediate packages as follows:

10-dose vials - 10 vials per package.
50-dose vials - 20 vials per package.

Each package shall be labeled in accordance with Paragraph S5.2.2.2 - Intermediate Containers of Federal Standard 123d. In addition to the requirements of the referenced Federal Standard, the following is required:

A. Labeling shall show applicable lot numbers.

B. A paste-on label shall be attached to each package. Label shall conform to the sample supplied with RFP.

C. Package inserts shall be placed in each intermediate package, a total of 10 inserts per package. Inserts shall be in accordance with Sub-paragraph 201.10(i) (2) of Title 21 CFR Part 600.3.

Packages of 10-dose vials shall be packed in a shipping container containing ten (10) such packages (i.e., 1,000 doses).

Packages of 50-dose vials shall be packed in a shipping container containing five (5) such packages (i.e., 5,000 doses).

Preservation, packaging, and packing shall furnish a degree of protection to preclude damage to containers and/or contents thereof under normal shipping conditions, handling, etc., and shall conform to applicable carrier rules and regulations, including carriers handling overseas shipments.

Shipment of vaccine will be made under refrigeration to the extent that the necessary insulated shipping containers can be procured by Contractor and in Contractor's possession at the time of shipment specified in the Delivery Orders placed by the Government. Said insulated shipping containers will be constructed of styrofoam in such a manner that when packed with coolant and vaccine the temperature inside the container will remain within the range of 2° C (34° F) and 15° C (60° F) for a period of 48 hours in an external environment of 100° F.

Any vaccine which Contractor is unable to ship under refrigeration due to lack of insulated shipping containers as aforesaid will be shipped to the delivery point(s) specified in the Delivery Orders placed by the Government by air freight, except in those instances where the specified delivery point(s) are located close enough to Contractor's warehouse in Detroit, Michigan, to enable delivery to be made by surface transportation to said specified delivery point(s) within approximately 24 hours.

H. Marking Provisions:

Shipping containers: Containers shall be marked in accordance with Federal Standard Number 123D, January 22, 1975, and shall contain as a minimum the following:

a. Quantity and Unit
b. Purchase Order Number
c. Item Name
d. Contractor Name and Address
e. Gross Weight
f. Lot Number(s)

ARTICLE III - QUANTITIES:

The number of doses, by vial sizes, to be furnished under the contract is:

Bivalent Vaccine	Monovalent Vaccine
10-dose vials - 25,400,000 doses	
50-dose vials - 2,300,000 doses	50-dose vials - 4,000,000 doses
Total - 27,700,000 doses	Total - 4,000,000 doses

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Variation in Quantity: A variation in the total quantity supplied hereunder will be accepted, provided that such variation is not in excess of 15% of the contract quantity as specified above, and is available for delivery prior to the final delivery date (January 15, 1977). The contractor shall notify the Government of availability of additional quantitites as soon as this status becomes known to the contractor.

ARTICLE IV - DISTRIBUTION:

A. Delivery Points:

The contractor shall deliver the vaccine, F.O.B. Destination, Within Consignee's Premises, as directed on delivery orders, to approximately 200 points in the 50 states and Trust Territories.

B. Delivery Schedule:

Deliveries shall begin on or before October 1, 1976, with the total amount of bivalent and monovalent vaccine to be delivered in accordance with the attached Availability Schedule. All deliveries shall be completed on or before January 15, 1977.

C. Overseas Delivery Requirements:

Overseas shipping and delivery methods shall be utilized for delivery to those points located outside the Continental United States.

D. Time of Delivery:

Delivery shall be made at destination within 10 days after receipt of written or telephonic order.

E. Shipments shall be made in minimum increments of 10,000 doses in full shipping containers

ARTICLE V - DELIVERY TERMS:

Delivery shall be made F.O.B. DESTINATION, WITHIN CONSIGNEE'S PREMISES, as defined below:

The term, "F.O.B. Destination, Within Consignee's Premises," to which this contract is subject, means:

(a) Delivery, free of expense to the Government, to within the doors of the Consignee's premises specified in the contract or delivery instructions.

(b) That it shall be the responsibility of the contractor to do the following:

(1) Pack and mark in such manner as to afford adequate protection against normal transportation hazards and secure prompt delivery to the consignee, and comply with all packing and marking specifications of the contract;

(2) Properly prepare and distribute commercial bills of lading;

(3) Make delivery laid down within the doors of the consignee's premises specified in the contract or delivery instructions;

OF OFFEROR OR CONTRACTOR

(4) Pay and bear all transportation and accessorial charges for such delivery laid down within the doors of the consignee's premises specified in the contract or delivery instructions;

(5) Be responsible for any loss or damage occurring before delivery is laid down within the doors of the consignee's premises specified in the contract or delivery instructions.

RTICLE VI - RETURN OF VACCINE:

requirement to accept unused vaccines at end of the contract period will be placed on ntractor.

RTICLE VII - METHOD OF ORDERING:

accine shall be ordered by Delivery Orders, each of which will designate the vaccine rdered, quantity required, and destination. Orders may be placed by telephone and confirmed in writing. Orders will be in conformity with Article IV.E.

RTICLE VIII - INSPECTION AND ACCEPTANCE:

ots of vaccine will be submitted by the contractor to the Bureau of Biologics for reviewing nd testing. Following release of the lots, Bureau of Biologics will send a notification of proval to the project officer at the Center for Disease Control. Final inspection shall made at consignee's locations. Final acceptance/rejection will be made by the Center for Disease Control. Defective or damaged material received at consignee's locations will be ejected in accordance with Article 5 of the General Provisions.

RTICLE IX - PAYMENT:

ayment shall be made within 30 days of contractor's invoice for all vaccine which has been elivered and accepted. Each invoice or voucher shall, as a minimum, identify the appropriate Delivery Order for which the delivery was made, the vaccine and amount delivered, the nit price, the total price, and the lot number(s). All payments shall be on a provisional asis pending definitization of a contract. Vouchers in accordance with the contractor's urrent proposal shall be submitted to the following address:

Center for Disease Control
Financial Management Office
255 East Paces Ferry Road, N. E.
Atlanta, GA 30305

RTICLE X - PROJECT OFFICER:

he Center for Disease Control, Atlanta, Georgia, will designate an individual to perform as Project Officer during the period of performance of the contract. The Project Officer shall responsible for guidance in regard to the technical aspect of the contract, provide a nt for liaison between the manufacturer and other Government agencies (Federal, State, and local) and be the general focal point to address technical and logistical problems relating to the performance under this contract. The Project Officer shall not have

(9) The arrangements for the implementation of the influenza immunization program, including the issuance of appropriate guidelines and information.

The contractor shall use due care and comply with all applicable laws and regulations in the manufacture and handling of the vaccine in accordance with the specifications herein

TICLE XIII - DEFINITIZATION:

A fixed price, redeterminable type contract is contemplated. To accomplish this result the contractor agrees to enter into negotiation promptly with the Contracting Officer over the terms of a definitive contract, which will include all clauses, terms, and conditions as may be mutually agreeable. The contractor agrees to make available cost and pricing data, and data relating to his accounting system.

The schedules for definitization of this contract are set forth below:

Negotiation of price and other terms and conditions - On or before November 10, 1976.

Target date for definitization - on or before December 1, 1976.

If agreement on a definitive contract to supersede this letter contract is not reached by the target date set forth in B, above, or any extension thereof by the Contracting Officer, the Contracting Officer may, with the approval of the Head of the Procurement Activity, determine a reasonable price subject to appeal by the contractor as provided in the clause "Disputes" of this contract. The contract shall be governed by:

(1) All clauses, terms, and conditions contained in this letter contract except which by their nature are applicable only to a letter contract.

(2) All clauses required by law as of the date of this letter contract..

(3) Such other clauses, terms, and conditions as may be mutually agreed upon.

TICLE XIV - LIMITATION ON CONTRACTOR'S PROFIT:

In accordance with the provisions of P.L. 94-380, the contract price for the vaccine delivered under the contract shall be subject to renegotiation to eliminate any profit realized by the contractor on the swine flu vaccine and to limit the profit realized by the contractor on the A/Victoria/75 vaccine to a reasonable profit. The Secretary of Health, Education, and Welfare has issued criteria for the determination of the costs of the contractor for the vaccines delivered under this contract and for the determinatic of a reasonable profit on the A/Victoria/75 vaccine, and is as Attachment A.

Any insurance premium amount of which is included in the price of the vaccine delivered under this contract and which is refunded to the contractor under any retrospective, experience-rating plan or similar rating plan shall be refunded to the Government not later than 30 days after receipt of the refund by the contractor. Any amount retained by the contractor for self-insurance retention which is included in the price of the vaccine delivered under this contract shall be segregated in a separate account in a federally insured commercial bank with assets in excess of $100,000,000. Said self-insurance retention shall be invested, to the extent possible, in Certificates of Deposit at the said bank's prevailing interest rate. Any interest earned on the Certificate of Deposit

uthority to make any commitments or authorize any changes which affect the contract price, ms, or conditions; any such changes shall be referred to the Contracting Officer for tion.

TICLE XI - PROJECT DIRECTOR:

he Contractor shall designate an individual who will serve as the point of contact egarding the technical performance of the contract. This individual shall have the uthority necessary to commit the company and shall be assigned responsibilities con- ruent with requirements of the contract. The Government reserves the right to pprove the Project Director and any successor to that position.

RTICLE XII - DELINEATION OF RESPONSIBILITIES OF THE GOVERNMENT AND THE CONTRACTOR:

. The parties recognize that the Government has initiated, planned, and is arranging for the implementation of the influenza immunization program. Because of the need to have the vaccine tested, manufactured, and delivered within a relatively short period of time in order that the population may be inoculated in an attempt to prevent an influenza epidemic, the Government has assumed certain responsibilities as specified herein which would ordinarily devolve upon the contractor. It is the intention of the parties that the contractor will be responsible solely for the performance of its obligations under Paragraph C herein. It is the purpose of this Article to delineate the separate responsibilities of the Government and the contractor.

. In the light of the circumstances described in Paragraph A hereof, the Government shall be responsible for:

(1) The adequacy of the standards and specifications for the vaccine required to be delivered under this contract, including their compliance with all applicable requirements of law and regulation.

(2) The safety and suitability of materials provided to the contractor by the Government under or in connection with this contract.

(3) The investigation and determination of the safe and effective dosages and adequate directions for the use of the vaccine.

(4) The investigation and determination of the risks and benefits of inoculation with the vaccine.

(5) The development of an adequate statement of information respecting the risks and benefits referred to in subparagraph (4).

(6) The taking of all appropriate steps to assure that each individual to be inoculated (or, where appropriate, a parent or guardian of such individual) is adequately informed of such risks and benefits.

(7) The content of the labeling of the vaccine, including its compliance with all applicable requirements of law and regulation.

(8) The taking of all appropriate steps to assure that each person responsible for administering the vaccine has adequate notice of the labeling of the vaccine, provided that nothing herein shall limit the responsibility which the manufacturer otherwise has to assure that labeling is included in and delivered with each ship-

shall be added to said self-insurance retention fund. Payment from the separate account shall be made only for self-insurance as provided herein and any amount, including interest, in the separate account not so expended on or before August 1, 1985, shall be refunded to the Government not later than August 31, 1985. It is the understanding of the parties that, since the contract shall be subject to renegotiation to eliminate any profit realized by the contractor on the swine flu vaccine and to limit the profit realized by the contractor on the A/Victoria/75 vaccine to a reasonable profit, the self-insurance retention fund and interest thereon shall not constitute income to the contractor. In the event the contractor is required to pay a claim by the Government pursuant to Section 317(k)(7) of the Public Health Service Act after the contractor has refunded the unexpended amount retained for self-insurance, such claim shall be deemed satisfied up to the amount of such refund.

- For the purposes of this Article, the contractor shall maintain and make available to the Secretary or his authorized representatives the records specified by the Articles of this contract entitled "Accounts, Audits, and Records"; Examination of Records by Comptroller General (Clause 10 of the General Provisions, SF-32); and Examination of Records by Department of Health, Education, and Welfare (Alterations to SF-32).

- In the event the Contracting Officer determines that the contractor has realized any profit on swine flu vaccine or has realized more than a reasonable profit on A/Victoria/75 vaccine, the contract price shall be adjusted in accordance with the requirements of Paragraph F of this Article. Costs will be determined in accordance with the Cost and Profit Criteria. The contract price will be adjusted upward and downward to reflect those costs as determined by the Contracting Officer and payment made within 30 days of receipt of the Contracting Officer's final decision. Failure of the parties to reach agreement on the renegotiation of the contract price shall be subject to Clause 12 of the General Provisions, entitled "Disputes." However, if the contractor takes an appeal from the Contracting Officer's final decision, it may withhold the funds in question until said appeal is decided. In the event that the decision on appeal is that the Government is entitled to a refund, such refund shall be made within thirty days from the date of the decision, with accrued interest at the rate determined by the Secretary of the Treasury pursuant to Public Law 92-41, 85 Stat. 97 from the date of the contractor's receipt of the Contracting Officer's final decision.

RTICLE XV - GOVERNMENT INTENTION:

t is the intent of the Government that the contractor shall suffer no loss by virtue of the pplication of the Cost and Profit Criteria (other than losses resulting from its gross negli-ence as contemplated in Paragraph 2.b.(1) of Attachment A) as a result of its participation n the Government's procurement of vaccines for the Swine Flu Program and that the contractor hall receive a reasonable profit on the A/Victoria/75 vaccine supplied to the Government.

RTICLE XVI - CLARIFICATION OF ATTACHMENT A:

or the purpose of clarifying Paragraph 2.b.(1) of Attachment A, it is agreed that the Govern-ent shall have the burden of establishing gross negligence on the part of the contractor.

RTICLE XVII - COOPERATION IN PROCESSING AND DEFENSE OF CLAIMS AND SUITS:

- Pursuant to the provisions of P.L. 94-380, the contractor shall cooperate with the Government in the processing or defense of any claim or suit brought against the United States under the Federal Tort Claims Act based upon alleged acts or omissions of the contractor.

- While any such claim is under consideration by the Department of Health, Education, and Welfare's Claims Officer, the contractor shall furnish information requested by the Claims Officer or his representatives as is reasonably necessary to enable the claim to be considered and determined.

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Should any action be filed against the United States under the Federal Tort Claims Act based upon alleged acts or omissions of the contractor, the contractor shall render all reasonable cooperation to the Government in the defense of such action as may be requested by the Department of Justice or cognizant United States Attorney. Such cooperation shall include, where appropriate, making records and personnel of the contractor available for pretrial proceedings and for the trial of the action.

TICLE XVIII - LIMITATION OF GOVERNMENT'S LIABILITY:

contractor is not authorized to make expenditures or to incur obligations, in performance this contract, which exceeds $19,000,000.00. In the event of a termination of this contract, Government's liability shall not exceed $19,000,000.00.

TICLE XIX - ORDER OF PRECEDENCE CLAUSE:

the event of an inconsistency between provisions of this contract, the inconsistency shall resolved by giving precedence in the following order: (a) the Contract Articles I through , including Attachment A and the Availability Schedules; (b) Solicitation Instructions and ditions; (c) General Provisions and Alterations of Article XX; (d) other Provisions of the tract, whether incorporated by reference or otherwise.

TICLE XX - GENERAL PROVISIONS AND ALTERATIONS:

General Provisions (SF-32), April 1975 edition are hereby incorporated in this contract. i are altered as follows:

Clause 21a, Small Business Subcontracting Program, is applicable if this contract eeds $500,000.00.

Clause 22a, Labor Surplus Area Subcontracting Program, is applicable if this contract exceeds $500,000.00

The attached clauses, listed below, are added to and made a part of the General Provisions:

A. Listing of Employment Openings
B. Minority Business Enterprises Subcontracting Program
C. Unsolicited Samples, Descriptive Literature, or Brand Name Reference
D. Examination of Records by Department of Health, Education, and Welfare
E. Federal, State, and Local Taxes, HEW-328
F. Employment of the Handicapped
G. Termination for Convenience
H. Price Reduction for Defective Cost or Pricing Data
I. Subcontracting Cost or Pricing Data
J. Audit
K. Accounts, Audits, and Records
L. Disclosure Statement - Cost Accounting Practices and Certification
M. Cost Accounting Standards
N. Cost Accounting Standards - Exemption for Contracts of $500,000.00 or Less - Certifications
O. Preaward Equal Opportunity Compliance Reviews
P. Clean Air and Water
Q. Equal Opportunity Clause

AVAILABILITY SCHEDULE

Bivalent vaccine - each 0.5 ml. dose contains
200 CCA units of A/New Jersey/76 (Swine)
and 200 CCA units of A/Victoria/3/75

Availability Date	Doses *	Packaged In
9-28-76	10.3	10-dose vials
9-28-76	11.6	50-dose vials
9-28-76	10.3	10-dose vials
9-29-76	10.	10-dose vials
9-29-76	10.7	50-dose vials
9-30-76	10.	10-dose vials
10-11-76	10.	10-dose vials
10-12-76	10.	10-dose vials
10-13-76	10.	10-dose vials
10-19-76	10.	10-dose vials
10-25-76	10.	10-dose vials
10-26-76	10.	10-dose vials
10-27-76	10.	10-dose vials
11-1-76	10.	10-dose vials
11-2-76	10.	10-dose vials
11-3-76	10.	10-dose vials
11-8-76	10.	10-dose vials
11-9-76	10.	10-dose vials
11-15-76	10.	10-dose vials
11-16-76	10.	10-dose vials
11-17-76	10.	10-dose vials
11-22-76	10.	10-dose vials
11-23-76	10.	10-dose vials
11-29-76	10.	10-dose vials
11-30-76	10.	10-dose vials
12-6-76	10.	10-dose vials
12-7-76	10.	10-dose vials
12-13-76	4.	10-dose vials

* expressed in units of 100,000

ATTACHMENT A

COST AND PROFIT CRITERIA FOR THE
PROCUREMENT OF SWINE FLU VACCINE

Pursuant to §317(j)(3) of the Public Health Service Act (42 U.S.C. 247(b)), as amended by the National Swine Flu Immunization Program of 1976 (P.L. 94-380), I hereby prescribe the following criteria for renegotiation to eliminate any profit realized from procurement of swine flu vaccine under the Swine Flu Program.

1. "Profit realized" from any procurement shall be the amount by which the amount paid by the Government to the contractor in the procurement exceeds the costs to the contractor of performing the contract.

2. The contractor will be paid its costs in performing the contract as follows:

   a. All direct and indirect costs actually and reasonably incurred by the contractor resulting from its participation in the Government's procurement of vaccine for the Swine Flu Program shall be reimbursed by the Government. The amount of such costs shall be determined in accordance with reasonable methods of allocation, practices and procedures applied on a basis consistent with those applied by the contractor in preparing his proposal and reviewed by the Department's audit agency.

   b. Reimbursable costs shall include, but not be limited to:

      1) Costs resulting from the production of vaccine that fails, through no gross negligence of the contractor, to meet the specifications of the contract because it is refused certification by the Bureau of Biologics of the Food and Drug Administration.

      2) Costs incurred prior to execution of the contract in order to meet the reasonably anticipated delivery dates for the vaccine under the Program.

      3) Imputed interest on working capital, at rates determined by the Secretary of Treasury pursuant to P.L. 92-41, 85 Stat. 97.

      4) Actual and unrecoverable costs due to interruption of production or sale of other biologicals in order to devote staff and facilities to the production of vaccine for the Program.

3. Profit will only be allowed on A/Victoria/75 vaccine and shall be negotiated at arm's length based on the contractor's degree of risk, difficulty and complexity of performance, type of contract, and cooperation with the Government in meeting the needs of this health emergency.

4. Any insurance premium amount which is included in the price of any procurement of swine flu vaccine under the Program and which is refunded to the contractor under any retrospective, experience-rating plan or similar rating plan shall in turn be refunded to the Government.

GENERAL PROVISIONS

(Supply Contract)

1. DEFINITIONS

As used throughout this contract, the following terms shall have the meaning set forth below:

(a) The term "head of the agency" or "Secretary" as used herein means the Secretary, the Under Secretary, any Assistant Secretary, or any other head or assistant head of the executive or military department or other Federal agency; and the term "his duly authorized representative" means any person or persons or board (other than the Contracting Officer) authorized to act for the head of the agency or the Secretary.

(b) The term "Contracting Officer" means the person executing this contract on behalf of the Government, and any other officer or civilian employee who is a properly designated Contracting Officer; and the term includes, except as otherwise provided in this contract, the authorized representative of a Contracting Officer acting within the limits of his authority.

(c) Except as otherwise provided in this contract, the term "subcontracts" includes purchase orders under this contract.

2. CHANGES

The Contracting Officer may at any time, by a written order, and without notice to the sureties, make changes, within the general scope of this contract, in any one or more of the following: (i) Drawings, designs, or specifications, where the supplies to be furnished are to be specially manufactured for the Government in accordance therewith; (ii) method of shipment or packing; and (iii) place of delivery. If any such change causes an increase or decrease in the cost of, or the time required for, the performance of any part of the work under this contract, whether changed or not changed by any such order, an equitable adjustment shall be made in the contract price or delivery schedule, or both, and the contract shall be modified in writing accordingly. Any claim by the Contractor for adjustment under this clause must be asserted within 30 days from the date of receipt by the Contractor of the notification of change: *Provided, however,* That the Contracting Officer, if he decides that the facts justify such action, may receive and act upon any such claim asserted at any time prior to final payment under this contract. Where the cost of property made obsolete or excess as a result of a change is included in the Contractor's claim for adjustment, the Contracting Officer shall have the right to prescribe the manner of disposition of such property. Failure to agree to any adjustment shall be a dispute concerning a question of fact within the meaning of the clause of this contract entitled "Disputes." However, nothing in this clause shall excuse the Contractor from proceeding with the contract as changed.

3. EXTRAS

Except as otherwise provided in this contract, no payment for extras shall be made unless such extras and the price therefor have been authorized in writing by the Contracting Officer.

4. VARIATION IN QUANTITY

No variation in the quantity of any item called for by this contract will be accepted unless such variation has been caused by conditions of loading, shipping, or packing, or allowances in manufacturing processes, and then only to the extent, if any, specified elsewhere in this contract.

5. INSPECTION

(a) All supplies (which term throughout this clause includes without limitation raw materials, components, intermediate assemblies, and end products) shall be subject to inspection and test by the Government, to the extent practicable at all times and places including the period of manufacture, and in any event prior to acceptance.

(b) In case any supplies or lots of supplies are defective in material or workmanship or otherwise not in conformity with the requirements of this contract, the Government shall have the right either to reject them (with or without instructions as to their disposition) or to require their correction. Supplies or lots of supplies which have been rejected or required to be corrected shall be removed or, if permitted or required by the Contracting Officer, corrected in place by and at the expense of the Contractor promptly after notice, and shall not thereafter be tendered for acceptance unless the former rejection or requirement of correction is disclosed. If the Contractor fails promptly to remove such supplies or lots of supplies which are required to be removed, or promptly to replace or correct such supplies or lots of supplies, the Government either (i) may by contract or otherwise replace or correct such supplies and charge to the Contractor the cost occasioned the Government thereby, or (ii) may terminate this contract for default as provided in the clause of this contract entitled "Default." Unless the Contractor corrects or replaces such supplies within the delivery schedule, the Contracting Officer may require the delivery of such supplies at a reduction in price which is equitable under the circumstances. Failure to agree to such reduction of price shall be a dispute concerning a question of fact within the meaning of the clause of this contract entitled "Disputes."

(c) If any inspection or test is made by the Government on the premises of the Contractor or a subcontractor, the Contractor without additional charge shall provide all reasonable facilities and assistance for the safety and convenience of the Government inspectors in the performance of their duties. If Government inspection or test is made at a point other than the premises of the Contractor or a subcontractor, it shall be at the expense of the Government except as otherwise provided in this contract: *Provided,* That in case of rejection the Government shall not be liable for any reduction in value of samples used in connection with such inspection or test. All inspections and tests by the Government shall be performed in such a manner as not to unduly delay the work. The Government reserves the right to charge to the Contractor any additional cost of Government inspection and test when supplies are not ready at the time such inspection and test is requested by the Contractor or when reinspection or retest is necessitated by prior rejection. Acceptance or rejection of the supplies shall be made as promptly as practicable after delivery, except as otherwise provided in this contract; but failure to inspect and accept or reject supplies shall neither relieve the Contractor from responsibility for such supplies as are not in accordance with the contract requirements nor impose liability on the Government therefor.

(d) The inspection and test by the Government of any supplies or lots thereof does not relieve the Contractor from any responsibility regarding defects or other failures to meet the contract requirements which may be discovered prior to acceptance. Except as otherwise provided in this contract, acceptance shall be conclusive except as regards latent defects, fraud, or such gross mistakes as amount to fraud.

(e) The Contractor shall provide and maintain an inspection system acceptable to the Government covering the supplies hereunder. Records of all inspection work by the Contractor shall be kept complete and available to the Government during

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the performance of this contract and for such longer period as may be specified elsewhere in this contract.

6. RESPONSIBILITY FOR SUPPLIES

Except as otherwise provided in this contract, (i) the Contractor shall be responsible for the supplies covered by this contract until they are delivered at the designated delivery point, regardless of the point of inspection; (ii) after delivery to the Government at the designated point and prior to acceptance by the Government or rejection and giving notice thereof by the Government, the Government shall be responsible for the loss or destruction of or damage to the supplies only if such loss, destruction, or damage results from the negligence of officers, agents, or employees of the Government acting within the scope of their employment; and (iii) the Contractor shall bear all risks as to rejected supplies after notice of rejection, except that the Government shall be responsible for the loss, or destruction of, or damage to the supplies only if such loss, destruction or damage results from the gross negligence of officers, agents, or employees of the Government acting within the scope of their employment.

7. PAYMENTS

The Contractor shall be paid, upon the submission of proper invoices or vouchers, the prices stipulated herein for supplies delivered and accepted or services rendered and accepted, less deductions, if any, as herein provided. Unless otherwise specified, payment will be made on partial deliveries accepted by the Government when the amount due on such deliveries so warrants; or, when requested by the Contractor, payment for accepted partial deliveries shall be made whenever such payment would equal or exceed either $1,000 or 50 percent of the total amount of this contract.

8. ASSIGNMENT OF CLAIMS

(a) Pursuant to the provisions of the Assignment of Claims Act of 1940, as amended (31 U.S.C. 203, 41 U.S.C. 15), if this contract provides for payments aggregating $1,000 or more, claims for moneys due or to become due the Contractor from the Government under this contract may be assigned to a bank, trust company, or other financing institution, including any Federal lending agency, and may thereafter be further assigned and reassigned to any such institution. Any such assignment or reassignment shall cover all amounts payable under this contract and not already paid, and shall not be made to more than one party, except that any such assignment or reassignment may be made to one party as agent or trustee for two or more parties participating in such financing. Unless otherwise provided in this contract, payments to an assignee of any moneys due or to become due under this contract shall not, to the extent provided in said Act, as amended, be subject to reduction or setoff. (The preceding sentence applies only if this contract is made in time of war or national emergency as defined in said Act and is with the Department of Defense, the General Services Administration, the Energy Research and Development Administration, the National Aeronautics and Space Administration, the Federal Aviation Administration, or any other department or agency of the United States designated by the President pursuant to Clause 4 of the proviso of section 1 of the Assignment of Claims Act of 1940, as amended by the Act of May 15, 1951, 65 Stat. 41.)

(b) In no event shall copies of this contract or of any plans, specifications, or other similar documents relating to work under this contract, if marked "Top Secret," "Secret," or "Confidential," be furnished to any assignee of any claim arising under this contract or to any other person not entitled to receive the same. However, a copy of any part or all of this contract so marked may be furnished, or any information contained therein may be disclosed, to such assignee upon the prior written authorization of the Contracting Officer.

9. ADDITIONAL BOND SECURITY

If any surety upon any bond furnished in connection with this contract becomes unacceptable to the Government or if any such surety fails to furnish reports as to his financial condition from time to time as requested by the Government, the Contractor shall promptly furnish such additional security as may be required from time to time to protect the interests of the Government and of persons supplying labor or materials in the prosecution of the work contemplated by this contract.

10. EXAMINATION OF RECORDS BY COMPTROLLER GENERAL

(a) This clause is applicable if the amount of this contract exceeds $10,000 and was entered into by means of negotiation, including small business restricted advertising, but is not applicable if this contract was entered into by means of formal advertising.

(b) The Contractor agrees that the Comptroller General of the United States or any of his duly authorized representatives shall, until the expiration of 3 years after final payment under this contract or such lesser time specified in either Appendix M of the Armed Services Procurement Regulation or the Federal Procurement Regulations Part 1-20, as appropriate, have access to and the right to examine any directly pertinent books, documents, papers, and records of the Contractor involving transactions related to this contract.

(c) The Contractor further agrees to include in all his subcontracts hereunder a provision to the effect that the subcontractor agrees that the Comptroller General of the United States or any of his duly authorized representatives shall, until the expiration of 3 years after final payment under the subcontract or such lesser time specified in either Appendix M of the Armed Services Procurement Regulation or the Federal Procurement Regulations Part 1-20, as appropriate, have access to and the right to examine any directly pertinent books, documents, papers, and records of such subcontractor, involving transactions related to the subcontract. The term "subcontract" as used in this clause excludes (1) purchase orders not exceeding $10,000 and (2) subcontracts or purchase orders for public utility services at rates established for uniform applicability to the general public.

(d) The periods of access and examination described in (b) and (c), above, for records which relate to (1) appeals under the "Disputes" clause of this contract, (2) litigation or settlement of claims arising out of the performance of this contract, or (3) costs and expenses of this contract as to which exception has been taken by the Comptroller General or any of his duly authorized representatives, shall continue until such appeals, litigation, claims, or exceptions have been disposed of.

11. DEFAULT

(a) The Government may, subject to the provisions of paragraph (c) below, by written notice of default to the Contractor, terminate the whole or any part of this contract in any one of the following circumstances:

(i) If the Contractor fails to make delivery of the supplies or to perform the services within the time specified herein or any extension thereof; or

(ii) If the Contractor fails to perform any of the other provisions of this contract, or so fails to make progress as to endanger performance of this contract in accordance with its terms, and in either of these two circumstances does not cure such failure within a period of 10 days (or such longer period as the Contracting Officer may authorize in writing) after receipt of notice from the Contracting Officer specifying such failure.

(b) In the event the Government terminates this contract in whole or in part as provided in paragraph (a) of this clause, the Government may procure, upon such terms and in such manner as the Contracting Officer may deem appropriate, supplies or services similar to those so terminated, and the Contractor shall be liable to the Government for any excess costs for such similar supplies or services: *Provided*, That the Contractor shall continue the performance of this contract to the extent not terminated under the provisions of this clause.

(c) Except with respect to defaults of subcontractors, the

Contractor shall not be liable for any excess costs if the failure to perform the contract arises out of causes beyond the control and without the fault or negligence of the Contractor. Such causes may include, but are not restricted to, acts of God or of the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, freight embargoes, and unusually severe weather; but in every case the failure to perform must be beyond the control and without the fault or negligence of the Contractor. If the failure to perform is caused by the default of a subcontractor, and if such default arises out of causes beyond the control of both the Contractor and subcontractor, and without the fault or negligence of either of them, the Contractor shall not be liable for any excess costs for failure to perform, unless the supplies or services to be furnished by the subcontractor were obtainable from other sources in sufficient time to permit the Contractor to meet the required delivery schedule.

(d) If this contract is terminated as provided in paragraph (a) of this clause, the Government, in addition to any other rights provided in this clause, may require the Contractor to transfer title and deliver to the Government, in the manner and to the extent directed by the Contracting Officer, (i) any completed supplies, and (ii) such partially completed supplies and materials, parts, tools, dies, jigs, fixtures, plans, drawings, information, and contract rights (hereinafter called "manufacturing materials") as the Contractor has specifically produced or specifically acquired for the performance of such part of this contract as has been terminated; and the Contractor shall, upon direction of the Contracting Officer, protect and preserve property in possession of the Contractor in which the Government has an interest. Payment for completed supplies delivered to and accepted by the Government shall be at the contract price. Payment for manufacturing materials delivered to and accepted by the Government and for the protection and preservation of property shall be in an amount agreed upon by the Contractor and Contracting Officer; failure to agree to such amount shall be a dispute concerning a question of fact within the meaning of the clause of this contract entitled "Disputes." The Government may withhold from amounts otherwise due the Contractor for such completed supplies or manufacturing materials such sum as the Contracting Officer determines to be necessary to protect the Government against loss because of outstanding liens or claims of former lien holders.

(e) If, after notice of termination of this contract under the provisions of this clause, it is determined for any reason that the Contractor was not in default under the provisions of this clause, or that the default was excusable under the provisions of this clause, the rights and obligations of the parties shall, if the contract contains a clause providing for termination for convenience of the Government, be the same as if the notice of termination had been issued pursuant to such clause. If, after notice of termination of this contract under the provisions of this clause, it is determined for any reason that the Contractor was not in default under the provisions of this clause, and if this contract does not contain a clause providing for termination for convenience of the Government, the contract shall be equitably adjusted to compensate for such termination and the contract modified accordingly; failure to agree to any such adjustment shall be a dispute concerning a question of fact within the meaning of the clause of this contract entitled "Disputes."

(f) The rights and remedies of the Government provided in this clause shall not be exclusive and are in addition to any other rights and remedies provided by law or under this contract.

(g) As used in paragraph (e) of this clause, the terms "subcontractor" and "subcontractors" mean subcontractor(s) at any tier.

12. DISPUTES

(a) Except as otherwise provided in this contract, any dispute concerning a question of fact arising under this contract which is not disposed of by agreement shall be decided by the Contracting Officer, who shall reduce his decision to writing and mail or otherwise furnish a copy thereof to the Contractor. The decision of the Contracting Officer shall be final and conclusive unless, within 30 days from the date of receipt of such copy, the Contractor mails or otherwise furnishes to the Contracting Officer a written appeal addressed to the Secretary. The decision of the Secretary or his duly authorized representative for the determination of such appeals shall be final and conclusive unless determined by a court of competent jurisdiction to have been fraudulent, or capricious, or arbitrary, or so grossly erroneous as necessarily to imply bad faith, or not supported by substantial evidence. In connection with any appeal proceeding under this clause, the Contractor shall be afforded an opportunity to be heard and to offer evidence in support of its appeal. Pending final decision of a dispute hereunder, the Contractor shall proceed diligently with the performance of the contract and in accordance with the Contracting Officer's decision.

(b) This "Disputes" clause does not preclude consideration of law questions in connection with decisions provided for in paragraph (a) above: *Provided*, That nothing in this contract shall be construed as making final the decision of any administrative official, representative, or board on a question of law.

13. NOTICE AND ASSISTANCE REGARDING PATENT AND COPYRIGHT INFRINGEMENT

The provisions of this clause shall be applicable only if the amount of this contract exceeds $10,000.

(a) The Contractor shall report to the Contracting Officer, promptly and in reasonable written detail, each notice or claim of patent or copyright infringement based on the performance of this contract of which the Contractor has knowledge.

(b) In the event of any claim or suit against the Government on account of any alleged patent or copyright infringement arising out of the performance of this contract or out of the use of any supplies furnished or work or services performed hereunder, the Contractor shall furnish to the Government, when requested by the Contracting Officer, all evidence and information in possession of the Contractor pertaining to such suit or claim. Such evidence and information shall be furnished at the expense of the Government except where the Contractor has agreed to indemnify the Government.

14. BUY AMERICAN ACT

(a) In acquiring end products, the Buy American Act (41 U.S. Code 10 a–d) provides that the Government give preference to domestic source end products. For the purpose of this clause:

(i) "Components" means those articles, materials, and supplies, which are directly incorporated in the end products;

(ii) "End products" means those articles, materials, and supplies, which are to be acquired under this contract for public use; and

(iii) A "domestic source end product" means (A) an unmanufactured end product which has been mined or produced in the United States and (B) an end product manufactured in the United States if the cost of the components thereof which are mined, produced, or manufactured in the United States exceeds 50 percent of the cost of all its components. For the purposes of this (a) (iii) (B), components of foreign origin of the same type or kind as the products referred to in (b) (i) or (iii) of this clause shall be treated as components mined, produced, or manufactured in the United States.

(b) The Contractor agrees that there will be delivered under this contract only domestic source end products, except end products:

(i) Which are for use outside the United States;

(ii) Which the Government determines are not mined, produced, or manufactured in the United States in sufficient and reasonably available commercial quantities and of a satisfactory quality;

(iii) As to which the Secretary determines the domestic preference to be inconsistent with the public interest; or

(iv) As to which the Secretary determines the cost to the Government to be unreasonable.

(The foregoing requirements are administered in accordance with Executive Order No. 10582, dated December 17, 1954.)

15. CONVICT LABOR

In connection with the performance of work under this contract, the Contractor agrees not to employ any person undergoing sentence of imprisonment at hard labor except as provided by Public Law 89-176, September 10, 1965 (18 U.S.C. 4082(c)(2)) and Executive Order 11755, December 29, 1973.

16. CONTRACT WORK HOURS AND SAFETY STANDARDS ACT—OVERTIME COMPENSATION

This contract, to the extent that it is of a character specified in the Contract Work Hours and Safety Standards Act (40 U.S.C. 327-333), is subject to the following provisions and to all other applicable provisions and exceptions of such Act and the regulations of the Secretary of Labor thereunder.

(a) Overtime requirements. No Contractor or subcontractor contracting for any part of the contract work which may require or involve the employment of laborers, mechanics, apprentices, trainees, watchmen, and guards shall require or permit any laborer, mechanic, apprentice, trainee, watchman, or guard in any workweek in which he is employed on such work to work in excess of eight hours in any calendar day or in excess of forty hours in such workweek on work subject to the provisions of the Contract Work Hours and Safety Standards Act unless such laborer, mechanic, apprentice, trainee, watchman, or guard receives compensation at a rate not less than one and one-half times his basic rate of pay for all such hours worked in excess of eight hours in any calendar day or in excess of forty hours in such workweek, whichever is the greater number of overtime hours.

(b) Violation; liability for unpaid wages; liquidated damages. In the event of any violation of the provisions of paragraph (a), the Contractor and any subcontractor responsible therefor shall be liable to any affected employee for his unpaid wages. In addition, such Contractor and subcontractor shall be liable to the United States for liquidated damages. Such liquidated damages shall be computed with respect to each individual laborer, mechanic, apprentice, trainee, watchman, or guard employed in violation of the provisions of paragraph (a) in the sum of $10 for each calendar day on which such employee was required or permitted to be employed on such work in excess of eight hours or in excess of his standard workweek of forty hours without payment of the overtime wages required by paragraph (a).

(c) Withholding for unpaid wages and liquidated damages. The Contracting Officer may withhold from the Government Prime Contractor, from any moneys payable on account of work performed by the Contractor or subcontractor, such sums as may administratively be determined to be necessary to satisfy any liabilities of such Contractor or subcontractor for unpaid wages and liquidated damages as provided in the provisions of paragraph (b).

(d) Subcontracts. The Contractor shall insert paragraphs (a) through (d) of this clause in all subcontracts, and shall require their inclusion in all subcontracts of any tier.

(e) Records. The Contractor shall maintain payroll records containing the information specified in 29 CFR 516.2(a). Such records shall be preserved for three years from the completion of the contract.

17. WALSH-HEALEY PUBLIC CONTRACTS ACT

If this contract is for the manufacture or furnishing of materials, supplies, articles, or equipment in an amount which exceeds or may exceed $10,000 and is otherwise subject to the Walsh-Healey Public Contracts Act, as amended (41 U.S. Code 35-45), there are hereby incorporated by reference all representations and stipulations required by said Act and regulations issued thereunder by the Secretary of Labor, such representations and stipulations being subject to all applicable rulings and interpretations of the Secretary of Labor which are now or may hereafter be in effect.

18. EQUAL OPPORTUNITY

(The following clause is applicable unless this contract is exempt under the rules, regulations, and relevant orders of the Secretary of Labor (41 CFR, ch. 60).)

During the performance of this contract, the Contractor agrees as follows:

(a) The Contractor will not discriminate against any employee or applicant for employment because of race, color, religion, sex, or national origin. The Contractor will take affirmative action to ensure that applicants are employed, and that employees are treated during employment, without regard to their race, color, religion, sex, or national origin. Such action shall include, but not be limited to, the following: Employment, upgrading, demotion, or transfer; recruitment or recruitment advertising; layoff or termination; rates of pay or other forms of compensation; and selection for training, including apprenticeship. The Contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices to be provided by the Contracting Officer setting forth the provisions of this Equal Opportunity clause.

(b) The Contractor will, in all solicitations or advertisements for employees placed by or on behalf of the Contractor, state that all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, or national origin.

(c) The Contractor will send to each labor union or representative of workers with which he has a collective bargaining agreement or other contract or understanding, a notice, to be provided by the agency Contracting Officer, advising the labor union or workers' representative of the Contractor's commitments under this Equal Opportunity clause, and shall post copies of the notice in conspicuous places available to employees and applicants for employment.

(d) The Contractor will comply with all provisions of Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, and of the r regulations, and relevant orders of the Secretary of Labor.

(e) The Contractor will furnish all information and reports required by Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, and by the rules, regulations, and orders of the Secretary of Labor, or pursuant thereto, and will permit access to his books, records, and accounts by the contracting agency and the Secretary of Labor for purposes of investigation to ascertain compliance with such rules, regulations, and orders.

(f) In the event of the Contractor's noncompliance with the Equal Opportunity clause of this contract or with any of the said rules, regulations, or orders, this contract may be canceled, terminated, or suspended, in whole or in part, and the Contractor may be declared ineligible for further Government contracts in accordance with procedures authorized in Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, and such other sanctions may be imposed and remedies invoked as provided in Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, or by rule, regulation, or order of the Secretary of Labor, or as otherwise provided by law.

(g) The Contractor will include the provisions of paragraphs (a) through (g) in every subcontract or purchase order unless exempted by rules, regulations, or orders of the Secretary of Labor issued pursuant to section 204 of Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, so that such provisions will be binding upon each subcontractor or vendor. The Contractor will take such action with respect to any subcontract or purchase order as the contracting agency may direct as a means of enforcing s h provisions, including sanctions for noncompliance: *Provided, however*, That in the event the Contractor becomes involved in,

or is threatened with, litigation with a subcontractor or vendor as a result of such direction by the contracting agency, the Contractor may request the United States to enter into such litigation to protect the interests of the United States.

19. OFFICIALS NOT TO BENEFIT

No member of or delegate to Congress, or resident Commissioner, shall be admitted to any share or part of this contract, or to any benefit that may arise therefrom; but this provision shall not be construed to extend to this contract if made with a corporation for its general benefit.

20. COVENANT AGAINST CONTINGENT FEES

The Contractor warrants that no person or selling agency has been employed or retained to solicit or secure this contract upon an agreement or understanding for a commission, percentage, brokerage, or contingent fee, excepting bona fide employees or bona fide established commercial or selling agencies maintained by the Contractor for the purpose of securing business. For breach or violation of this warranty the Government shall have the right to annul this contract without liability or in its discretion to deduct from the contract price or consideration, or otherwise recover, the full amount of such commission, percentage, brokerage, or contingent fee.

21. UTILIZATION OF SMALL BUSINESS CONCERNS

(a) It is the policy of the Government as declared by the Congress that a fair proportion of the purchases and contracts for supplies and services for the Government be placed with small business concerns.

(b) The Contractor agrees to accomplish the maximum amount of subcontracting to small business concerns that the Contractor finds to be consistent with the efficient performance of this contract.

22. UTILIZATION OF LABOR SURPLUS AREA CONCERNS

(a) It is the policy of the Government to award contracts to labor surplus area concerns that (1) have been certified by the Secretary of Labor (hereafter referred to as certified-eligible concerns with first or second preferences) regarding the employment of a proportionate number of disadvantaged individuals and have agreed to perform substantially (i) in or near sections of concentrated unemployment or underemployment or in persistent or substantial labor surplus areas or (ii) in other areas of the United States, respectively, or (2) are noncertified concerns which have agreed to perform substantially in persistent or substantial labor surplus areas, where this can be done consistent with the efficient performance of the contract and at prices no higher than are obtainable elsewhere. The Contractor agrees to use his best efforts to place his subcontracts in accordance with this policy.

(b) In complying with paragraph (a) of this clause and with paragraph (b) of the clause of this contract entitled "Utilization of Small Business Concerns" the Contractor in placing his subcontracts shall observe the following order of preference: (1) Certified-eligible concerns with a first preference which are also small business concerns; (2) other certified-eligible concerns with a first preference; (3) certified-eligible concerns with a second preference which are also small business concerns; (4) other certified-eligible concerns with a second preference; (5) persistent or substantial labor surplus area concerns which are also small business concerns; (6) other persistent or substantial labor surplus area concerns; and (7) small business concerns which are not labor surplus area concerns.

23. UTILIZATION OF MINORITY BUSINESS ENTERPRISES

(a) It is the policy of the Government that minority business enterprises shall have the maximum practicable opportunity to participate in the performance of Government contracts.

(b) The Contractor agrees to use his best efforts to carry out this policy in the award of his subcontracts to the fullest extent consistent with the efficient performance of this contract. As used in this contract, the term "minority business enterprise" means a business, at least 50 percent of which is owned by minority group members or, in case of publicly-owned businesses, at least 51 percent of the stock of which is owned by minority group members. For the purposes of this definition, minority group members are Negroes, Spanish-speaking American persons, American-Orientals, American-Indians, American-Eskimos, and American Aleuts. Contractors may rely on written representations by subcontractors regarding their status as minority business enterprises in lieu of an independent investigation.

24. PRICING OF ADJUSTMENTS

When costs are a factor in any determination of a contract price adjustment pursuant to the Changes clause or any other provision of this contract, such costs shall be in accordance with the contract cost principles and procedures in Part 1-15 of the Federal Procurement Regulations (41 CFR 1-15) or Section XV of the Armed Services Procurement Regulation, as applicable, which are in effect on the date of this contract.

25. PAYMENT OF INTEREST ON CONTRACTORS' CLAIMS

(a) If an appeal is filed by the Contractor from a final decision of the Contracting Officer under the Disputes clause of this contract, denying a claim arising under the contract, simple interest on the amount of the claim finally determined owed by the Government shall be payable to the Contractor. Such interest shall be at the rate determined by the Secretary of the Treasury pursuant to Public Law 92-41, 85 Stat. 97, from the date the Contractor furnishes to the Contracting Officer his written appeal under the Disputes clause of this contract, to the date of (1) a final judgment by a court of competent jurisdiction, or (2) mailing to the Contractor of a supplemental agreement for execution either confirming completed negotiations between the parties or carrying out a decision of a board of contract appeals.

(b) Notwithstanding (a), above, (1) interest shall be applied only from the date payment was due, if such date is later than the filing of appeal, and (2) interest shall not be paid for any period of time that the Contracting Officer determines the Contractor has unduly delayed in pursuing his remedies before a board of contract appeals or a court of competent jurisdiction.

Clause 21(a) SMALL BUSINESS SUBCONTRACTING PROGRAM

FPR 1-1.710-3(b)

(a) The Contractor agrees to establish and conduct a small business subcontracting program which will enable small business concerns to be considered fairly as subcontractors and suppliers under this contract. In this connection, the Contractor shall:

(1) Designate a liaison officer who will (i) maintain liaison with the Government on small business matters, (ii) supervise compliance with the Utilization of Small Business Concerns clause, and (iii) administer the Contractor's "Small Business Subcontracting Program."

(2) Provide adequate and timely consideration of the potentialities of small business concerns in all "make-or-buy" decisions.

(3) Assure that small business concerns will have an equitable opportunity to compete for subcontracts, particularly by arranging solicitations, time for the preparation of bids, quantities, specifications, and delivery schedules so as to facilitate the participation of small business concerns. Where the Contractor's lists of potential small business subcontractors are excessively long, reasonable effort shall be made to give all such small business concerns an opportunity to compete over a period of time.

(4) Maintain records showing (i) whether each prospective subcontractor is a small business concern, (ii) procedures which have been adopted to comply with the policies set forth in this clause, and (iii) with respect to the letting of any subcontract (including purchase orders) exceeding $10,000, information substantially as follows:

(A) Whether the award went to large or small business.

(B) Whether less than three or more than two small business firms were solicited.

(C) The reason for nonsolicitation of small business if such was the case.

(D) The reason for small business failure to receive the award if such was the case when small business was solicited.

The records maintained in accordance with (iii) above may be in such form as the Contractor may determine, and the information shall be summarized quarterly and submitted by the purchasing department of each individual plant or division to the Contractor's cognizant small business liaison officer. Such quarterly summaries will be considered to be management records only and need not be submitted routinely to the Government; however, records maintained pursuant to this clause will be kept available for review by the Government until the expiration of 1 year after the award of this contract, or for such longer period as may be required by any other clause of this contract or by applicable law or regulation.

(5) Notify the Contracting Officer before soliciting bids or quotations on any subcontract (including purchase orders) in excess of $10,000 if (i) no small business concern is to be solicited, and (ii) the Contracting Officer's consent to the subcontract (or ratification) is required by a "Subcontracts" clause in this contract. Such notice will state the Contractor's reasons for nonsolicitation of small business concerns, and will be given as early in the procurement cycle as possible so that the Contracting Officer may give SBA timely notice to permit SBA a reasonable period to suggest potentially qualified small business concerns through the Contracting Officer. In no case will the procurement action be held up when to do so would, in the Contractor's judgment, delay performance under the contract.

(6) Include the Utilization of Small Business Concerns clause in subcontracts which offer substantial small business subcontracting opportunities.

(7) Cooperate with the Contracting Officer in any studies and surveys of the Contractor's subcontracting procedures and practices that the Contracting Officer may from time to time conduct.

(8) Submit quarterly reports of subcontracting to small business concerns on either Optional Form 61, Small Business Subcontracting Program Quarterly Report of Participating Large Company on Subcontract Committments to Small Business Concerns, or such other form as may be specified in the contract. Except as otherwise provided in this contract, the reporting requirements of this subparagraph (8) do not apply to small business contractors, small business subcontractors, educational and nonprofit institutions, and contractors or subcontractors for standard commercial items.

(b) A "small business concern" is a concern that meets the pertinent criteria established by the Small Business Administration and set forth in § 1-701 of the Federal Procurement Regulations.

(c) The Contractor agrees that, in the event he fails to comply with his contractual obligations concerning the small business subcontracting program, this contract may be terminated, in whole or in part, for default.

(d) The Contractor further agrees to insert, in any subcontract hereunder which may exceed $500,000 and which contains the Utilization of Small Business Concerns clause, provisions which shall conform substantially to the language of this clause, including this paragraph (d), and to notify the Contracting Officer of the names of such subcontractors.

Listing of Employment Openings

(This clause is applicable pursuant to 41 CFR 50-250 if this contract is for $10,000 or more.)

(a) The Contractor agrees, in order to provide special emphasis to the employment of qualified disabled veterans and veterans of the Vietnam era, that all suitable employment openings of the contractor which exist at the time of the execution of this contract and those which occur during the performance of this contract, including those not generated by this contract and including those occurring at an establishment other than the one wherein the contract is being performed but excluding those of independently operated corporate affiliates, shall be offered for listing at an appropriate local office of the State employment service system wherein the opening occurs and to provide such reports to such local office regarding employment openings and hires as may be required: Provided, That if this contract is for less than $10,000 or if it is with a State or local government the reports set forth in paragraphs (c) and (d) are not required.

(b) Listing of employment openings with the employment service system pursuant to this clause shall be made at least concurrently with the use of any other recruitment service or effort and shall involve the normal obligations which attach to the placing of a bona fide job order, including the acceptance of referrals of veterans and nonveterans. This listing of employment openings does not require the hiring of any particular job applicant or from any particular group of job applicants, and nothing herein is intended to relieve the contractor from any requirements in any statutes, Executive orders, or regulations regarding nondiscrimination in employment.

(c) The reports required by paragraph (a) of this clause shall include, but not be limited to, periodic reports which shall be filed at least quarterly with the appropriate local office or, where the contractor has more than one establishment in a State, with the central office of the State employment service. Such reports shall indicate for each establishment (i) the number of individuals who were hired during the reporting period, (ii) the number of those hired who were disabled veterans, and (iii) the number of those hired who were nondisabled veterans of the Vietnam era. The contractor shall submit a report within 30 days after the end of each reporting period wherein any performance is made under this contract. The contractor shall maintain copies of the reports submitted until the expiration of 1 year after final payment under the contract, during which time they shall be made available, upon request, for examination by any authorized representatives of the Contracting Officer or of the Secretary of Labor.

(d) Whenever the contractor becomes contractually bound by the listing provisions of this clause, he shall advise the employment service system in each State wherein he has establishments of the name and location of each such establishment in the State. As long as the contractor is contractually bound to these provisions and has so advised the State employment system, there is no need to advise the State system of subsequent contracts. The contractor may advise the State system when it is no longer bound by this contract clause.

(e) This clause does not apply to the listing of employment openings which occur and are filed outside of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, and the Virgin Islands.

(f) This clause does not apply to openings which the contractor proposes to fill from within his own organization or to fill pursuant to a customary and traditional employer-union hiring arrangement. This exlusion does not apply to a particular opening once an employer decides to consider applicants outside of his own organization or employer-union arrangement for that opening.

(g) As used in this clause:

(1) "All suitable employment openings" includes, but is not limited to, openings which occur in the following job categories: Production and nonproduction; plant and office; laborers and mechanics; supervisory and nonsupervisory; technical; and executive, administrative, and professional openings which are compensated on a salary basis of less than $18,000 per year. The term includes full-time employment, temporary employment of more than 3 days' duration, and part-time employment. It does not include openings which the contractor proposes to fill from within his own organization or to fill pursuant to a customary and traditional employer-union hiring arrangement.

(2) "Appropriate office of the State employment service system" means the local office of the Federal-State national system of public employment offices with assigned responsibility for serving the area of the establishment where the employment opening is to be filled, including the District of Columbia, the Commonwealth of Puerto Rico, Guam, and the Virgin Islands.

(3) "Openings which the Contractor proposes to fill from within his own organization" means employment openings for which no consideration will be given to persons outside the contractor's own organization (including any affiliates, subsidiaries, and parent companies), and includes any openings which the contractor proposes to fill from regularly established "recall" or "rehire" lists.

(4) "Openings which the Contractor proposes to fill pursuant to a customary and traditional employer-union hiring arrangement" means employment openings for which no consideration will be given to persons outside of a special hiring arrangement, including openings which the contractor proposes to fill from union halls, which is part of the customary and traditional hiring relationship which exists between the Contractor and representative of his employees.

(5) "Disabled veteran" means a person entitled to disability compensation under laws administered by the Veterans Administration for a disability rated at 30 percentum or more, or a person whose discharge or release from active duty was for a disability incurred or aggravated in line of duty.

(6) "Veteran of the Vietnam era" means a person (a) who (i) served on active duty with the Armed Forces for a period of more than 180 days, any part of which occurred after August 5, 1964, and was discharged or released therefrom with other than a dishonorable discharge, or (ii) was discharged or released from active duty for service-connected disability if any part of such duty was performed after August 5, 1964, and (b) who was so discharged or released within the 48 months preceding his application for employment covered by this clause.

(h) If any disabled veteran or veteran of the Vietnam era believes that the contractor (or any first-tier subcontractor) has failed or refuses to comply with the provisions of this contract clause relating to giving special emphasis in employment to veterans, such veteran may file a complaint with the veterans' employment representative at a local State employment service office who will attempt to informally resolve the complaint and then refer the complaint with a report on the attempt to resolve the matter to the State office of the Veterans' Employment Service of the Department of Labor. Such complaint shall then be promptly referred through the Regional Manpower Administrator to the Secretary of Labor who shall investigate such complaint and shall take such action thereon as the facts and circumstances warrant consistent with the terms of this contract and the laws and regulations applicable thereto.

(i) The contractor agrees to place this clause (excluding this paragraph (i)) in any subcontract directly under this contract.

LABOR SURPLUS AREA SUBCONTRACTING PROGRAM

FPR 1-1.805-3(b)

(This clause is applicable if this contract exceeds $500,000.00)

(a) The Contractor agrees to establish and conduct a program which will encourage labor surplus area concerns to compete for subcontracts within their capabilities. In this connection, the Contractor shall:

(1) Designate a liaison officer who will (i) maintain liaison with duly authorized representatives of the Government on labor surplus area matters, (ii) supervise compliance with the Utilization of Concerns in Labor Surplus Areas clause, and (iii) administer the Contractor's "Labor Surplus Area Subcontracting Program";

(2) Provide adequate and timely consideration of the potentialities of labor surplus area concerns in all "make-or-buy" decisions;

(3) Assure that labor surplus area concerns will have an equitable opportunity to compete for subcontracts, particularly by arranging solicitations, time for the preparation of bids, quantities, specifications, and delivery schedules so as to facilitate the participation of labor surplus area concerns;

(4) Maintain records showing procedures which have been adopted to comply with the policies set forth in this clause. Records maintained pursuant to this clause will be kept available for review by the Government until the expiration of 1 year after the award of this contract, or for such longer period as may be required by any other clause of this contract or by applicable law or regulations; and

(5) Include the Utilization of Concerns in Labor Surplus Areas clause in subcontracts which offer substantial labor surplus area subcontracting opportunities.

(b) A "labor surplus area concern" is a concern that (1) has been certified by the Secretary of Labor (hereafter referred to as a certified-eligible concern) regarding the employment of a proportionate number of disadvantaged individuals and has agreed to perform substantially in or near sections of concentrated unemployment or underemployment, in persistent or substantial labor surplus

areas, or in other areas of the United States or (2) is a noncertified concern which has agreed to perform a substantial proportion of a contract in persistent or substantial labor surplus areas. A certified-eligible concern shall be deemed to have performed a substantial proportion of a contract in or near sections of concentrated unemployment or underemployment, in persistent or substantial labor surplus areas, or in other areas if the costs that the concern will incur on account of manufacturing or production in or near such sections or in such areas (by itself, if a certified concern, or by certified concerns acting as first-tier subcontractors) amount to more than 25 percent of the contract price. A concern shall be deemed to have performed a substantial proportion of a contract in persistent of substantial surplus areas (by itself or its first-tier subcontractors) if the costs that the concern will incur on account of production or manufacturing in such areas amount to more than 50 percent of the contract price.

(c) The Contractor further agrees to insert, in any subcontract hereunder which may exceed $500,000 and which contains the Utilization of Concerns in Labor Surplus Areas clause, provisions which shall conform substantially to the language of this clause, including this paragraph (c), and to notify the Contracting Officer of the names of such subcontractors.

MINORITY BUSINESS ENTERPRISES SUBCONTRACTING PROGRAM

FPR 1-1.1310-2(b)

(This clause is applicable if this contract exceeds $500,000.00.)

(a) The Contractor agrees to establish and conduct a program which will enable minority business enterprises (as defined in the clause entitled "Utilization of Minority Business Enterprises") to be considered fairly as subcontractors and suppliers under this contract. In this connection, the Contractor shall:

(1) Designate a liaison officer who will administer the Contractor's minority business enterprises program.

(2) Provide adequate and timely consideration of the potentialities of known minority business enterprises in all "make-or-buy" decisions.

(3) Assure that known minority business enterprises will have an equitable opportunity to compete for subcontracts, particularly by arranging solicitations, time for the preparation of bids, quantities, specifications, and delivery schedules so as to facilitate the participation of minority business enterprises.

(4) Maintain records showing (i) procedures which have been adopted to comply with the policies set forth in this clause, including the establishment of a source list of minority business enterprises on the source list, and (iii) specific efforts to identify and award contracts to minority business enterprises.

(5) Include the Utilization of Minority Business Enterprises clause in subcontracts which offer substantial minority business enterprises subcontracting opportunities.

(6) Cooperate with the Contracting Officer in any studies and surveys of the Contractor's minority business enterprises procedures and practices that the Contracting Officer may from time to time conduct.

(7) Submit periodic reports of subcontracting to known minority business enterprises with respect to the records referred to in subparagraph (4), above, in such form and manner and at such time (not more often than quarterly) as the Contracting Officer may prescribe.

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(b) The Contractor further agrees to insert, in any subcontract hereunder which may exceed $500,000, provisions which shall conform substantially to the language of this clause, including this paragraph (b), and to notify the Contracting Officer of the names of such subcontractors.

ALTERATION TO SF-32, General Provisions

UNSOLICITED SAMPLES, DESCRIPTIVE LITERATURE, OR BRAND NAME REFERENCES:

Where procurement is effected under specifications or purchase descriptions (other than "brand name or equal") and the Government does not specifically request bid samples, descriptive literature, or references to brand names, models, or part numbers as an integral part of the bid, bids which are accompanied by any of the foregoing will be rejected unless it is clear from the bid or accompanying papers that the samples, descriptive literature, or references to brand names, models, or part numbers are not intended to qualify the bid and that the bidder proposes to furnish items fully in accordance with the specifications or purchase descriptions. Where offers contain unsolicited material such as samples, descriptive literature, or references to brand names, models, or part numbers, the Government will not be responsible in any way for determining whether the items which are offered meet the Government's requirements set forth in the applicable specifications or purchase descriptions.

EXAMINATION OF RECORDS BY DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE:
(Applicable to negotiated contracts only.)

The provisions of the clause included herein, entitled "Examination of Records by the Comptroller General," are extended to provide equal rights to duly authorized representatives of the Secretary or of the Contracting Officer.

ALTERATIONS TO SF-32, GENERAL PROVISIONS (Supply Contract)

(See Federal Procurement Regulations, Subpart 1-11.4 Regarding Use.)

FEDERAL, STATE AND LOCAL TAXES

(a) Except as may be otherwise provided in this contract, the contract price includes all applicable Federal, State, and local taxes and duties.

(b) Nevertheless, with respect to any Federal excise tax or duty on the transactions or property covered by this contract, if a statute, court decision, written ruling, or regulation takes effect after the contract date, and—

(1) Results in the Contractor being required to pay or bear the burden of any such Federal excise tax or duty or increase in the rate thereof which would not otherwise have been payable on such transactions or property, the contract price shall be increased by the amount of such tax or duty or rate increase: *Provided*, That the Contractor if requested by the Contracting Officer, warrants in writing that no amount for such newly imposed Federal excise tax or duty or rate increase was included in the contract price as a contingency reserve or otherwise; or

(2) Results in the Contractor not being required to pay or bear the burden of, or in his obtaining a refund or drawback of, any such Federal excise tax or duty which would otherwise have been payable on such transactions or property or which was the basis of an increase in the contract price, the contract price shall be decreased by the amount of the relief, refund, or drawback, or that amount shall be paid to Government, as directed by the Contracting Officer. The contract price shall be similarly decreased if the Contractor, through his fault or negligence or his failure to follow instructions of the Contracting Officer, is required to pay or bear the burden of, or does not obtain a refund or drawback of, any such Federal excise tax or duty.

(c) No adjustment pursuant to paragraph (b) above will be made under this contract unless the aggregate amount thereof is or may reasonably be expected to be over $100.

(d) As used in paragraph (b) above, the term "contract date" means the date set for the bid opening, or if this is a negotiated contract, the date of this contract. As to additional supplies or services procured by modification to this contract, the term "contract date" means the date of such modification.

(e) Unless there does not exist any reasonable basis to sustain an exemption, the Government, upon request of the Contractor, without further liability, agrees, except as otherwise provided in this contract, to furnish evidence appropriate to establish exemption from any tax which the Contractor warrants in writing was excluded from the contract price. In addition, the Contracting Officer may furnish evidence to establish exemption from any tax that may, pursuant to this clause, give rise to either an increase or decrease in the contract price. Except as otherwise provided in this contract, evidence appropriate to establish exemption from duties will be furnished only at the direction of the Contracting Officer.

(f) The Contractor shall promptly notify the Contracting Officer of matters which will result in either an increase or decrease in the contract price, and shall take action with respect thereto as directed by the Contracting Officer.

ALTERATION TO SF-32, GENERAL PROVISIONS

EMPLOYMENT OF THE HANDICAPPED

(a) The contractor will not discriminate against any employee or applicant for employment because of physical or mental handicap in regard to any position for which the employee or applicant for employment is qualified. The contractor agrees to take affirmative action to employ, advance in employment and otherwise treat qualified handicapped individuals without discrimination based upon their physicial or mental handicap in all employment practices such as the following: employment, upgrading, demotion or transfer, recruitment, advertising, layoff or termination, rates of pay or other forms of compensation, and selection for training, including apprenticeship.

(b) The contractor agrees to comply with the rules, regulations, and relevant orders of the Secretary of Labor issued pursuant to the Act.

(c) In the event of the contractor's noncompliance with the requirements of this clause, actions for noncompliance may be taken in accordance with the rules, regulations and relevant orders of the Secretary of Labor issued pursuant to the Act.

(d) The contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices in a form to be prescribed by the Director, provided by or through the Contracting Officer. Such notices shall state the contractor's obligation under the law to take affirmative action to employ and advance in employment qualified handicapped employees and applicants for employment, and the rights of applicants and employees.

(e) The contractor will notify each labor union or representative of workers with which it has a collective bargaining agreement or other contract understanding, that the contractor is bound by the terms of section 503 of the Rehabilitation Act of 1973, and is committed to take affirmative action to employ and advance in employment physically and mentally handicapped individuals.

(f) The contractor will include the provisions of this clause in every subcontract or purchase order of $2,500 or more unless exempted by rules, regulations, or orders of the Secretary issued pursuant to section 503 of the Act, so that such provisions will be binding upon each subcontractor or vendor. The contractor will take such action with respect to any subcontract or purchase order as the Director of the Office of Federal Contract Compliance Programs may direct to enforce such provisions, including action for noncompliance.

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TERMINATION FOR CONVENIENCE
OF THE GOVERNMENT

(a) The performance of work under this contract may be terminated by the Government in accordance with this clause in whole, or from time to time in part, whenever the Contracting Officer shall determine that such termination is in the best interest of the Government. Any such termination shall be effected by delivery to the Contractor of a Notice of Termination specifying the extent to which performance of work under the contract is terminated, and the dates upon which such termination becomes effective.

(b) After receipt of a Notice of Termination, and except as otherwise directed by the Contracting Officer, the Contractor shall:

(1) Stop work under the contract on the date and to the extent specified in the Notice of Termination;

(2) Place no further orders or subcontracts for materials, services, or facilities, except as may be necessary for completion of such portion of the work under the contract as is not terminated;

(3) Terminate all orders and subcontracts to the extent that they relate to the performance of work terminated by the Notice of Termination;

(4) Assign to the Government, in the manner, at the times, and to the extent directed by the Contracting Officer, all of the right, title, and interest of the Contractor under the orders and subcontracts so terminated, in which case the Government shall have the right, in its discretion, to settle or pay any or all claims arising out of the termination of such orders and subcontracts;

(5) Settle all outstanding liabilities and all claims arising out of such termination of orders and subcontracts, with the approval or ratification of the Contracting Officer, to the extent he may require, which approval or ratification shall be final for all the purposes of this clause;

(6) Transfer title to the Government and deliver in the manner, at the times, and to the extent, if any, directed by the Contracting Officer, (i) the fabricated or unfabricated parts, work in process, completed work, supplies, and other material produced as a part of, or acquired in connection with the performance of, the work terminated by the Notice of Termination, and (ii) the completed or partially completed plans, drawings, information and other property which, if the contract had been completed, would have been required to be furnished to the Government;

(7) Use his best efforts to sell, in the manner, at the times, to the extent, and at the price or prices directed or authorized by the Contracting Officer, any property of the types referred to in (6) above: Provided, however, that the Contractor (i) shall not be required to extend credit to any purchaser, and (ii) may acquire any such property under the conditions prescribed by and at a price or prices approved by the Contracting Officer: And provided further, that the proceeds of any such transfer or disposition shall be applied in reduction of any payments to be made by the Government to the Contractor under this contract or shall otherwise be credited to the price or cost of the work covered by this contract or paid in such other manner as the Contracting Officer may direct;

(8) Complete performance of such part of the work as shall not have been terminated by the Notice of Termination; and

(9) Take such action as may be necessary, or as the Contracting Officer may direct, for the protection and preservation of the property related to this contract which is in the possession of the Contractor and in which the Government has or may acquire an interest.

At any time after expiration of the plant clearance period, as defined in Subpart 1-8.1 of the Federal Procurement Regulations (41 CFR 1-8.1), as the definition may be amended from time to time, the Contractor may submit to the Contracting Officer a list, certified as to quantity and quality, of any or all items of termination inventory not previously disposed of, exclusive of items the disposition of which has been directed or authorized by the Contracting Officer, and may request the Government to remove such items or enter into a storage agreement covering them. Not later than fifteen (15) days thereafter, the Government will accept title to such items and remove them or enter into a storage agreement covering the same: Provided, that the list submitted shall be subject to verification by the Contracting Officer upon removal of the items or, if the items are stored, within forty-five (45) days from the date of submission of the list, and any necessary adjustment to correct the list as submitted shall be made prior to final settlement.

(c) After receipt of a Notice of Termination, the Contractor shall submit to the Contracting Officer his termination claim, in the form and with certification prescribed by the Contracting Officer. Such claim shall be submitted promptly but in no event later than one year from the effective date of termination, unless one or more extensions in writing are granted by the Contracting Officer upon request of the Contractor made in writing within such one-year period or authorized extensiton thereof. However, if the Contracting Officer determines that the facts justify such action, he may receive and act upon any such termination claim at any time after such one-year period or any extension thereof. Upon failure of the Contractor to submit his termination claim within the time allowed, the Contracting Officer may, subject to any review

required by the contracting agency's procedures in effect as of the date of execution of this contract, determine, on the basis of information available to him, the amount, if any, due to the Contractor by reason of the termination and shall thereupon pay to the Contractor the amount so determined.

(d) Subject to the provisions of paragraph (c), and subject to any review required by the contracting agency's procedures in effect as of the date of execution of this contract, the Contractor and the Contracting Officer may agree upon the whole or any part of the amount or amount to be paid to the Contractor by reason of the total or partial termination of work pursuant to this clause, which amount or amounts may include a reasonable allowance for profit on work done: Provided, that such agreed amount or amounts, exclusive of settlement costs, shall not exceed the total contract price as reduced by the amount of payments otherwise made and as further reduced by the contract price of work not terminated. The contract shall be amended accordingly, and the Contractor shall be paid the agreed amount. Nothing in paragraph (e) of this clause, prescribing the amount to be paid to the Contractor in the event of failure of the Contractor and the Contracting Officer to agree upon the whole amount to be paid to the Contractor by reason of the termination of work pursuant to this clause, shall be deemed to limit, restrict, or otherwise determine or affect the amount or amounts which may be agreed upon to be paid to the Contractor pursuant to this paragraph (d).

(e) In the event of the failure of the Contractor and the Contracting Officer to agree as provided in paragraph (d) upon the whole amount to be paid to the Contractor by reason of the termination of work pursuant to this clause, the Contracting Officer shall, subject to any review required by the contracting agency's procedures in effect as of the date of execution of this contract, determine, on the basis of information available to him, the amount, if any, due to the Contractor by reason of the termination and shall pay to the Contractor the amounts determined as follows:

(1) For completed supplies accepted by the Government (or sold or acquired as provided in paragraph (b)(7) above) and not theretofore paid for, a sum equivalent to the aggregate price for such supplies computed in accordance with the price or prices specified in the contract, appropriately adjusted for any saving of freight or other charges;

(2) The total of --

(i) The costs incurred in the performance of the work terminated, including initial costs and preparatory expense allocable thereto, but exclusive of any costs attributable to supplies paid or to be paid for under paragraph (e)(1) hereof;

(ii) The cost of settling and paying claims arising out of the termination of work under subcontracts or orders, as provided in paragraph (b)(5) above, which are properly chargeable to the terminated portion of the contract (exclusive of amounts paid or payable on account of supplies or materials delivered or services furnished by subcontractors or vendors prior to the effective date of the Notice of Termination, which amounts shall be included in the costs payable under (i) above); and

(iii) A sum, as a profit, equal to 2 percent of that part of the amout determined under (i) above which represents the cost of articles and materials not processed by the Contractor, plus a sum equal to 8 percent of the remainder of such amount, but the aggregate of such sums shall not exceed 6 percent of the whole of the amount determined under (i) above: Provided, however, that if it appears that the Contractor would have sustained a loss on the entire contract had it been completed, no profit shall be included or allowed under this subdivision (iii) and an appropriate adjustment shall be made reducing the amount of the settlement to reflect the indicated rate of loss; and

(3) The reasonable costs of settlement, including accounting, legal, clerical, and other expenses reasonably necessary for the preparation of settlement claims and supporting data with respect to the terminated portion of the contract and for the termination and settlement of subcontracts thereunder, together with reasonable storage, transportation, and other costs incurred in connection with the protection or disposition of property allocable to this contract.

The total sum to be paid to the Contractor under (1) and (2) of this paragraph (e) shall not exceed the total contract price as reduced by the amount of payments otherwise made and as further reduced by the contract price of work not terminated. Except for normal spoilage, and except to the extent that the Government shall have otherwise expressly assumed the risk of loss, there shall be excluded from the amounts payable to the Contractor as provided in (e)(1) and (2)(i) above, the fair value, as determined by the Contracting Officer, of property which is destroyed, lost, stolen, or damaged so as to become undeliverable to the Government, or to a buyer pursuant to paragraph (b)(7).

(f) Costs claimed, agreed to, or determined pursuant to paragraphs (c), (d), and (e) of this clause shall be in accordance with the contract cost principles and procedures in Part 1-15 of the Federal Procurement Regulations (41 CFR 1-15) in effect on the date of this contract.

(g) The Contractor shall have the right to appeal, under the clause of this contract entitled "Disputes," from any determination made by the Contracting Officer under paragraph (c) or (e) above, except that, if the Contractor has failed to submit his claim within the time provided in paragraph (c) above and has failed to request extension of such time, he shall have no such right of appeal. In any case where the Contracting Officer has made a determination of the amount due under paragraph (c) or (e) above, the Government shall pay to the Contractor the following: (1) if there is no right of appeal hereunder or if no timely appeal has been taken, the amount so determined by the Contracting Officer; or (2) if an appeal has been taken, the amount finally determined on such appeal.

(h) In arriving at the amount due the Contractor under this clause there shall be deducted (1) all unliquidated advance or other payments on account theretofore made to the Contractor, applicable to the terminated portion of this contract; (2) any claim which the Government may have against the Contractor in connection with this contract; and (3) the agreed price for, or the proceeds of sale of, any materials, supplies, or other things acquired by the Contractor or sold, pursuant to the provisions of this clause, and not otherwise recovered by or credited to the Government.

(i) If the termination hereunder be partial, prior to the settlement of the terminated portion of this contract, the Contractor may file with the Contracting Officer a request in writing for an equitable adjustment of the price or prices specified in the contract relating to the continued portion of the contract (the portion not terminated by the Notice of Termination), and such equitable adjustment as may be agreed upon shall be made in such price or prices.

(j) The Government may from time to time, under such terms and conditions as it may prescribe, make partial payments and payments on account against costs incurred by the Contractor in connection with the terminated portion of this contract whenever in the opinion of the Contracting Officer the aggregate of such payments shall be within the amount to which the Contractor will be entitled hereunder. If the total of such payments is in excess of the amount finally agreed or determined to be due under this clause, such excess shall be payable by the Contractor to the Government upon demand, together with interest computed at the rate of 6 percent per annum for the period from the date such excess payment is received by the Contractor to the date on which such excess is repaid to the Government: Provided, however, that no interest shall be charged with respect to any such excess payment attributable to a reduction in the Contractor's claim by reason of retention or other disposition of termination inventory until ten days after the date of such retention or disposition, or such later date as determined by the Contracting Officer by reason of the circumstances.

(k) Unless otherwise provided for in this contract, or by applicable statute, the Contractor, from the effective date of termination and for a period of three years after final settlement under this contract, shall

preserve and make available to the Government at all reasonable times at the office of the Contractor but without direct charge to the Government, all his books, records, documents, and other evidence bearing on the costs and expenses of the Contractor under this contract and relating to the work terminated hereunder, or, to the extent approved by the Contracting Officer, photographs, microphotographs, or other authentic reproductions thereof.

PRICE REDUCTION FOR DEFECTIVE COST OR PRICING DATA (FPR 1-3.814-1(a))

If any price, including profit or fee, negotiated in connection with this contract or any cost reimbursable under this contract was increased by any significant sums because:

(a) The Contractor furnished cost or pricing data which was not accurate, complete and current as certified in the Contractor's Certificate of Current Cost or Pricing Data;

(b) A subcontractor, pursuant to the clause of this contract entitled "Subcontractor Cost or Pricing Data" or "Subcontractor Cost or Pricing Data -Price Adjustments" or any subcontract clause therein required, furnished cost of pricing data which was not accurate, complete and current as certified in the subcontractor's Certificate of Current Cost or Pricing Data;

(c) A subcontractor or prospective subcontractor furnished cost of pricing data which was required to be accurate, complete and current and to be submitted to support a subcontract cost estimate furnished by the Contractor but which was not accurate, complete and current as of the date certified in the Contractor's Certificate of Current Cost or Pricing Data; or

(d) The Contractor or a subcontractor or prospective subcontractor furnished any data, not within (a), (b), or (c) above, which was not accurate as submitted; the price or cost shall be reduced accordingly and the contract shall be modified in writing as may be necessary to reflect such reduction. However, any reduction in the contract price due to defective subcontract data of a prospective subcontractor when the subcontract was not subsequently awarded to such subcontractor, will be limited to the amount (plus applicable overhead and profit markup) by which the actual subcontract, or actual cost to the Contractor if there was no subcontract, was less than the prospective subcontract cost estimate submitted by the Contractor: PROVIDED, The actual subcontract price was not affected by defective cost or pricing data.

(NOTE: Since the contract is subject to reduction under this clause by reason of defective cost or pricing data submitted in connection with certain subcontracts, it is expected that the Contractor may wish to include a clause in each such subcontract requiring the subcontractor to appropriately indemnify the Contractor. It is also expected that any subcontractor subject to such indemnification will generally require substantially similar indemnification for defective cost or pricing data required to be submitted by his lower tier subcontractors.)

SUBCONTRACTOR COST OR PRICING DATA (FPR 1-3.814-3)

(a) The Contractor shall require subcontractors hereunder to submit, actually or by specific indentification in writing, cost or pricing data under the following circumstances:

(1) Prior to the award of any subcontract the amount of which is expected to exceed $100,000 when entered into;

(2) Prior to the pricing of any subcontract modification which involves aggregate increases and/or decreases in costs plus applicable profits expected to exceed $100,000; except where the price is based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation.

(b) The Contractor shall require subcontractors to certify, in substantially the same form as that used in the certificate by the Prime Contractor to the Government, that to the best of their knowledge and belief, the cost and pricing data submited under (a) above is accurate, complete, and current as of the date of agreement on the negotiated price of the subcontract or subcontract change or modification.

(c) The Contractor shall insert the substance of this clause including this paragraph (c) in each subcontract hereunder which exceeds $100,000 when entered into except where the price thereof is based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation. In each such excepted subcontract hereunder in excess of $100,000, the Contractor shall insert the substances of the following clause:

SUBCONTRACTOR COST OR PRICING DATA -
PRICE ADJUSTMENTS

(a) Paragraphs (b) and (c) of this clause shall become operative only with respect to any modification made pursuant to one or more provisions of this contract which involves aggregate increases and/or decreases in costs plus applicable profits expected to exceed $100,000. The requirements of this clause shall be limited to such contract modifications.

(b) The Contractor shall require subcontractors hereunder to submit, actually or by specific identification in writing, cost or pricing data under the following circumstances.

(1) Prior to award of any subcontract, the amount of which is expected to exceed $100,000 when entered into;

(2) Prior to the pricing of any subcontract modification which involves aggregate increases and/or decreases in costs plus applicable profits expected to exceed $100,000; except where the price is based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation.

(c) The Contractor shall require subcontractors to certify, in substantially the same form as that used in the certificate by the Prime Contractor to the Government, that to the best of their knowledge and belief the cost and pricing data submitted under (b) above is accurate, complete, and current as of the date of agreement on the negotiated price of the subcontract or subcontract change or modification."

(d) The Contractor shall insert the substance of this clause including this paragraph (d) in each subcontract hereunder which exceeds $100,000 when entered into.

ALTERATIONS (Continued)

AUDIT (FPR 1-3.814-2)

(a) GENERAL. The Contracting Officer or his representatives shall have the audit and inspection rights described in the applicable paragraphs (b), (c), and (d) below.

(b) EXAMINATION OF COSTS: If this is a cost-reimbursement type, incentive, time and materials, labor hour, or price redeterminable contract, or any combination thereof, the Contractor shall maintain, and the Contracting Officer or his represetnatives shall have the right to examine books, records, documents, and other evidence and accounting procedures and practices, sufficient to reflect properly all direct and indirect costs of whatever nature claimed to have been incurred and anticipated to be incurred for the performance of this contract. Such right of examination shall include inspection at all reasonable times of the Contractor's plants, or such parts thereof, as may be engaged in the performance of this contract.

(c) COST OR PRICING DATA. If the Contractor submitted cost or pricing data in connection with the pricing of this contract or any change or modification thereto, unless such pricing was based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation, the Contracting Officer or his representatives who are employees of the United States Government shall have the right to examine all books, records, documents and other data of the Contractor related to the negotiation, pricing or performance of such contract, change or modification, for the purpose of evaluating the accuracy, completeness and currency of the cost or pricing data submitted. Additionally, in the case of pricing any change or modification exceeding $100,000 to formally advertised contracts, the Comptroller General of the United States or his representatives who are employees of the United States Government shall have such rights. The right of examination shall extend to all documents necessary to permit adequate evaluation of the cost or pricing data submitted, along with the computations and projections used therein.

(d) AVAILABILITY. The materials described in (b) and (c) above, shall be made available at the office of the Contractor, at all reasonable times, for inspection, audit or reproduction, until the expiration of 3 years from the date of final payment under this contract or such lesser time specified in Part 1-20 of the Federal Procurement Regulations (41 CFR Part 1-20) and for such longer period, if any, as is required by applicable statute, or by other clauses of this contract, or by (1) and (2) below:

(1) If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for a period of 3 years from the date of any resulting final settlement.

(2) Records which relate to appeals under the "Disputes" clause of this contract, or litigation or the settlement of claims arising out of the performance of this contract, shall be made available until such appeals, litigation, or claims have been disposed of.

(e) The Contractor shall insert a clause containing all the provisions of this clause, including this paragraph (e), in all subcontracts hereunder except altered as necessary for proper identification of the contracting parties and the Contracting Officer under the Government prime contract.

July 1974

ACCOUNTS, AUDITS, AND RECORDS

(a) The Contractor shall maintain books, records, documents, and other evidence, accounting procedures and practices sufficient to reflect properly all direct and indirect costs of whatever nature claimed to have been incurred for the performance of this contract. The foregoing constitutes "records" for the purpose of this clause.

(b) The Contractor's facility(ies) or such part thereof as may be engaged in the performance of this contract, and his records shall be subject at all reasonable time to inspection and audit by the Secretary or his authorized representatives.

(c) The Contractor shall preserve and make available his records (1) until the expiration of 3 years from the date of final payment under this contract, or the time periods for particular records specified in 41 CFR Part 1-20, whichever expires earlier, and (2) for such longer period, if any, as is required by applicable statute, or by other clauses of this contract, or by (i) or (ii) below:

(i) If this contract is completely or partially terminated, the records relating to the work terminated shall be preserved and made available for a period of 3 years from the date of any resulting final payment.

(ii) Records which relate to (A) appeals under the "Disputes" clause of this contract, (B) litigation or the settlement of claims arising out of the performance of this contract, or (C) costs and expenses of this contract to which exception has been taken by the Contracting Officer or any of his duly authorized representatives, shall be retained until such appeals, litigation, claims, or exceptions have been disposed of.

(d) The Contractor shall insert the substance of this clause, including this paragraph (d) in each subcontract hereunder with the exceptions of (1) purchase orders not exceeding $2,500 and (2) subcontracts or purchase orders for public utility services at rates established for uniform applicability to the general public. When so inserted, changes shall be made to designate the higher-tier subcontractor at this level involved in place of the Contractor; to add "of the Government prime contract," in place of "this contract" in (B) of subparagraph (c)(ii) above.

FPR 1-3.1203(2)(iv)
11/74

DISCLOSURE STATEMENT

COST ACCOUNTING PRACTICES AND CERTIFICATION

Any contract in excess of $100,000 resulting from this solicitation except (1) when the price negotiated is based on (a) established catalog or market prices of commercial items sold in substantial quantities to the general public, or (b) prices set by law or regulation, or (2) contracts which are otherwise exempt (see 4 CFR 331.30(b) and FPR § 1-3.1203(a)(2), shall be subject to the requirements of the Cost Accounting Standards Board. Any offeror submitting a proposal, which, if accepted, will result in a contract subject to the requirements of the Cost Accounting Standards Board must, as a condition of contracting, submit a Disclosure Statement as required by regulations of the Board. The Disclosure Statement must be submitted as a part of the offeror's proposal under this solicitation (see (i) below) unless (i) the offeror, together with all divisions, subsidiaries, and affiliates under common control, did not receive net awards of negotiated national defense prime contracts totaling more than $30,000,000 in Federal Fiscal Year 1971 or net awards of negotiated national defense prime contracts of the type (as defined in the first sentence above) which are subject to Cost Accounting Standards totaling more than $10,000,000 in either Federal Fiscal Year 1972 or 1973 (see (II) below), (ii) the offeror has alread submitted a Disclosure Statement disclosing the practices used in connection with the pricing of this proposal (see (III) below), or (iii) post award submission has been authorized by the Contracting Officer. See 4 CFR 351.70 for submission of a copy of the Disclosure Statement to the Cost Accounting Standards Board.

CAUTION: A practice disclosed in a Disclosure Statement shall not, by virtue of such disclosure, be deemed to be a proper, approved, or agreed to practice for pricing proposals or accumulating and reporting contract performance cost data.

Check the appropriate box below:

( ) 1. CERTIFICATE OF CONCURRENT SUBMISSION OF DISCLOSURE STATEMENT(S)

The offeror hereby certifies that he has submitted, as a part of his proposal under this solicitation, copies of the Disclosure Statement(s) as follows: (i) Original and one copy to the cognizant Contracting Officer; (ii) one copy to the cognizant contract auditor.

Date of Disclosure Statement(s): Name(s) and address(es) of Cognizant Contracting Officer(s) where filed:

98-930 O - 78 -- 19

The offeror further certifies that practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the Disclosure Statement(s).

( ) 2. CERTIFICATION OF MONETARY EXEMPTION

The offeror hereby certifies that, together with all divisions, subsidiaries, and affiliates under common control, he did not receive net award of negotiated national defense prime contracts totaling more than $30 million in Federal Fiscal Year 1971 or net awards of negotiated national defense prime contracts of the type which are subject to Cost Accounting Standards more than $10,000,000 in either Federal Fiscal Year 1972 or 1973.

( ) 3. CERTIFICATE OF PREVIOUSLY SUBMITTED DISCLOSURE STATEMENT(S)

The offeror hereby certifies that the Disclosure Statement(s) were filed as follows:

Date of Disclosure Statement(s):	Name(s) and address(es) of Cognizant Contracting Officer(s) where filed:

The offeror further certifies that practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the Disclosure Statement(s).

COST ACCOUNTING STANDARDS

FPR 1-3.1204

(a) Unless the Cost Accounting Standards Board, or the General Services Administration in the case of nondefense contracts, has prescribed rules or regulation exempting the Contractor or this contract from standards, rules, and regulations promulgated pursuant to 50 U.S.C. App. 2168 (P.L. 91-379, August 15, 1970), or other statutory authority, the Contractor, in connection with this contract, shall:

(1) By submission of a Disclosure Statement, disclose in writing his cost accounting practices as required by regulations of the Cost Accounting Standards Board. The required disclosures must be made prior to contract award unless the Contracting Officer provides a written notice to the Contractor authorizing postaward submission in accordance with regulations of the Cost Accounting Standards Board. The practices disclosed for this contract shall be the same as the practices currently disclosed and applied on all other contract and subcontracts being performed by the Contractor and which contain this Cost Accounting Standards clause. If the Contractor has notified the Contracting Officer that the Disclosure Statement contains trade secrets and commercial or financial information which is privileged and confidential, the Disclosure Statement will not be released outside of the Government.

(2) Follow consistently the cost accounting practices disclosed pursuant to (1), above in accumulating and reporting contract performance cost data concerning this contract. If any change in disclosed practices is made for purposes of any contract or subcontract subject to Cost Accounting Standards Board requirements, the change must be applied prospectively to this contract, and the Disclosure Statement must be amended accordingly. If the contract price or cost allowance of this contract is affected by such changes, adjustment shall be made in accordance with subparagraph (a)(4) or (a)(5), below, as appropriate.

(3) Comply with all Cost Accounting Standards in effect on the date of award of this contract or if the Contractor has submitted cost or pricing data, on the date of final agreement on price as shown on the Contractor's signed certificate of current cost or pricing data. The Contractor shall also comply with any Cost Accounting Standard which hereafter becomes applicable to a contract or subcontract of the Contractor. Such compliance shall be required prospectively from the date of applicability to such contract or subcontract.

(4)(A) Agree to an equitable adjustment (as provided in the Changes clause of this contract, if any) if the contract cost is affected by a change which, purusant to (3) above, the Contractor is required to make to his established cost accounting practices whether such practices are covered by a Disclosure Statement or not.

(B) Negotiate with the Contracting Officer to determine the terms and conditions under which a change to either a disclosed cost accounting practice or an established cost accounting practice, other than a change under (4)(A), above, may be made. A change to a practice may be proposed by either the Government or the Contractor, provided, however, that no agreement may be made under this provision that will increase costs paid by the United States.

(5) Agree to an adjustment of the contract price or cost allowance, as appropriate, if he or a subcontractor fails to comply with an applicable Cost Accounting Standard or to follow any practice disclosed pursuant to subparagraphs (a)(1) and (a)(2), above, and such failure results in any increased costs paid by the United States. Such adjustment shall provide for recovery of the increased costs to the United States together with interest thereon computed at the rate determined by the Secretary of the Treasury pursuant to P.L. 92-41, 85 Stat. 97, or 7 percent per annum, whichever is less, from the time the payment by the United States was made to the time the adjustment is effected.

(b) If the parties fail to agree whether the Contractor or a subcontractor has complied with an applicable Cost Accounting Standard, rule, or regulation of the Cost Accounting Standards Board and as to any cost adjustment demanded by the United States, such failure to agree shall be a dispute concerning a question of fact within the meaning of the Disputes clause of this contract.

(c) The Contractor shall permit any authorized representatives of the head of the agency, of the Cost Accounting Standards Board, or of the Comptroller General of the United States to examine and make copies of any documents, papers, or records relating to compliance with the requirements of this clause.

(d) The Contractor shall include in all negotiated subcontracts which he enters into the substance of this clause except paragraph (b), and shall require such inclusion in all other subcontracts of any tier, except that this requirement shall apply only to negotiated subcontracts in excess of $100,000 where the price negotiated is not based on:

(1) Established catalog or market prices of commercial items sold in substantial quantities to the general public; or

(2) Prices set by law or regulation, and except that the requirement shall not apply to negotiated subcontracts otherwise exempt from the requirement to accept the Cost Accounting Standards clause by reason of § 331.30(b) of Title 4, Code of Federal Regulations (4CFR 331.30(b)) or § 103.1203 (a)(2) of Title 41, Code of Federal Regulations (41 CFR 1-3.1203(a)(2)).

However, if this is a contract with an agency which permits subcontractors to appeal final decisions of the Contracting Officer directly to the head of the agency or his duly authorized representative, then the Contractor shall include the substance of paragraph (b) as well.

NOTE:

(1) Subcontractors shall be required to submit their Disclosure Statements to the Contractor. However, if a subcontractor has previously submitted his Disclosure Statement to a Government Contracting Officer he may satisfy that requirement by certifying to the Contractor the date of such Statement and the address of the Contracting Officer.

(2) In any case where a subcontractor determines that the Disclosure Statement information is privileged and confidential and declines to provide it to his Contractor or higher tier subcontractor, the Contractor may authorize direct submission of that subcontractor's Disclosure Statement to the same Government offices to which the Contractor was required to make submission of his Disclosure Statement. Such authorization shall in no way relieve the Contractor of liability as provided in paragraph (a)(5) of this clause. In view of the foregoing and since the contract may be subject to adjustment under this clause by reason of any failure to comply with rules, regulations, and standards of the Cost Accounting Standards Board in connection with covered subcontracts, it is expected that the Contractor may wish to include a clause in each such subcontract requiring the subcontractor to appropriately indemnify the Contractor. However, the inclusion of such a clause and the terms thereof are matters of negotiation and agreement between the Contractor and the subcontractor, provided that they do not conflict with the duties of the Contractor under its contract with the Government. It is also expected that any subcontractor subject to such indemnification will generally require substantially similar indemnification to be submitted by his subcontractors.

(e) The terms defined in Sec. 331.20 of Part 331 of Title 4, Code of Federal Regulations (4 CFR 331.20) shall have the same meanings herein. As there defined, "negotiated subcontract" means "any subcontract except a firm fixed-price subcontract made by a Contractor or subcontractor after receiving offers from at least two firms not associated with each other or such Contractor or subcontractor, providing (1) the solicitation to all competing firms is identical, (2) price is the only consideration in selecting the subcontractor from among the competing firms solicited, and (3) the lowest offer received in compliance with the solicitation from among those solicited is accepted."

COST ACCOUNTING STANDARDS
EXEMPTION FOR CONTRACTS OF $500,000 OR LESS
CERTIFICATION (FPR 1-3.1203(h))

If this proposal is expected to result in the award of a contract of $500,000 or less and the offeror is otherwise eligible for an exemption, he shall inidcate by checking the box below that the exemption to the Cost Accounting Standards clause (FPR § 1-3.1204) under the provisions of 4 CFR 331.30(b)(8) (see FPR § 1-3.1203(h)) is claimed. Where the offeror fails to check the box, he shall be given the opportunity to make an election in writing to the Contracting Officer prior to award. Failure to check the box below or to make such an election shall mean that the offeror cannot claim the exemption to the Cost Accounting Standards clause or that the offeror elects to comply with such clause.

( ) Certificate of Exemption for Contracts of $500,000 or Less.

The offeror hereby claims an exemption from the Cost Accounting Standards clause under the provisions of 4 CFR 331.30(b)(8) and certifies that he has received notification of final acceptance of all items or work on (i) any prime contract or subcontract in excess of $500,000 which contains the Cost Accounting Standards clause, and (ii) any prime contract or subcontract of $500,000 or less awarded after January 1, 1975, which contains the Cost Accounting Standards clause. The offeror further certifies he will immediately notify the Contracting Officer in writing in the event he is awarded any other contract or subcontract containing the Cost Accounting Standards Clause subsequent to the date of this certificate but priot to the date of any award resulting from this proposal.

PREAWARD EQUAL OPPORTUNITY COMPLIANCE REVIEWS

Where the bid of the apparent low responsible bidder is in the amount of $1 million or more, the bidder and his known first-tier subcontractors which will be awarded subcontracts of $1 million or more will be subject to full, preaward equal opportunity compliance reviews before the award of the contract for the purpose of determining whether the bidder and his subcontractors are able to comply with the provisions of the Equal Opportunity clause.

ALTERATION TO SF-32, General Provisions

CLEAN AIR AND WATER CLAUSE

(Applicable only if the contract exceeds $100,000, or the contracting officer has determined that the orders under an indefinite quantity contract in any one year will exceed $100,000, or a facility to be used has been the subject of a conviction under the Clean Air Act (42 U.S.C. 1857C-8(C)(1)) or the Federal Water Pollution Control Act (33 U.S.C. 1319 (C)) and is listed by EPA, or the contract is not otherwise exempt.)

(A) The contractor agrees as follows:

(I) To comply with all the requirements of Section 114 of the Clean Air Act, as amended (42 U.S.C. 1857, et seq., as amended by Public Law 91-604 and Section 308 of the Federal Water Pollution Control Act (33 U.S.C. 1251, as amended by Public Law 92-500), respectively, relating to inspection, monitoring, entry, reports, and information, as well as other requirements specified in Section 114 and Section 308 of the Air Act and the Water Act, respectively, and all regulation and guidelines issued thereunder before the award of this contract.

(II) That no portion of the work required by this prime contract will be performed in a facility listed on the Environmental Protection Agency list of violating facilities on the date when this contract was awarded unless and until the EPA eliminates the name of such facility or facilities from listing.

(III) To use his best efforts to comply with Clean Air Standards and Clean Water Standards at the facilities in which the contract is being performed.

(IV) To insert the substance of the provisions of this clause in any nonexempt subcontract, including this paragraph (IV).

(B) The terms used in this clause have the following meanings:

(I) The term "Air Act" means the Clean Air Act, as amended (42 U.S.C. 1857 et seq., as amended by Public Law 91-604).

(II) The term "Water Act" means Federal Water Pollution Control Act, as amended (33 U.S.C. 1251 et seq., as amended by Public Law 92-500).

(III) The term "Clean Air Standards" means any enforceable rules, regulations, guidelines, standards, limitations, orders, controls, prohibitions, or other requirements which are contained in, issued under, or otherwise adopted pursuant to the Air Act or Executive Order 11738, an applicable implementation plan as described in Section 110(D) of the Clean Air Act (42 U.S.C. 1857C-5(D)), an approved implementation procedure or plan under Section 111(C) or Section 111(D), respectively, of the Air Act (42 U.S.C. 1857C-6(C) or (D)), or an approved implementation procedure under Section 112(D) of the Air Act (42 U.S.C. 1857C-7(D)).

AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	5. REQUISITION/PURCHASE REQUEST NO.	4. PROJECT NO. (If applicable)
7	6-30-77		

ISSUED BY CODE

CO, Center for Disease Control
East Paces Ferry Road, N.E.
Atlanta, GA 30305

6. ADMINISTERED BY (If other than Block 5) CODE

Same as shown in Block 5.

ORIGINAL

CONTRACTOR CODE FACILITY CODE
NAME AND ADDRESS
(Street, city, county, state, and ZIP code)

Wyeth Laboratories
Division of American Home Products
P. O. Box 8299
Philadelphia, PA 19101

8.
☐ AMENDMENT OF SOLICITATION NO. _____
DATED _____ (See Block 9)
☒ MODIFICATION OF CONTRACT/ORDER NO. Letter 200-76-0427
DATED 9/13/76 (See Block 11)

THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Block 13. The hour and date specified for receipt of Offers ☐ is unchanged, ☐ is changed to

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation, or as amended, by one of the following methods:

(a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided such telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

ACCOUNTING AND APPROPRIATION DATA (If required)

THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) ☒ This Change Order is issued pursuant to: the authorization for Letter Contract by the Secretary, 9/1/76.

The Changes set forth in Block 13 are made to the above numbered contract/order.

(b) ☐ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation date, etc.) set forth in Block 13.

☐ This Supplemental Agreement is entered into pursuant to authority of _____

It modifies the above numbered contract as set forth in Block 13.

DESCRIPTION OF AMENDMENT/MODIFICATION

The target date for definitization, set forth in Subparagraph B, Article III - DEFINITIZATION, as established by Modification No. 6 dated May 31, 1977, is further extended to August 15, 1977.

Except as provided herein, all terms and conditions of the document referenced in Block 9, as heretofore changed, remain unchanged and in full force and effect.

☒ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT ☐ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN _____ COPIES TO ISSUING OFFICE

15A. NAME OF CONTRACTOR/OFFEROR
Signature of person authorized to sign

15B. UNITED STATES OF AMERICA
BY John L. Williams
Signature of Contracting Officer

15C. NAME AND TITLE OF SIGNER (Type or print)

15D. DATE SIGNED

16A. NAME OF CONTRACTING OFFICER (Type or print)
John L. Williams

16B. DATE SIGNED
6-30-77

FED. PROC. REG. (41 CFR) 1-16.103

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. AMENDMENT/MODIFICATION NO.	2. EFFECTIVE DATE	3. REQUISITION/PURCHASE REQUEST NO.	4. PROJECT NO. (If applicable)
6	5-31-77		

5. ISSUED BY — CODE

PGO, Center for Disease Control
255 East Paces Ferry Road, N.E.
Atlanta, GA 30305

6. ADMINISTERED BY (If other than block 5) — CODE

Same as shown in Block 5.

7. CONTRACTOR NAME AND ADDRESS (Street, city, county, state, and ZIP Code) — CODE — FACILITY CODE

Wyeth Laboratories
Division of American Home Products
P. O. Box 8299
Philadelphia, PA 19101

8.
☐ AMENDMENT OF SOLICITATION NO. _____
DATED _____ (See block 9)
☒ MODIFICATION OF CONTRACT/ORDER NO. Letter 200-76-0427
DATED 9/13/76 (See block 11)

9. THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in block 12. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation, or as amended, by one of the following methods:

(a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

10. ACCOUNTING AND APPROPRIATION DATA (If required)

11. THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) ☐ This Change Order is issued pursuant to _____
The Changes set forth in block 12 are made in the above numbered contract/order.

(b) ☒ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation data, etc.) set forth in block 12.

(c) ☐ This Supplemental Agreement is entered into pursuant to authority of _____
It modifies the above numbered contract as set forth in block 12.

12. DESCRIPTION OF AMENDMENT/MODIFICATION

The target date for definitization of referenced contract, as set forth in ARTICLE XIII - DEFINITIZATION, is extended hereby to July 1, 1977.

Except as provided herein, all terms and conditions of the document referenced in block 8, as heretofore changed, remain unchanged and in full force and effect.

13.
☒ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT ☐ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN _____ COPIES TO ISSUING OFFICE

NAME OF CONTRACTOR/OFFEROR		17. UNITED STATES OF AMERICA
BY _____ (Signature of person authorized to sign)		BY John L. Williams (Signature of Contracting Officer)
15. NAME AND TITLE OF SIGNER (Type or print)	16. DATE SIGNED	18. NAME OF CONTRACTING OFFICER (Type or print) John L. Williams

20-101

GENERAL SERVICES ADMINISTRATION
FED. PROC. REG. (41 CFR) 1-16.101

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. AMENDMENT/MODIFICATION NO.	2. EFFECTIVE DATE	3. REQUISITION/PURCHASE REQUEST NO.	4. PROJECT NO. (If applicable)
5	4-14-77		

5. ISSUED BY — CODE
30, Center for Disease Control
255 East Paces Ferry Rd. N.E.
Atlanta, GA 30305

6. ADMINISTERED BY (If other than block 5) — CODE
Same as shown in Block 5.

7. CONTRACTOR NAME AND ADDRESS (Street, city, county, state, and ZIP Code) — CODE — FACILITY CODE

Wyeth Laboratories
Division of American Home Products
P. O. Box 8299,
Philadelphia, PA 19101

8.
☐ AMENDMENT OF SOLICITATION NO. _____
DATED _____ (See block 9)
☒ MODIFICATION OF CONTRACT/ORDER NO. 200-76-0437 Letter
9/13/76
DATED _____ (See block 11)

9. THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in block 12. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation, or as amended, by one of the following methods:

(a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

10. ACCOUNTING AND APPROPRIATION DATA (If required)

11. THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) ☐ This Change Order is issued pursuant to _____
The Changes set forth in block 12 are made in the above numbered contract/order.

(b) ☒ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation data, etc.) set forth in block 12.

(c) ☐ This Supplemental Agreement is entered into pursuant to authority of _____

It modifies the above numbered contract as set forth in block 12.

12. DESCRIPTION OF AMENDMENT/MODIFICATION

The target date for definitization of referenced contract, as set forth in ARTICLE XIII - DEFINITIZATION, is extended hereby to May 31, 1977.

Except as provided herein, all terms and conditions of the document referenced in block 8, as heretofore changed, remain unchanged and in full force and effect.

13.
☒ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT ☐ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN _____ COPIES TO ISSUING OFFICE

NAME OF CONTRACTOR/OFFEROR

14. _____
(Signature of person authorized to sign)

15. NAME AND TITLE OF SIGNER (Type or print)

16. DATE SIGNED

17. UNITED STATES OF AMERICA
BY John L. Williams
(Signature of Contracting Officer)

18. NAME OF CONTRACTING OFFICER (Type or print)
John L. Williams

19. DATE SIGNED
6-14-77

-101

U.S. GOVERNMENT PRINTING OFFICE: 1976

GENERAL SERVICES ADMINISTRATION FED. PROC. REG. (41 CFR) 1-16.101

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1 | 1

1. AMENDMENT/MODIFICATION NO.	2. EFFECTIVE DATE	3. REQUISITION/PURCHASE REQUEST NO.	4. PROJECT NO. (If applicable)
Modification No. 4	1/26/77		

5. ISSUED BY (CODE)	6. ADMINISTERED BY (If other than Block 5) (CODE)
Center for Disease Control 255 East Paces Ferry Road N.E. Atlanta, Georgia 30305	Same as shown in Block 5.

ORIGINAL

7. CONTRACTOR (CODE) / FACILITY CODE NAME AND ADDRESS (Street, city, county, state, and ZIP Code)	8. ☐ AMENDMENT OF SOLICITATION NO. _____ DATED _____ (See Block 9) ☒ MODIFICATION OF CONTRACT/ORDER NO. Letter 200-76-0427 DATED 9/13/76 (See Block 11)
Wyeth Laboratories Division of American Home Products P. O. Box 8299 Philadelphia, PA 19101	

9. THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Block 12. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation, or as amended, by one of the following methods:

(a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

10. ACCOUNTING AND APPROPRIATION DATA (If required)

No change in obligation.

11. THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) ☒ This Change Order is issued pursuant to: Article 2, "Changes" of the General Provisions.

The Changes set forth in block 12 are made to the above numbered contract/order.

(b) ☐ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation data, etc.) set forth in block 12.

(c) ☐ This Supplemental Agreement is entered into pursuant to authority of: _____

It modifies the above numbered contract as set forth in block 12.

12. DESCRIPTION OF AMENDMENT/MODIFICATION

ARTICLE III - QUANTITIES is deleted hereby and the following is substituted therefor:

ARTICLE III - QUANTITIES:

The number of doses, by vial sizes, to be furnished under the contract is:

Bivalent Vaccine - 50-dose vials - 7.2 million doses
Monovalent Vaccine - 10 dose vials- 2.3 million doses
Monovalent Vaccine - 50-dose vials- 2.5 million doses

Variation in Quantity: A variation in the total quantity supplied hereunder will be accepted, provided that such variation is not in excess of 15% of the contract quantity as specified above, and is available for delivery prior to the final delivery date (January 15, 1977). The contractor shall notify the Government of availability of additional quantities as soon as this status becomes known to the contractor.

This confirms the Contracting Officer's verbal request and Contractor's compliance agreement of November 17, 1976.

Except as provided herein, all terms and conditions of the document referenced in Block 8, as heretofore changed, remain unchanged and in full force and effect.

13. ☒ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT ☐ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN _____ COPIES TO ISSUING OFFICE

14. NAME OF CONTRACTOR/OFFEROR	15. UNITED STATES OF AMERICA
BY _____ (Signature of person authorized to sign)	BY _____ (Signature of Contracting Officer)
15. NAME AND TITLE OF SIGNER (Type or print)	16. DATE SIGNED
	17. NAME OF CONTRACTING OFFICER (Type or print): John L. Williams
	18. DATE SIGNED: 1/26/77

1. AMENDMENT/MODIFICATION NO.: Modification No. 3
2. EFFECTIVE DATE: 1/26/77
3. ISSUED BY: HEW - CDC, Center for Disease Control, 255 East Paces Ferry Rd., Atlanta, GA 30305
4. PROJECT NO. (If applicable)
5. ADMINISTERED BY (If other than block 3): Same as shown in Block 5
ORIGINAL

7. CONTRACTOR NAME AND ADDRESS (Street, city, county, state, and ZIP Code): Wyeth Laboratories, Div. of American Home Products, P. O. Box 8299, Philadelphia, PA 19101

8. AMENDMENT OF SOLICITATION NO. ____ DATED ____ (See block 9)
MODIFICATION OF CONTRACT/ORDER NO. 200-76-0427 Letter
DATED 9/13/76 (See block 11)

9. THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS
☐ The above numbered solicitation is amended as set forth in block 12. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.
Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation, or as amended, by one of the following methods:
(a) By signing and returning ____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

10. ACCOUNTING AND APPROPRIATION DATA (If required)
No Change in obligation.

11. THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS
(a) ☐ This Change Order is issued pursuant to ____
The Changes set forth in block 12 are made to the above numbered contract/order.
(b) ☐ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation data, etc.) set forth in block 12.
(c) ☒ This Supplemental Agreement is entered into pursuant to authority of 41 USC 252 (c) (7)
It modifies the above numbered contract as set forth in block 12.

12. DESCRIPTION OF AMENDMENT/MODIFICATION

The purpose of this Modification is to add the following price for Monovalent Vaccine packaged in 10-dose vials to Article IX - Payment as set forth in Modification No. 1:

	10-dose vials
Monovalent Vaccine	$2.99

Except as provided herein, all terms and conditions of the document referenced in block 9, as heretofore changed, remain unchanged and in full force and effect.

13. ☐ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT ☒ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 4 COPIES TO ISSUING OFFICE

14. NAME OF CONTRACTOR/OFFEROR: B.J. Gray (Signature of person authorized to sign)
15. NAME AND TITLE OF SIGNER (Type or print): B.J. GRAY, VICE PRESIDENT
16. DATE SIGNED: 1/21/77
17. UNITED STATES OF AMERICA: BY John L. Williams (Signature of Contracting Officer)
18. NAME OF CONTRACTING OFFICER (Type or print): John L. WILLIAMS
19. DATE SIGNED: 1/26/77

GENERAL SERVICES ADMINISTRATION — AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT — 1

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST NO.	5. PROJECT NO. (If applicable)
Modification No. 2	1/26/77		

6. ISSUED BY — CODE
Center for Disease Control
255 East Paces Ferry Road N.D.
Atlanta, Georgia 30305

7. ADMINISTERED BY (If other than Item 6) — CODE
Center for Disease Control
255 East Paces Ferry Road N.E.
Atlanta, Georgia 30305

ORIGINAL

8. CONTRACTOR NAME AND ADDRESS (Street, city, county, state, and ZIP code) — CODE — FACILITY CODE

Wyeth Laboratories
Division of American Home Products
P. O. Box 8299
Philadelphia, PA 19101

9. ☐ AMENDMENT OF SOLICITATION NO. _____ DATED _____ (See Item 9)

10. ☒ MODIFICATION OF CONTRACT/ORDER NO. Letter 200-76-0427 DATED 9/13/76 (See Item 11)

THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 12. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation, or as amended, by one of the following methods:

(a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

11. ACCOUNTING AND APPROPRIATION DATA (If required)

THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) ☐ This Change Order is issued pursuant to _____

The Changes set forth in Item 12 are made to the above numbered contract/order.

(b) ☐ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation data, etc.) set forth in Item 12.

(c) ☒ This Supplemental Agreement is entered into pursuant to authority of 41 USC 252 (c) (7)

(d) It modifies the above numbered contract as set forth in Item 12.

12. DESCRIPTION OF AMENDMENT/MODIFICATION

Subparagraph B. of Article XIV - LIMITATION ON CONTRACTOR'S PROFIT is deleted hereby in its entirety, and the following is substituted therefor:

ARTICLE XIV - LIMITATION ON CONTRACTOR'S PROFIT:

B. (1) The cost of the premium for the liability insurance which is solely attributable to this Program is not included in the vaccine price. (See Article IX B; Payment.) In the event that the insurance premium for liability insurance, or any part thereof, is refunded to the contractor under any retrospective, experience-rating plan or similar rating plan, it shall be refunded to the Government not later than thirty (30) days after receipt by the contractor.

(2) Any money provided to the contractor by the Government for a self-insurance retention fund ("Fund") (see Article IX B;Payment) shall be segregated in a separate account in a federally insured commercial bank with assets in excess of $100,000,000. Said Fund shall be invested in an interest bearing arrangement or arrangements, e.g., Certificates of Deposit, at the bank's prevailing interest rates. In the event any payment by the contractor is required to be made from the invested principal

(continued)

Except as provided herein, all terms and conditions of the document referenced in Item 8, as heretofore changed, remain unchanged and in full force and effect.

13. ☐ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT ☐ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN _____ COPIES TO ISSUING OFFICE

14. NAME OF CONTRACTOR/OFFEROR
BY _____ (Signature of person authorized to sign)

15. UNITED STATES OF AMERICA
BY _____ (Signature of Contracting Officer)

15A. NAME AND TITLE OF SIGNER (Type or print)
B.J. GRAY
VICE PRESIDENT

15B. DATE SIGNED
1/31/77

16. NAME OF CONTRACTING OFFICER (Type or print)
John L. Williams

16A. DATE SIGNED
1/26/77

BOARD FORM 36, JULY 1966
GSA SERVICES ADMINISTRATION
PROC. REG. (41 CFR) 1-16.101

CONTINUATION SHEET

Modification No. 2
Letter Contract 200-76-0427

PAGE 2

OF OFFEROR OR CONTRACTOR
Wyeth Laboratories

NO.	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT

(2) (continued)

of the Fund prior to the stated maturity date or dates of such invested principal, the total proceeds of such liquidated investment or investments shall be deemed to apply first to principal and secondly to interest. To the extent such total proceeds are less than the original invested principal, the difference shall be charged against all other accrued interest due the Government. Payments shall be made only from the principal of said account and only for self-insurance losses and related expenditures of the contractor as follows:

(a) All sums which the United States shall have the right to recover from the contractor as damages under section 317(k) (7) of the Public Health Service Act (42 U.S.C. 247(b)), and any costs of litigation or attorney fees incurred by the contractor and attributable thereto; and

(b) All payments made by the contractor for expenses (other than office expenses or expenses for salaries of employees of the contractor) incurred in the investigation, negotiation, settlement, or defense of any claim or suit pursuant to section 317 (k)(7) of the Public Health Service Act (42 U.S.C. 247(b)) or in the investigation of a case reasonably likely to result in such claim or suit. Such losses and related expenditures are more particularly described in the insurance policy between the contractor and its respective insurers. Any interest earned on the Fund shall be reinvested with the balance of the principal remaining in the Fund. Any amount provided the contractor by the Government for the Fund, which is not expended by August 1, 1985, including accrued interest to such date, shall be returned to the Government not later than August 31, 1985.

(3) In the event the contractor is required to pay a claim by the Government pursuant to section 317(k)(7) of the Public Health Service Act (42 U.S.C. 247(b)) after the contractor has returned the unexpended amount provided for self-insurance, including accrued interest, such claim shall be deemed satisfied up to the amount of principal returned to the Government. Therefore, the total of the payments made from the Fund by the contractor and the credits provided to the contractor by the Government, after the unexpended principal and accrued interest have been returned to the Government, shall not exceed $2,500,000.

(4) It is the understanding of the parties to this contract that since the Fund may only be expended for the reasons stated in B.2 above, and since the unexpended principal of the Fund, including accrued interest, shall be returned to the Government under the circumstances set forth above, they do not constitute income to the contractor.

1. AMENDMENT/MODIFICATION NO.	EFFECTIVE DATE	2. REQUISITION/PURCHASE REQUEST	4. PROJECT NO. (If applicable)
Modification No. 1	10/27/76		

3. ISSUED BY	CODE	6. ADMINISTERED BY (If other than Block 5)	CODE
HEW, PHS Center for Disease Control 255 East Paces Ferry Road, N. E. Atlanta, GA 30305		Same as shown in Block 5.	

ORIGINAL

7. CONTRACTOR NAME AND ADDRESS (Street, city, county, state, and ZIP Code)

Wyeth Laboratories
Division of American Home Products
P. O. Box 8299
Philadelphia, PA 19101

CODE _____ FACILITY CODE _____

8. ☐ AMENDMENT OF SOLICITATION NO. _____
DATED _____ (See Block 9)
☒ MODIFICATION OF CONTRACT/ORDER NO. Letter Contract 200-76-0435
DATED 9/13/76 (See Block 11)

9. THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in block 12. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation, or as amended, by one of the following methods:

(a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

10. ACCOUNTING AND APPROPRIATION DATA (If required)

11. THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) ☐ This Change Order is issued pursuant to: _____
The Changes set forth in Block 12 are made to the above numbered contract/order.

(b) ☐ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation date, etc.) set forth in Block 12.

(c) ☒ This Supplemental Agreement is entered into pursuant to authority of: 41 U.S.C. 252(c)(7)

It modifies the above numbered contract as set forth in block 12.

12. DESCRIPTION OF AMENDMENT/MODIFICATION

The purpose of this Modification is to revise Article I, Scope of Contract, of the Letter Contract and to expand on Article IX, Payment.

1. Article I - Scope of Contract is hereby deleted in its entirety, and the following Article substituted therefor:

Article I - Scope of Contract:

The contractor shall manufacturer and distribute influenza vaccine in accordance with the specifications set forth below during the contract period to the destinations and in the quantities specified on Delivery Orders issued by the Center for Disease Control. The only obligations or responsibilites of the contractor in connection with the National Swine Flu Immunization Program of 1976 are contained in this contract. There are no warranties, expressed or implied, imposed on the contractor except as stated in this contract.

2. Article IX - Payment is deleted in its entirety, and the following Article substituted therefor:

Except as provided herein, all terms and conditions of the document referenced in Block 8, as heretofore changed, remain unchanged and in full force and effect.

13. ☐ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT ☒ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 6 COPIES TO ISSUING OFFICE

14. NAME OF CONTRACTOR/OFFEROR		17. UNITED STATES OF AMERICA	
BY _____ (Signature of person authorized to sign)		BY John L. Williams (Signature of Contracting Officer)	
15. NAME AND TITLE OF SIGNER (Type or print)	16. DATE SIGNED	18. NAME OF CONTRACTING OFFICER (Type or print)	19. DATE SIGNED
Vice President-Administration	10/12/76	John L. Williams	10/27/76

30-101

rticle IX - Payment:

. Payment shall be made within 30 days for all vaccine which has been accepted. Each invoice r voucher shall, as a minimum, identify the appropriate Delivery Order for which the delivery as made, the vaccine type and amount delivered, the unit price, the total price, and the iccine lot number(s). All payments shall be on a provisional basis pending definitization of contract. The following prices shall be used for provisional payments for vaccine:

50-dose vials

Bivalent Vaccine	$24.37
Monovalent Vaccine	$15.09

uchers shall be submitted to the following address:

Center for Disease Control
Bureau of State Services
Immunization Division
1600 Clifton Road, N.E.
Atlanta, GA 30333

. Payment for self-insurance retention and Insurance Premium on Liability shall be made ithin 30 days of receipt of contractor's invoice for same. The vaccine prices do not include ie costs for self-insurance ($2,500,000) or premiums for liability insurance ($2,176,693.25) h are solely attributable to the National Swine Flu Immunization Program of 1976.

WYETH LABORATORIES

Wyeth

P.O. Box 8299, Philadelphia, Pennsylvania 19101

VICE PRESIDENT - ADMINISTRATION

October 12, 1976

Mr. John Williams
Contracting Officer
Center for Disease Control
255 East Paces Ferry Road, N.E.
Atlanta, Georgia 30305

Re: Swine Influenza Vaccine
Letter Contract No. 200-76-0427

Dear Mr. Williams:

As requested in your letter of September 25, 1976, I have executed and am enclosing herewith four copies of Modification No. 1 to the above letter contract. We have made two changes in Article IX - Payment; the price for Bivalent Vaccine was changed from $24.38 to $24.37 and the exact insurance premium amount for Wyeth should be $2,176,693.25.

We will look forward to your return of one copy of the modification upon execution by the Government.

Very truly yours,

B. J. Gray

BJG:wj

STANDARD FORM 26, JULY 1966
GENERAL SERVICES ADMINISTRATION
FED. PROC. REG. (41CFR) 1-16.101

AWARD/CONTRACT

PAGE 1 OF 1

1. CONTRACT (Proc. Inst. Ident.) NO.
Letter Contract
No. 200-76-0427

2. EFFECTIVE DATE

3. REQUISITION/PURCHASE REQUEST/PROJECT NO.

4. CERTIFIED FOR NATIONAL DEFENSE UNDER BDSA REG. 3 AND/OR DMS REG. 1. RATING:

5. ISSUED BY CODE
HEW, PHS
enter for Disease Control
255 East Paces Ferry Road, N.E.
Atlanta, GA 30305

6. ADMINISTERED BY (If other than block 5) CODE
Same as shown in Block 5.

7. DELIVERY
☐ FOB DESTINATION
☒ OTHER (See below)

8. CONTRACTOR NAME AND ADDRESS (Street, city, county, State, and ZIP code) CODE FACILITY CODE
Wyeth Laboratories
Div. of American Home Products
P.O. Box 8299
Philadelphia, PA 19101

9. DISCOUNT FOR PROMPT PAYMENT
None

10. SUBMIT INVOICES (4 copies unless otherwise specified) TO ADDRESS SHOWN IN BLOCK 12

11. SHIP TO/MARK FOR CODE
As directed on Delivery Orders.

12. PAYMENT WILL BE MADE BY CODE
Center for Disease Control
Financial Management Office
Atlanta, GA 30333

13. THIS PROCUREMENT WAS ☐ ADVERTISED, ☒ NEGOTIATED, PURSUANT TO:
☐ 10 U.S.C. 2304 (a)( )
☒ 41 U.S.C. 252 (a)(7)

14. ACCOUNTING AND APPROPRIATION DATA
75X0943 PHS (Influenza Immunization)
6-6140/6944 4591 (26.11) $12,000,000

15. ITEM NO.	16. SUPPLIES/SERVICES	17. QUANTITY	18. UNIT	19. UNIT PRICE	20. AMOUNT
1.	INFLUENZA VIRUS VACCINE, Monovalent, 200 CCA units, A/New Jersey/76, and Bivalent, 200/200, CCA units, A/New Jersey/76-A/Victoria/3/75, to be supplied in accordance with the Scope of Work, Delivery Schedule, and terms set forth herein.				

21. TOTAL AMOUNT OF CONTRACT $

CONTRACTING OFFICER WILL COMPLETE BLOCK 22 OR 26 AS APPLICABLE

22. ☒ CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 3 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)

23. NAME OF CONTRACTOR
B. F. Gray
(Signature of person authorized to sign)

24. NAME AND TITLE OF SIGNER (Type or print)
B.F. GRAY
VICE PRESIDENT

25. DATE SIGNED
9/13/76

26. ☐ AWARD (Contractor is not required to sign this document.) Your offer on Solicitation Number ____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual document is necessary.

27. UNITED STATES OF AMERICA
BY John L. Williams
(Signature of Contracting Officer)

28. NAME OF CONTRACTING OFFICER (Type or print)
JOHN L WILLIAMS

29. DATE SIGNED
9/16/76

1-103

U.S. GOVERNMENT PRINTING OFFICE: 1975

ARTICLE I - SCOPE OF CONTRACT:

The contractor shall manufacture and distribute influenza vaccine in accordance with the specifications set forth below during the contract period to the points and in the quantities specified on Delivery Orders issued by the Center for Disease Control. The only obligations or responsibilities of the Contractor in connection with the National Swine Flu Immunization Program of 1976 are contained in this contract (with exception that the contractor agrees to enter into good faith negotiations to definitize the contract.)

ARTICLE II - SPECIFICATIONS:

A. Type of Vaccine:
The vaccine shall be Influenza Monovalent A/New Jersey/76 (Swine) and/or Bivalent A/New Jersey/76 (Swine) - A/Victoria/3/75 manufactured under a current establishment and product license as set forth below. Formulation, standards, specifications and applicable tests of the vaccine shall be as set forth in the approved product license or as otherwise directed by the Food and Drug Administration.

B. Product Licensure:

The vaccine supplied under this contract shall be produced under U. S. Establishment License No. 3 and Amendment to the product license for influenza vaccine issued by the Bureau of Biologics. If, during the contract period of performance, the product or establishment license is suspended or revoked for any reason, production of the vaccine shall be discontinued until such time as the license is renewed. In the event production is suspended for the above reason, the Government shall not be held liable for failure to procure the vaccine contained in this contract nor shall the contractor be liable for failure to supply vaccine.

C. Shelf Life:

Delivered vaccine shall have an expiration date through August 1, 1977. The Government agrees to take all appropriate steps to see to it that all persons who are responsible for administering vaccine are notified that the vaccine must not be administered after August 1, 1977.

D. Containers:

Vaccine shall be contained in vials of 50-dose capacity, with 2ml overfill. Fifty-dose vials shall have an internal neck size 6.86mm-7.24mm and outside lip diameter of 12.95mm-13.34mm. Vials shall be supplied with stoppers made of nonpyrogenic, high-grade rubber: Vaccine dosage will be .5ml.

E. Labeling:

Labeling of vials shall be in accordance with 21 CFR 610.60. In addition, the color of label for the monovalent vaccine shall be red with black or white markings, and the color of the bivalent vaccine shall be blue with black or white markings. Lot number shall be specified on each vial label. Text of the labels shall be supplied by the Government.

NAME OF OFFEROR OR CONTRACTOR

. Caps:

Caps shall be metallic in color.

G. Packaging:

For shipping purposes, vials shall be packaged as follows:

50-dose vials - 20 vials

Each package shall be labeled in accordance with Paragraph 85.2.2.2 - Intermediate Containers of Federal Standard 123D. In addition to the requirements of the referenced Federal Standard, the following is required:

A. Labeling shall show applicable lot numbers.

B. A paste-on label shall be attached to each package. Label shall conform to the sample supplied with RFP.

C. Package inserts shall be placed in each intermediate package, a total of 10 inserts per package. Inserts shall be in accordance with Sub-paragraph 201.10(1) (2) of Title 21 CFR Part 600.3.

Preservation, packaging, and packing shall furnish a degree of protection to preclude damage to containers and/or contents thereof under normal shipping conditions, handling, etc., and shall conform to applicable carrier rules and regulations, including carriers handling overseas shipments.

Vaccine shall be shipped under refrigeration at a temperature between 2° and 15°C (34° to 60°F). Packing and packaging shall be such that this temperature is maintained during shipment for a period of up to 72 hours and that shipments shall arrive at destination in undamaged condition.

H. Marking Provisions:

Shipping containers: Containers shall be marked in accordance with Federal Standard Number 123D, January 22, 1975, and shall contain as a minimum the following:

a. Quantity and Unit
b. Purchase Order Number
C. Item Name
d. Contractor Name and Address
e. Gross Weight
f. Lot Number(s)

ARTICLE III - QUANTITIES:

The number of doses, by vial sizes, to be furnished under the contract is:

Bivalent Vaccine 50-dose vials 8.8 million doses
Monovalent Vaccine 50-dose vials 5 million doses

Variation in Quantity: A variation in the total quantity supplied hereunder will be accepted, provided that such variation is not in excess of 15% of the contract quantity specified above, and is available for delivery prior to the final delivery date (January 15, 1977). The contractor shall notify the Government of availability of additional quantities as soon as this status becomes known to the contractor.

NAME OF OFFEROR OR CONTRACTOR

ARTICLE IV - DISTRIBUTION:

A. Delivery Points:

The contractor shall deliver the vaccine F.O.B. Destination Within Consignee's Premises, Freight Charges Added, as directed on Delivery Orders, to approximately 200 points in the 50 states and Trust Territories.

B. Delivery Schedule:

Deliveries shall begin on or before October 1, 1976, with the total amount of bivalent and monovalent vaccine to be delivered in accordance with the attached Availability Schedule. All deliveries shall be completed on or before January 15, 1977. The Government agrees that the vaccine delivered by the Contractor shall not be administered prior to October 1, 1976.

C. Overseas Delivery Requirements:

Overseas shipping and delivery methods shall be utilized for delivery to those points located outside the Continental United States.

D. Time of Delivery:

Contractor shall deliver vaccine to consignees specified in the Government's Delivery Orders within 15 business days after receipt of such Delivery Orders provided the Government's Delivery Orders shall not exceed quantities of vaccine which have been released for marketing by the Government's Bureau of Biologics and which have been filled into final dosage form and packaged by the Contractor prior to the Contractor's receipt of Delivery Orders.

E. Shipments shall be made in increments of 8,000 doses.

ARTICLE V - DELIVERY TERMS:

Delivery shall be made F.O.B. DESTINATION, WITHIN CONSIGNEE'S PREMISES, FREIGHT CHARGES ADDED, as defined below:

The term, "F.O.B. Destination, Within Consignee's Premises, Freight Charges Added," to which this contract is subject, means:

(a) The Contractor shall deliver to within the doors of the Consignee's premises specified in the contract or delivery instructions. The Government shall bear all transportation expenses necessary to effect such delivery and the Contractor shall include such charges on pertinent invoices to the Government. Supportive documents of Freight Charges in excess of $50 shall be supplied with the invoices.

(b) That it shall be the responsibility of the contractor to do the following:

(1) Pack and mark in such manner as to afford adequate protection against normal transportation hazards and secure prompt delivery to the consignee, and comply with all packing and marking specifications of the contract;

(2) Properly prepare and distribute commercial bills of lading;

(3) Make delivery laid down within the doors of the consignee's premises specified in the contract or delivery instructions;

(4) Be responsible for any loss or damage occurring before delivery is laid down within the doors of the consignee's premises specified in the contract or delivery instructions.

ARTICLE VI - RETURN OF VACCINE:

All vaccine shipped by the Offeror shall, unless received at consignees locations in damaged condition, be shipped on a no return basis and the Offeror shall have no obligation at any time to accept vaccine returned to it nor shall any adjustment be made in any invoices submitted by the Offeror. If any attempt is made by any consignee or other person to return vaccine to the Offeror the Offeror may refuse to accept such vaccine or may, at its option, accept the vaccine for the Government's account in which event the Offeror will notify the Contracting Officer of the action taken and await the Contracting Officer's instructions as to disposition.

ARTICLE VII - METHOD OF ORDERING:

Vaccine shall be ordered by Delivery Orders, each of which will designate the vaccine ordered, quantity required, and destination. Orders may be placed by telephone and confirmed in writing.

ARTICLE VIII - INSPECTION AND ACCEPTANCE:

Vaccine will be submitted by the contractor to the Bureau of Biologics for reviewing and testing. Following release of the lots, Bureau of Biologics will send a notification of approval to the project officer at the Center for Disease Control. Final inspection shall be made at consignee's locations. Final acceptance/rejection will be made by the Center for Disease Control. Defective or damaged material received at consignee's locations will be rejected in accordance with Article 5 of the General Provisions.

ARTICLE IX - PAYMENT:

Payment shall be made for all vaccine which has been delivered and accepted. Each invoice or voucher shall, as a minimum, identify the appropriate Delivery Order for which the delivery was made, the vaccine and amount delivered, the unit price, the total price, and the lot number(s). All payments shall be on a provisional basis pending definitization of the contract. Vouchers shall be submitted to the following address:

Center for Disease Control
Financial Management Office
255 East Paces Ferry Road, N. E.
Atlanta, GA 30305

ARTICLE X - PROJECT OFFICER:

The Center for Disease Control, Atlanta, Georgia, will designate an individual to perform as Project Officer during the period of performance of the contract. The Project Officer shall be responsible for guidance in regard to the technical aspect of the contract, provide a point for liaison between the manufacturer and other Government agencies (Federal, State, and local) and be the general focal point to address technical and logistical problems relating to the performance under this contract. The Project Officer shall not have the

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thority to make any commitments or authorize any changes which affect the contract price, ms, or conditions; any such changes shall be referred to the Contracting Officer for ction.

RTICLE XI - PROJECT DIRECTOR:

The Contractor shall designate an individual who will serve as the point of contact regarding the technical performance of the contract. This individual shall have the authority necessary to commit the company and shall be assigned responsibilities congruent with requirements of the contract. The Government reserves the right to approve the Project Director and any successor to that position.

RTICLE XII - DELINEATION OF RESPONSIBILITIES OF THE GOVERNMENT AND THE CONTRACTOR:

. The parties recognize that the Government has initiated, planned, and is arranging for the implementation of the influenza immunization program. Because of the need to have the vaccine tested, manufactured, and delivered within a relatively short period of time in order that the population may be inoculated in an attempt to prevent an influenza epidemic, the Government has assumed certain responsibilities as specified herein which would ordinarily devolve upon the contractor. It is the intention of the parties that the contractor will be responsible solely for the performance of its obligations under Paragraph C herein. It is the purpose of this Article to delineate the separate responsibilities of the Government and the contractor.

In the light of the circumstances described in Paragraph A hereof, the Government shall be responsible for:

(1) The adequacy of the standards and specifications for the vaccine required to be delivered under this contract, including their compliance with all applicable requirements of law and regulation.

(2) The safety and suitability of materials provided to the contractor by the Government under or in connection with this contract.

(3) The investigation and determination of the safe and effective dosages and adequate directions for the use of the vaccine.

(4) The investigation and determination of the risks and benefits of inoculation with the vaccine.

(5) The development of an adequate statement of information respecting the risks and benefits referred to in subparagraph (4).

(6) The taking of all appropriate steps to assure that each individual to be inoculated (or, where appropriate, a parent or guardian of such individual) is adequately informed of such risks and benefits.

(7) The content of the labeling of the vaccine, including its compliance with all applicable requirements of law and regulation.

(8) The taking of all appropriate steps to assure that each person responsible for administering the vaccine has adequate notice of the labeling of the vaccine, provided that nothing herein shall limit the responsibility which the manufacturer otherwise has to assure that labeling is included in and delivered with each shipment of the vaccine.

(9) The arrangements for the implementation of the influenza immunization program, including the issuance of appropriate guidelines and information.

The contractor shall use due care and comply with all applicable laws and regulations in the manufacture and handling of the vaccine in accordance with the specifications herein.

RTICLE XIII - DEFINITIZATION:

A fixed price, redeterminable type contract is contemplated. To accomplish this result, the contractor agrees to enter into negotiation promptly with the Contracting Officer over the terms of a definitive contract, which will include all clauses, terms, and conditions as may be mutually agreeable. The contractor agrees to make available cost and pricing data, and data relating to his accounting system.

The schedules for definitization of this contract are set forth below:

Negotiation of price and other terms and conditions - On or before November 10, 1976.

Target date for definitization - on or before December 1, 1976.

If agreement on a definitive contract to supersede this letter contract is not reached by the target date set forth in B, above, or any extension thereof by the Contracting Officer, the Contracting Officer may, with the approval of the Head of the Procurement Activity, determine a reasonable price subject to appeal by the contractor as provided in the clause "Disputes" of this contract. The contract shall be governed by:

(1) All clauses, terms, and conditions contained in this letter contract except which by their nature are applicable only to a letter contract.

(2) All clauses required by law as of the date of this letter contract..

(3) Such other clauses, terms, and conditions as may be mutually agreed upon.

RTICLE XIV - LIMITATION ON CONTRACTOR'S PROFIT:

In accordance with the provisions of P.L. 94-380, the contract price for the vaccine delivered under the contract shall be subject to renegotiation to eliminate any profit realized by the contractor on the swine flu vaccine and to limit the profit realized by the contractor on the A/Victoria/75 vaccine to a reasonable profit. The Secretary of Health, Education, and Welfare will issue criteria for the determination of the costs of the contractor for the vaccine delivered under this contract and for the determination of a reasonable profit on the A/Victoria/75 vaccine.

Any insurance premium amount of which is included in the price of the vaccine delivered under this contract and which is refunded to the contractor under any retrospective, experience-rating plan or similar rating plan shall be refunded to the Government not later than 30 days after receipt of the refund by the contractor. Any amount retained by the contractor for self-insurance which is included in the price of the vaccine delivered under this contract and not expended on or before August 1, 1985, shall be refunded to the Government not later than August 31, 1985. The amount refunded shall include accrued interest at the rate determined by the Secretary of the Treasury pursuant to Public Law 92-41, 85 Stat. 97 from the date the contractor received payment from the

Government for the vaccine delivered under this contract. In the event the contractor is required to pay a claim by the Government pursuant to Section 317(k)(7) of the Public Health Service Act after the contractor has refunded the unexpended amount retained for self-insurance, such claim shall be deemed satisfied up to the amount of such refund.

C. For the purposes of this Article, the contractor shall maintain and make available to the Secretary or his authorized representatives the records specified by the Articles of this contract entitled "Accounts, Audits, and Records"; Examination of Records by Comptroller General (Clause 10 of the General Provisions, SF-32); and Examination of Records by Department of Health, Education, and Welfare (Alterations to SF-32).

D. In the event the Contracting Officer determines that the contractor has realized any profit on swine flu vaccine or has realized more than a reasonable profit on A/Victoria/75 vaccine, the contract price shall be adjusted in accordance with the requirements of Paragraph A of this Article. Failure of the parties to reach agreement on the renegotiation of the contract price shall be subject to Clause 12 of the General Provisions, entitled "Disputes." The contractor shall make any necessary refunds to the Government not later than thirty days after receipt of the Contracting Officer's final decision. However, if the contractor takes an appeal from the Contracting Officer's final decision, it may withhold the funds in question until said appeal is decided. In the event that the decision on appeal is that the Government is entitled to a refund, such refund shall be made within thirty days from the date of the decision, with accrued interest at the rate determined by the Secretary of the Treasury pursuant to Public Law 92-41, 85 Stat. 97 from the date of the contractor's receipt of the Contracting Officer's final decision.

ARTICLE XV - COOPERATION IN PROCESSING AND DEFENSE OF CLAIMS AND SUITS:

A. Pursuant to the provisions of provisions of P.L. 94-380, the contractor shall cooperate with the Government in the processing or defense of any claim or suit brought against the United States under the Federal Tort Claims Act based upon alleged acts or omissions of the contractor.

B. While any such claim is under consideration by the Department of Health, Education, and Welfare's Claims Officer, the contractor shall furnish information requested by the Claims Officer or his representatives as is reasonably necessary to enable the claim to be considered and determined.

C. Should any action be filed against the United States under the Federal Tort Claims Act based upon alleged acts or omissions of the contractor, the contractor shall render all reasonable cooperation to the Government in the defense of such action as may be requested by the Department of Justice or cognizant United States Attorney. Such cooperation shall include, where appropriate, making records and personnel of the contractor available for pretrial proceedings and for the trial of the action.

ARTICLE XVI - LIMITATION OF GOVERNMENT'S LIABILITY:

The contractor is not authorized to make expenditures or to incur obligations, in performance of this contract, which exceeds $12,000,000.00 In the event of a termination of this contract, the Government's liability shall not exceed $12,000,000.00

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ARTICLE XVII- GENERAL PROVISIONS AND ALTERATIONS:

The General Provisions (SF-32), April 1975 edition are hereby incorporated in this contract, and are altered as follows:

a. Clause 21a, Small Business Subcontracting Program, is applicable if this contract exceeds $500,000.00.

b. Clause 22a, Labor Surplus Area Subcontracting Program, is applicable if this contract exceeds $500,000.00

c. The attached clauses, listed below, are added to and made a part of the General Provisions:

A. Listing of Employment Openings
B. Minority Business Enterprises Subcontracting Program
C. Unsolicited Samples, Descriptive Literature, or Brand Name Reference
D. Examination of Records by Department of Health, Education, and Welfare
E. Federal, State, and Local Taxes, HEW-328
F. Employment of the Handicapped
G. Termination for Convenience
H. Price Reduction for Defective Cost or Pricing Data
I. Subcontracting Cost or Pricing Data
J. Audit
K. Accounts, Audits, and Records
L. Disclosure Statement - Cost Accounting Practices and Certification
M. Cost Accounting Standards
N. Cost Accounting Standards - Exemption for Contracts of $500,000.00 or Less - Certifications
O. Preaward Equal Opportunity Compliance Reviews
P. Clean Air and Water
Q. Equal Opportunity Clause

ARTICLE XVIII - CONTRACTOR'S PRODUCTS LIABILITY INSURANCE

The contractor shall have no obligation to deliver vaccine hereunder unless the contractor is able to obtain and participate in a products liability insurance program covering influenza vaccine to be delivered to the Government which shall include $2,500,000 of self-insurance, $5,000,000 of primary insurance, and a sharing in pooled excess insurance with other influenza vaccine manufacturers to an aggregate limit of not less than $50,000,000 per manufacturer.

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AVAILABILITY SCHEDULE

Bivalent vaccine - each 0.5 ml./dose contains
200 CCA units of A/New Jersey/76 (Swine)
and 200 CCA units of A/Victoria/3/75
Bivalent 50-dose vials

Week of:	Doses Available:
10-1-76	1.2 mil
10-4-76	1.2 mil
10-11-76	800,000
10-18-76	1.2 mil
10-25-76	1.2 mil
11-1-76	800,000
11-8-76	1.2 mil
11-15-76	1.2 mil
	8.8 mil

Monovalent vaccine-each 0.5 ml. dose contains
200 CCA units of A/New Jersey/76 (Swine)

Monolvalent 50-dose vials

Contractor shall use all reasonable efforts to deliver an estimated 5,000,000 doses prior to January 15, 1977. Contractor shall notify the Government regarding availability when such information is known.

GENERAL PROVISIONS

(Supply Contract)

1. DEFINITIONS

As used throughout this contract, the following terms shall have the meaning set forth below:

(a) The term "head of the agency" or "Secretary" as used herein means the Secretary, the Under Secretary, any Assistant Secretary, or any other head or assistant head of the executive or military department or other Federal agency; and the term "his duly authorized representative" means any person or persons or board (other than the Contracting Officer) authorized to act for the head of the agency or the Secretary.

(b) The term "Contracting Officer" means the person executing this contract on behalf of the Government, and any other officer or civilian employee who is a properly designated Contracting Officer; and the term includes, except as otherwise provided in this contract, the authorized representative of a Contracting Officer acting within the limits of his authority.

(c) Except as otherwise provided in this contract, the term "subcontracts" includes purchase orders under this contract.

2. CHANGES

The Contracting Officer may at any time, by a written order, and without notice to the sureties, make changes, within the general scope of this contract, in any one or more of the following: (i) Drawings, designs, or specifications, where the supplies to be furnished are to be specially manufactured for the Government in accordance therewith; (ii) method of shipment or packing; and (iii) place of delivery. If any such change causes an increase or decrease in the cost of, or the time required for, the performance of any part of the work under this contract, whether changed or not changed by any such order, an equitable adjustment shall be made in the contract price or delivery schedule, or both, and the contract shall be modified in writing accordingly. Any claim by the Contractor for adjustment under this clause must be asserted within 30 days from the date of receipt by the Contractor of the notification of change: *Provided, however*, That the Contracting Officer, if he decides that the facts justify such action, may receive and act upon any such claim asserted at any time prior to final payment under this contract. Where the cost of property made obsolete or excess as a result of a change is included in the Contractor's claim for adjustment, the Contracting Officer shall have the right to prescribe the manner of disposition of such property. Failure to agree to any adjustment shall be a dispute concerning a question of fact within the meaning of the clause of this contract entitled "Disputes." However, nothing in this clause shall excuse the Contractor from proceeding with the contract as changed.

3. EXTRAS

Except as otherwise provided in this contract, no payment for extras shall be made unless such extras and the price therefor have been authorized in writing by the Contracting Officer.

4. VARIATION IN QUANTITY

No variation in the quantity of any item called for by this contract will be accepted unless such variation has been caused by conditions of loading, shipping, or packing, or allowances in manufacturing processes, and then only to the extent, if any, specified elsewhere in this contract.

5. INSPECTION

(a) All supplies (which term throughout this clause includes without limitation raw materials, components, intermediate assemblies, and end products) shall be subject to inspection and test by the Government, to the extent practicable at all times and places including the period of manufacture, and in any event prior to acceptance.

(b) In case any supplies or lots of supplies are defective in material or workmanship or otherwise not in conformity with the requirements of this contract, the Government shall have the right either to reject them (with or without instructions as to their disposition) or to require their correction. Supplies or lots of supplies which have been rejected or required to be corrected shall be removed or, if permitted or required by the Contracting Officer, corrected in place by and at the expense of the Contractor promptly after notice, and shall not thereafter be tendered for acceptance unless the former rejection or requirement of correction is disclosed. If the Contractor fails promptly to remove such supplies or lots of supplies which are required to be removed, or promptly to replace or correct such supplies or lots of supplies, the Government either (i) may by contract or otherwise replace or correct such supplies and charge to the Contractor the cost occasioned the Government thereby, or (ii) may terminate this contract for default as provided in the clause of this contract entitled "Default." Unless the Contractor corrects or replaces such supplies within the delivery schedule, the Contracting Officer may require the delivery of such supplies at a reduction in price which is equitable under the circumstances. Failure to agree to such reduction of price shall be a dispute concerning a question of fact within the meaning of the clause of this contract entitled "Disputes."

(c) If any inspection or test is made by the Government on the premises of the Contractor or a subcontractor, the Contractor without additional charge shall provide all reasonable facilities and assistance for the safety and convenience of the Government inspectors in the performance of their duties. If Government inspection or test is made at a point other than the premises of the Contractor or a subcontractor, it shall be at the expense of the Government except as otherwise provided in this contract: *Provided*, That in case of rejection the Government shall not be liable for any reduction in value of samples used in connection with such inspection or test. All inspections and tests by the Government shall be performed in such a manner as not to unduly delay the work. The Government reserves the right to charge to the Contractor any additional cost of Government inspection and test when supplies are not ready at the time such inspection and test is requested by the Contractor or when reinspection or retest is necessitated by prior rejection. Acceptance or rejection of the supplies shall be made as promptly as practicable after delivery, except as otherwise provided in this contract; but failure to inspect and accept or reject supplies shall neither relieve the Contractor from responsibility for such supplies as are not in accordance with the contract requirements nor impose liability on the Government therefor.

(d) The inspection and test by the Government of any supplies or lots thereof does not relieve the Contractor from any responsibility regarding defects or other failures to meet the contract requirements which may be discovered prior to acceptance. Except as otherwise provided in this contract, acceptance shall be conclusive except as regards latent defects, fraud, or such gross mistakes as amount to fraud.

(e) The Contractor shall provide and maintain an inspection system acceptable to the Government covering the supplies hereunder. Records of all inspection work by the Contractor shall be kept complete and available to the Government during

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the performance of this contract and for such longer period as may be specified elsewhere in this contract.

6. RESPONSIBILITY FOR SUPPLIES

Except as otherwise provided in this contract, (i) the Contractor shall be responsible for the supplies covered by this contract until they are delivered at the designated delivery point, regardless of the point of inspection; (ii) after delivery to the Government at the designated point and prior to acceptance by the Government or rejection and giving notice thereof by the Government, the Government shall be responsible for the loss or destruction of or damage to the supplies only if such loss, destruction, or damage results from the negligence of officers, agents, or employees of the Government acting within the scope of their employment; and (iii) the Contractor shall bear all risks as to rejected supplies after notice of rejection, except that the Government shall be responsible for the loss, or destruction of, or damage to the supplies only if such loss, destruction or damage results from the gross negligence of officers, agents, or employees of the Government acting within the scope of their employment.

7. PAYMENTS

The Contractor shall be paid, upon the submission of proper invoices or vouchers, the prices stipulated herein for supplies delivered and accepted or services rendered and accepted, less deductions, if any, as herein provided. Unless otherwise specified, payment will be made on partial deliveries accepted by the Government when the amount due on such deliveries so warrants; or, when requested by the Contractor, payment for accepted partial deliveries shall be made whenever such payment would equal or exceed either $1,000 or 50 percent of the total amount of this contract.

8. ASSIGNMENT OF CLAIMS

(a) Pursuant to the provisions of the Assignment of Claims Act of 1940, as amended (31 U.S.C. 203, 41 U.S.C. 15), if this contract provides for payments aggregating $1,000 or more, claims for moneys due or to become due the Contractor from the Government under this contract may be assigned to a bank, trust company, or other financing institution, including any Federal lending agency, and may thereafter be further assigned and reassigned to any such institution. Any such assignment or reassignment shall cover all amounts payable under this contract and not already paid, and shall not be made to more than one party, except that any such assignment or reassignment may be made to one party as agent or trustee for two or more parties participating in such financing. Unless otherwise provided in this contract, payments to an assignee of any moneys due or to become due under this contract shall not, to the extent provided in said Act, as amended, be subject to reduction or setoff. (The preceding sentence applies only if this contract is made in time of war or national emergency as defined in said Act and is with the Department of Defense, the General Services Administration, the Energy Research and Development Administration, the National Aeronautics and Space Administration, the Federal Aviation Administration, or any other department or agency of the United States designated by the President pursuant to Clause 4 of the proviso of section 1 of the Assignment of Claims Act of 1940, as amended by the Act of May 15, 1951, 65 Stat. 41.)

(b) In no event shall copies of this contract or of any plans, specifications, or other similar documents relating to work under this contract, if marked "Top Secret," "Secret," or "Confidential," be furnished to any assignee of any claim arising under this contract or to any other person not entitled to receive the same. However, a copy of any part or all of this contract so marked may be furnished, or any information contained therein may be disclosed, to such assignee upon the prior written authorization of the Contracting Officer.

9. ADDITIONAL BOND SECURITY

If any surety upon any bond furnished in connection with this contract becomes unacceptable to the Government or if any such surety fails to furnish reports as to his financial condition from time to time as requested by the Government, the Contractor shall promptly furnish such additional security as may be required from time to time to protect the interests of the Government and of persons supplying labor or materials in the prosecution of the work contemplated by this contract.

10. EXAMINATION OF RECORDS BY COMPTROLLER GENERAL

(a) This clause is applicable if the amount of this contract exceeds $10,000 and was entered into by means of negotiation, including small business restricted advertising, but is not applicable if this contract was entered into by means of formal advertising.

(b) The Contractor agrees that the Comptroller General of the United States or any of his duly authorized representatives shall, until the expiration of 3 years after final payment under this contract or such lesser time specified in either Appendix M of the Armed Services Procurement Regulation or the Federal Procurement Regulations Part 1-20, as appropriate, have access to and the right to examine any directly pertinent books, documents, papers, and records of the Contractor involving transactions related to this contract.

(c) The Contractor further agrees to include in all his subcontracts hereunder a provision to the effect that the subcontractor agrees that the Comptroller General of the United States or any of his duly authorized representatives shall, until the expiration of 3 years after final payment under the subcontract or such lesser time specified in either Appendix M of the Armed Services Procurement Regulation or the Federal Procurement Regulations Part 1-20, as appropriate, have access to and the right to examine any directly pertinent books, documents, papers, and records of such subcontractor, involving transactions related to the subcontract. The term "subcontract" as used in this clause excludes (1) purchase orders not exceeding $10,000 and (2) subcontracts or purchase orders for public utility services at rates established for uniform applicability to the general public.

(d) The periods of access and examination described in (b) and (c), above, for records which relate to (1) appeals under the "Disputes" clause of this contract, (2) litigation or settlement of claims arising out of the performance of this contract, or (3) costs and expenses of this contract as to which exception has been taken by the Comptroller General or any of his duly authorized representatives, shall continue until such appeals, litigation, claims, or exceptions have been disposed of.

11. DEFAULT

(a) The Government may, subject to the provisions of paragraph (c) below, by written notice of default to the Contractor, terminate the whole or any part of this contract in any one of the following circumstances:

(i) If the Contractor fails to make delivery of the supplies or to perform the services within the time specified herein or any extension thereof; or

(ii) If the Contractor fails to perform any of the other provisions of this contract, or so fails to make progress as to endanger performance of this contract in accordance with its terms, and in either of these two circumstances does not cure such failure within a period of 10 days (or such longer period as the Contracting Officer may authorize in writing) after receipt of notice from the Contracting Officer specifying such failure.

(b) In the event the Government terminates this contract in whole or in part as provided in paragraph (a) of this clause, the Government may procure, upon such terms and in such manner as the Contracting Officer may deem appropriate, supplies or services similar to those so terminated, and the Contractor shall be liable to the Government for any excess costs for such similar supplies or services: Provided, That the Contractor shall continue the performance of this contract to the extent not terminated under the provisions of this clause.

(c) Except with respect to defaults of subcontractors, the

Contractor shall not be liable for any excess costs if the failure to perform the contract arises out of causes beyond the control and without the fault or negligence of the Contractor. Such causes may include, but are not restricted to, acts of God or of the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, freight embargoes, and unusually severe weather; but in every case the failure to perform must be beyond the control and without the fault or negligence of the Contractor. If the failure to perform is caused by the default of a subcontractor, and if such default arises out of causes beyond the control of both the Contractor and subcontractor, and without the fault or negligence of either of them, the Contractor shall not be liable for any excess costs for failure to perform, unless the supplies or services to be furnished by the subcontractor were obtainable from other sources in sufficient time to permit the Contractor to meet the required delivery schedule.

(d) If this contract is terminated as provided in paragraph (a) of this clause, the Government, in addition to any other rights provided in this clause, may require the Contractor to transfer title and deliver to the Government, in the manner and to the extent directed by the Contracting Officer, (i) any completed supplies, and (ii) such partially completed supplies and materials, parts, tools, dies, jigs, fixtures, plans, drawings, information, and contract rights (hereinafter called "manufacturing materials") as the Contractor has specifically produced or specifically acquired for the performance of such part of this contract as has been terminated; and the Contractor shall, upon direction of the Contracting Officer, protect and preserve property in possession of the Contractor in which the Government has an interest. Payment for completed supplies delivered to and accepted by the Government shall be at the contract price. Payment for manufacturing materials delivered to and accepted by the Government and for the protection and preservation of property shall be in an amount agreed upon by the Contractor and Contracting Officer; failure to agree to such amount shall be a dispute concerning a question of fact within the meaning of the clause of this contract entitled "Disputes." The Government may withhold from amounts otherwise due the Contractor for such completed supplies or manufacturing materials such sum as the Contracting Officer determines to be necessary to protect the Government against loss because of outstanding liens or claims of former lien holders.

(e) If, after notice of termination of this contract under the provisions of this clause, it is determined for any reason that the Contractor was not in default under the provisions of this clause, or that the default was excusable under the provisions of this clause, the rights and obligations of the parties shall, if the contract contains a clause providing for termination for convenience of the Government, be the same as if the notice of termination had been issued pursuant to such clause. If, after notice of termination of this contract under the provisions of this clause, it is determined for any reason that the Contractor was not in default under the provisions of this clause, and if this contract does not contain a clause providing for termination for convenience of the Government, the contract shall be equitably adjusted to compensate for such termination and the contract modified accordingly; failure to agree to any such adjustment shall be a dispute concerning a question of fact within the meaning of the clause of this contract entitled "Disputes."

(f) The rights and remedies of the Government provided in this clause shall not be exclusive and are in addition to any other rights and remedies provided by law or under this contract.

(g) As used in paragraph (c) of this clause, the terms "subcontractor" and "subcontractors" mean subcontractor(s) at any tier.

12. DISPUTES

(a) Except as otherwise provided in this contract, any dispute concerning a question of fact arising under this contract which is not disposed of by agreement shall be decided by the Contracting Officer, who shall reduce his decision to writing and mail or otherwise furnish a copy thereof to the Contractor. The decision of the Contracting Officer shall be final and conclusive unless, within 30 days from the date of receipt of such copy, the Contractor mails or otherwise furnishes to the Contracting Officer a written appeal addressed to the Secretary. The decision of the Secretary or his duly authorized representative for the determination of such appeals shall be final and conclusive unless determined by a court of competent jurisdiction to have been fraudulent, or capricious, or arbitrary, or so grossly erroneous as necessarily to imply bad faith, or not supported by substantial evidence. In connection with any appeal proceeding under this clause, the Contractor shall be afforded an opportunity to be heard and to offer evidence in support of its appeal. Pending final decision of a dispute hereunder, the Contractor shall proceed diligently with the performance of the contract and in accordance with the Contracting Officer's decision.

(b) This "Disputes" clause does not preclude consideration of law questions in connection with decisions provided for in paragraph (a) above: *Provided*, That nothing in this contract shall be construed as making final the decision of any administrative official, representative, or board on a question of law.

13. NOTICE AND ASSISTANCE REGARDING PATENT AND COPYRIGHT INFRINGEMENT

The provisions of this clause shall be applicable only if the amount of this contract exceeds $10,000.

(a) The Contractor shall report to the Contracting Officer, promptly and in reasonable written detail, each notice or claim of patent or copyright infringement based on the performance of this contract of which the Contractor has knowledge.

(b) In the event of any claim or suit against the Government on account of any alleged patent or copyright infringement arising out of the performance of this contract or out of the use of any supplies furnished or work or services performed hereunder, the Contractor shall furnish to the Government, when requested by the Contracting Officer, all evidence and information in possession of the Contractor pertaining to such suit or claim. Such evidence and information shall be furnished at the expense of the Government except where the Contractor has agreed to indemnify the Government.

14. BUY AMERICAN ACT

(a) In acquiring end products, the Buy American Act (41 U.S. Code 10 a–d) provides that the Government give preference to domestic source end products. For the purpose of this clause:

(i) "Components" means those articles, materials, and supplies, which are directly incorporated in the end products;

(ii) "End products" means those articles, materials, and supplies, which are to be acquired under this contract for public use; and

(iii) A "domestic source end product" means (A) an unmanufactured end product which has been mined or produced in the United States and (B) an end product manufactured in the United States if the cost of the components thereof which are mined, produced, or manufactured in the United States exceeds 50 percent of the cost of all its components. For the purposes of this (a) (iii) (B), components of foreign origin of the same type or kind as the products referred to in (b) (ii) or (iii) of this clause shall be treated as components mined, produced, or manufactured in the United States.

(b) The Contractor agrees that there will be delivered under this contract only domestic source end products, except end products:

(i) Which are for use outside the United States;

(ii) Which the Government determines are not mined, produced, or manufactured in the United States in sufficient and reasonably available commercial quantities and of a satisfactory quality;

(iii) As to which the Secretary determines the domestic preference to be inconsistent with the public interest; or

(iv) As to which the Secretary determines the cost to the Government to be unreasonable.

(The foregoing requirements are administered in accordance with Executive Order No. 10582, dated December 17, 1954.)

15. CONVICT LABOR

In connection with the performance of work under this contract, the Contractor agrees not to employ any person undergoing sentence of imprisonment at hard labor except as provided by Public Law 89-176, September 10, 1965 (18 U.S.C. 4082(c)(2)) and Executive Order 11755, December 29, 1973.

16. CONTRACT WORK HOURS AND SAFETY STANDARDS ACT—OVERTIME COMPENSATION

This contract, to the extent that it is of a character specified in the Contract Work Hours and Safety Standards Act (40 U.S.C. 327-333), is subject to the following provisions and to all other applicable provisions and exceptions of such Act and the regulations of the Secretary of Labor thereunder.

(a) Overtime requirements. No Contractor or subcontractor contracting for any part of the contract work which may require or involve the employment of laborers, mechanics, apprentices, trainees, watchmen, and guards shall require or permit any laborer, mechanic, apprentice, trainee, watchman, or guard in any workweek in which he is employed on such work to work in excess of eight hours in any calendar day or in excess of forty hours in such workweek on work subject to the provisions of the Contract Work Hours and Safety Standards Act unless such laborer, mechanic, apprentice, trainee, watchman, or guard receives compensation at a rate not less than one and one-half times his basic rate of pay for all such hours worked in excess of eight hours in any calendar day or in excess of forty hours in such workweek, whichever is the greater number of overtime hours.

(b) Violation; liability for unpaid wages; liquidated damages. In the event of any violation of the provisions of paragraph (a), the Contractor and any subcontractor responsible therefor shall be liable to any affected employee for his unpaid wages. In addition, such Contractor and subcontractor shall be liable to the United States for liquidated damages. Such liquidated damages shall be computed with respect to each individual laborer, mechanic, apprentice, trainee, watchman, or guard employed in violation of the provisions of paragraph (a) in the sum of $10 for each calendar day on which such employee was required or permitted to be employed on such work in excess of eight hours or in excess of his standard workweek of forty hours without payment of the overtime wages required by paragraph (a).

(c) Withholding for unpaid wages and liquidated damages. The Contracting Officer may withhold from the Government Prime Contractor, from any moneys payable on account of work performed by the Contractor or subcontractor, such sums as may administratively be determined to be necessary to satisfy any liabilities of such Contractor or subcontractor for unpaid wages and liquidated damages as provided in the provisions of paragraph (b).

(d) Subcontracts. The Contractor shall insert paragraphs (a) through (d) of this clause in all subcontracts, and shall require their inclusion in all subcontracts of any tier.

(e) Records. The Contractor shall maintain payroll records containing the information specified in 29 CFR 516.2(a). Such records shall be preserved for three years from the completion of the contract.

17. WALSH-HEALEY PUBLIC CONTRACTS ACT

If this contract is for the manufacture or furnishing of materials, supplies, articles, or equipment in an amount which exceeds or may exceed $10,000 and is otherwise subject to the Walsh-Healey Public Contracts Act, as amended (41 U.S. Code 35-45), there are hereby incorporated by reference all representations and stipulations required by said Act and regulations issued thereunder by the Secretary of Labor, such representations and stipulations being subject to all applicable rulings and interpretations of the Secretary of Labor which are now or may hereafter be in effect.

18. EQUAL OPPORTUNITY

(The following clause is applicable unless this contract is exempt under the rules, regulations, and relevant orders of the Secretary of Labor (41 CFR, ch. 60).)

During the performance of this contract, the Contractor agrees as follows:

(a) The Contractor will not discriminate against any employee or applicant for employment because of race, color, religion, sex, or national origin. The Contractor will take affirmative action to ensure that applicants are employed, and that employees are treated during employment, without regard to their race, color, religion, sex, or national origin. Such action shall include, but not be limited to, the following: Employment, upgrading, demotion, or transfer; recruitment or recruitment advertising; layoff or termination; rates of pay or other forms of compensation; and selection for training, including apprenticeship. The Contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices to be provided by the Contracting Officer setting forth the provisions of this Equal Opportunity clause.

(b) The Contractor will, in all solicitations or advertisements for employees placed by or on behalf of the Contractor, state that all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, or national origin.

(c) The Contractor will send to each labor union or representative of workers with which he has a collective bargaining agreement or other contract or understanding, a notice, to be provided by the agency Contracting Officer, advising the labor union or workers' representative of the Contractor's commitments under this Equal Opportunity clause, and shall post copies of the notice in conspicuous places available to employees and applicants for employment.

(d) The Contractor will comply with all provisions of Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, and of the rules, regulations, and relevant orders of the Secretary of Labor.

(e) The Contractor will furnish all information and reports required by Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, and by the rules, regulations, and orders of the Secretary of Labor, or pursuant thereto, and will permit access to his books, records, and accounts by the contracting agency and the Secretary of Labor for purposes of investigation to ascertain compliance with such rules, regulations, and orders.

(f) In the event of the Contractor's noncompliance with the Equal Opportunity clause of this contract or with any of the said rules, regulations, or orders, this contract may be canceled, terminated, or suspended, in whole or in part, and the Contractor may be declared ineligible for further Government contracts in accordance with procedures authorized in Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, and such other sanctions may be imposed and remedies invoked as provided in Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, or by rule, regulation, or order of the Secretary of Labor, or as otherwise provided by law.

(g) The Contractor will include the provisions of paragraphs (a) through (g) in every subcontract or purchase order unless exempted by rules, regulations, or orders of the Secretary of Labor issued pursuant to section 204 of Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, so that such provisions will be binding upon each subcontractor or vendor. The Contractor will take such action with respect to any subcontract or purchase order as the contracting agency may direct as a means of enforcing such provisions, including sanctions for noncompliance: Provided, however, That in the event the Contractor becomes involved in,

or is threatened with, litigation with a subcontractor or vendor as a result of such direction by the contracting agency, the Contractor may request the United States to enter into such litigation to protect the interests of the United States.

19. Officials Not To Benefit

No member of or delegate to Congress, or resident Commissioner, shall be admitted to any share or part of this contract, or to any benefit that may arise therefrom; but this provision shall not be construed to extend to this contract if made with a corporation for its general benefit.

20. Covenant Against Contingent Fees

The Contractor warrants that no person or selling agency has been employed or retained to solicit or secure this contract upon an agreement or understanding for a commission, percentage, brokerage, or contingent fee, excepting bona fide employees or bona fide established commercial or selling agencies maintained by the Contractor for the purpose of securing business. For breach or violation of this warranty the Government shall have the right to annul this contract without liability or in its discretion to deduct from the contract price or consideration, or otherwise recover, the full amount of such commission, percentage, brokerage, or contingent fee.

21. Utilization of Small Business Concerns

(a) It is the policy of the Government as declared by the Congress that a fair proportion of the purchases and contracts for supplies and services for the Government be placed with small business concerns.

(b) The Contractor agrees to accomplish the maximum amount of subcontracting to small business concerns that the Contractor finds to be consistent with the efficient performance of this contract.

22. Utilization of Labor Surplus Area Concerns

(a) It is the policy of the Government to award contracts to labor surplus area concerns that (1) have been certified by the Secretary of Labor (hereafter referred to as certified-eligible concerns with first or second preferences) regarding the employment of a proportionate number of disadvantaged individuals and have agreed to perform substantially (i) in or near sections of concentrated unemployment or underemployment or in persistent or substantial labor surplus areas or (ii) in other areas of the United States, respectively, or (2) are noncertified concerns which have agreed to perform substantially in persistent or substantial labor surplus areas, where this can be done consistent with the efficient performance of the contract and at prices no higher than are obtainable elsewhere. The Contractor agrees to use his best efforts to place his subcontracts in accordance with this policy.

(b) In complying with paragraph (a) of this clause and with paragraph (b) of the clause of this contract entitled "Utilization of Small Business Concerns" the Contractor in placing his subcontracts shall observe the following order of preference: (1) Certified-eligible concerns with a first preference which are also small business concerns; (2) other certified-eligible concerns with a first preference; (3) certified-eligible concerns with a second preference which are also small business concerns; (4) other certified-eligible concerns with a second preference; (5) persistent or substantial labor surplus area concerns which are also small business concerns; (6) other persistent or substantial labor surplus area concerns; and (7) small business concerns which are not labor surplus area concerns.

23. Utilization of Minority Business Enterprises

(a) It is the policy of the Government that minority business enterprises shall have the maximum practicable opportunity to participate in the performance of Government contracts.

(b) The Contractor agrees to use his best efforts to carry out this policy in the award of his subcontracts to the fullest extent consistent with the efficient performance of this contract. As used in this contract, the term "minority business enterprise" means a business, at least 50 percent of which is owned by minority group members or, in case of publicly-owned businesses, at least 51 percent of the stock of which is owned by minority group members. For the purposes of this definition, minority group members are Negroes, Spanish-speaking American persons, American-Orientals, American-Indians, American-Eskimos, and American Aleuts. Contractors may rely on written representations by subcontractors regarding their status as minority business enterprises in lieu of an independent investigation.

24. Pricing of Adjustments

When costs are a factor in any determination of a contract price adjustment pursuant to the Changes clause or any other provision of this contract, such costs shall be in accordance with the contract cost principles and procedures in Part 1-15 of the Federal Procurement Regulations (41 CFR 1-15) or Section XV of the Armed Services Procurement Regulation, as applicable, which are in effect on the date of this contract.

25. Payment of Interest on Contractors' Claims

(a) If an appeal is filed by the Contractor from a final decision of the Contracting Officer under the Disputes clause of this contract, denying a claim arising under the contract, simple interest on the amount of the claim finally determined owed by the Government shall be payable to the Contractor. Such interest shall be at the rate determined by the Secretary of the Treasury pursuant to Public Law 92-41, 85 Stat. 97, from the date the Contractor furnishes to the Contracting Officer his written appeal under the Disputes clause of this contract, to the date of (1) a final judgment by a court of competent jurisdiction, or (2) mailing to the Contractor of a supplemental agreement for execution either confirming completed negotiations between the parties or carrying out a decision of a board of contract appeals.

(b) Notwithstanding (a), above, (1) interest shall be applied only from the date payment was due, if such date is later than the filing of appeal, and (2) interest shall not be paid for any period of time that the Contracting Officer determines the Contractor has unduly delayed in pursuing his remedies before a board of contract appeals or a court of competent jurisdiction.

Clause 21(a) SMALL BUSINESS SUBCONTRACTING PROGRAM

FPR 1-1.710-3(b)

(a) The Contractor agrees to establish and conduct a small business subcontracting program which will enable small business concerns to be considered fairly as subcontractors and suppliers under this contract. In this connection, the Contractor shall:

(1) Designate a liaison officer who will (i) maintain liaison with the Government on small business matters, (ii) supervise compliance with the Utilization of Small Business Concerns clause, and (iii) administer the Contractor's "Small Business Subcontracting Program."

(2) Provide adequate and timely consideration of the potentialities of small business concerns in all "make-or-buy" decisions.

(3) Assure that small business concerns will have an equitable opportunity to compete for subcontracts, particularly by arranging solicitations, time for the preparation of bids, quantities, specifications, and delivery schedules so as to facilitate the participation of small business concerns. Where the Contractor's lists of potential small business subcontractors are excessively long, reasonable effort shall be made to give all such small business concerns an opportunity to compete over a period of time.

(4) Maintain records showing (i) whether each prospective subcontractor is a small business concern, (ii) procedures which have been adopted to comply with the policies set forth in this clause, and (iii) with respect to the letting of any subcontract (including purchase orders) exceeding $10,000, information substantially as follows:

(A) Whether the award went to large or small business.

(B) Whether less than three or more than two small business firms were solicited.

(C) The reason for nonsolicitation of small business if such was the case.

(D) The reason for small business failure to receive the award if such was the case when small business was solicited.

The records maintained in accordance with (iii) above may be in such form as the Contractor may determine, and the information shall be summarized quarterly and submitted by the purchasing department of each individual plant or division to the Contractor's cognizant small business liaison officer. Such quarterly summaries will be considered to be management records only and need not be submitted routinely to the Government; however, records maintained pursuant to this clause will be kept available for review by the Government until the expiration of 1 year after the award of this contract, or for such longer period as may be required by any other clause of this contract or by applicable law or regulation.

(5) Notify the Contracting Officer before soliciting bids or quotations on any subcontract (including purchase orders) in excess of $10,000 if (i) no small business concern is to be solicited, and (ii) the Contracting Officer's consent to the subcontract (or ratification) is required by a "Subcontracts" clause in this contract. Such notice will state the Contractor's reasons for non-solicitation of small business concerns, and will be given as early in the procurement cycle as possible so that the Contracting Officer may give SBA timely notice to permit SBA a reasonable period to suggest potentially qualified small business concerns through the Contracting Officer. In no case will the procurement action be held up when to do so would, in the Contractor's judgment, delay performance under the contract.

(6) Include the Utilization of Small Business Concerns clause in subcontracts which offer substantial small business subcontracting opportunities.

(7) Cooperate with the Contracting Officer in any studies and surveys of the Contractor's subcontracting procedures and practices that the Contracting Officer may from time to time conduct.

(8) Submit quarterly reports of subcontracting to small business concerns on either Optional Form 61, Small Business Subcontracting Program Quarterly Report of Participating Large Company on Subcontract Committments to Small Business Concerns, or such other form as may be specified in the contract. Except as otherwise provided in this contract, the reporting requirements of this subparagraph (8) do not apply to small business contractors, small business subcontractors, educational and nonprofit institutions, and contractors or subcontractors for standard commercial items.

(b) A "small business concern" is a concern that meets the pertinent criteria established by the Small Business Administration and set forth in § 1-701 of the Federal Procurement Regulations.

(c) The Contractor agrees that, in the event he fails to comply with his contractual obligations concerning the small business subcontracting program, this contract may be terminated, in whole or in part, for default.

(d) The Contractor further agrees to insert, in any subcontract hereunder which may exceed $500,000 and which contains the Utilization of Small Business Concerns clause, provisions which shall conform substantially to the language of this clause, including this paragraph (d), and to notify the Contracting Officer of the names of such subcontractors.

Clause 22a

LABOR SURPLUS AREA SUBCONTRACTING PROGRAM

FPR 1-1.805-3(b)

(This clause is applicable if this contract exceeds $500,000.00)

(a) The Contractor agrees to establish and conduct a program which will encourage labor surplus area concerns to compete for subcontracts within their capabilities. In this connection, the Contractor shall:

(1) Designate a liaison officer who will (i) maintain liaison with duly authorized representatives of the Government on labor surplus area matters, (ii) supervise compliance with the Utilization of Concerns in Labor Surplus Areas clause, and (iii) administer the Contractor's "Labor Surplus Area Subcontracting Program";

(2) Provide adequate and timely consideration of the potentialities of labor surplus area concerns in all "make-or-buy" decisions;

(3) Assure that labor surplus area concerns will have an equitable opportunity to compete for subcontracts, particularly by arranging solicitations, time for the preparation of bids, quantities, specifications, and delivery schedules so as to facilitate the participation of labor surplus area concerns;

(4) Maintain records showing procedures which have been adopted to comply with the policies set forth in this clause. Records maintained pursuant to this clause will be kept available for review by the Government until the expiration of 1 year after the award of this contract, or for such longer period as may be required by any other clause of this contract or by applicable law or regulations; and

(5) Include the Utilization of Concerns in Labor Surplus Areas clause in subcontracts which offer substantial labor surplus area subcontracting opportunities.

(b) A "labor surplus area concern" is a concern that (i) has been certified by the Secretary of Labor (hereafter referred to as a certified-eligible concern) regarding the employment of a proportionate number of disadvantaged individuals and has agreed to perform substantially in or near sections of concentrated unemployment or underemployment, in persistent or substantial labor surplus

areas, or in other areas of the United States or (2) is a noncertified concern which has agreed to perform a substantial proportion of a contract in persistent or substantial labor surplus areas. A certified-eligible concern shall be deemed to have performed a substantial proportion of a contract in or near sections of concentrated unemployment or underemployment, in persistent or substantial labor surplus areas, or in other areas if the costs that the concern will incur on account of manufacturing or production in or near such sections or in such areas (by itself, if a certified concern, or by certified concerns acting as first-tier subcontractors) amount to more than 25 percent of the contract price. A concern shall be deemed to have performed a substantial proportion of a contract in persistent of substantial surplus areas (by itself or its first-tier subcontractors) if the costs that the concern will incur on account of production or manufacturing in such areas amount to more than 50 percent of the contract price.

(c) The Contractor further agrees to insert, in any subcontract hereunder which may exceed $500,000 and which contains the Utilization of Concerns in Labor Surplus Areas clause, provisions which shall conform substantially to the language of this clause, including this paragraph (c), and to notify the Contracting Officer of the names of such subcontractors.

Clause 24

PRICING OF ADJUSTMENTS

When costs are a factor in any determination of a contract price adjustment pursuant to the "Changes" clause or any other provision of this contract, such costs shall be in accordance with the contract cost and profit criteria contained in Appendix A of this contract.

MODIFICATIONS TO GENERAL PROVISIONS, STANDARD FORM 32 (Supply)

Disabled Veterans and Veterans of the Vietnam Era

(This clause is applicable pursuant to 41 CFR 50-250 if this contract is for $10,000 or more.)

(a) The contractor will not discriminate against any employee or applicant for employment because he or she is a disabled veteran or veteran of the Vietnam era in regard to any position for which the employee or applicant for employment is qualified. The contractor agrees to take affirmative action to employ, advance in employment, and otherwise treat qualified disabled veterans and veterans of the Vietnam era without discrimination based upon their disability or veterans status in all employment practices such as the following: employment upgrading, demotion or transfer, recruitment, advertising, layoff or termination, rates of pay or other forms of compensation, and selection for training, including apprenticeship.

(b) The contractor agrees that all suitable employment openings of the contractor which exist at the time of the execution of this contract and those which occur during the performance of this contract, including those not generated by this contract and including those occurring at an establishment of the contractor other than the one wherein the contract is being performed but excluding those of independently operated corporate affiliates, shall be listed at an appropriate local office of the State employment service system wherein the opening occurs. The contractor further agrees to provide such reports to such local office regarding employment openings and hires as may be required.

State and local government agencies holding Federal contracts of $10,000 or more shall also list all their suitable openings with the appropriate office of the State employment service, but are not required to provide those reports set forth in paragraphs (d) and (e).

(c) Listing of employment openings with the employment service system pursuant to this clause shall be made at least concurrently with the use of any other recruitment source or effort and shall involve the normal obligations which attache to the placing of a bona fide job order, including the acceptance of referrals of veterans and nonveterans. The listing of employment openings does not require the hiring of any particular job applicant or from any particular group of job applicants, and nothing herein is intended to relieve the contractor from any requirements in Executive orders or regulations regarding nondiscrimination in employment.

(d) The reports required by paragraph (b) of this clause shall include, but not be limited to, periodic reports which shall be filed at least quarterly with the appropriate local office or, where the contractor has more than one hiring location in a State, with the central office of that State employment service. Such reports shall indicate for each hiring location (a) the number of individuals hired during the reporting period, (2) the number of nondisabled veterans of the Vietnam era hired, (3) the number of disabled veterans of the Vietnam era hired, and (4) the total number of disabled veterans hired. The reports should include covered veterans hired for on-the-job training under

38 U.S.C. 1787. The contractor shall submit a report within 30 days after the end of each reporting period wherein any performance is made on this contract identifying data for each hiring location. The contractor shall maintain at each hiring location copies of the reports submitted until the expiration of one year after final payment under the contract during which time these reports and related documentation shall be made available, upon request, for examination by any authorized representatives of the Contracting Officer or of the Secretary of Labor. Documentation would include personnel records respecting job openings, recruitment, and placement.

(e) Whenever the contractor becomes contractually bound to the listing provisions of this clause, it shall advise the employment service system in each State where it has establishments of the name and location of each hiring location in the State. As long as the contractor is contractually bound to these provisions and has so advised the State system, there is no need to advise the State system of subsequent contracts. The contractor may advise the State system when it is no longer bound by this contract clause.

(f) This clause does not apply to the listing of employment openings which occur and are filled outside the 50 States, the District of Columbia, Puerto Rico, Guam, and the Virgin Islands.

(g) The provisions of paragraphs (b), (c), (d), and (e) of this clause do not apply to openings which the contractor proposes to fill from within his own organization or to fill pursuant to a customary and traditional employer-union hiring arrangement. This exclusion does not apply to a particular opening once an employer decides to consider applicants outside of his own organization or employer-union arrangement for that opening.

(h) As used in this clause: (1) "All suitable employment openings" includes, but is not limited to, openings which occur in the following job categories: production and non-production; plant and office; laborers and mechanics; supervisory and nonsupervisory; technical; and executive, administrative, and professional openings that are compensated on a salary basis of less than $25,000 per year. This term includes full-time employment, temporary employment of more than 3 days' duration, and part-time employment. It does not include openings which the contractor proposes to fill from within his own organization or to fill pursuant to a customary and traditional employer-union hiring arrangement nor openings in an educational institution which are restricted to students of that institution. Under the most compelling circumstances an employment opening may not be suitable for listing, including such situations where the needs of the Government cannot reasonably be otherwise supplies, where listing would be contrary to national security, or where the requirement of listing would otherwise not be for the best interest of the Government.

(2) "Appropriate office of the State employment service system" means the local office of the Federal/State national system of public employment offices with assigned responsibility for serving the area where the employment

opening is to be filled, including the Distric of Columbia, Guam, Puerto Rico, and the Virgin Islands.

(3) "Openings which the contractor proposes to fill from within his own organization" means employment openings for which no consideration will be given to persons outside the contractor's organization (including affiliates, subsidiaries, and the parent companies) and includes any openings which the contractor proposes to fill from regularly established "recall" lists.

(4) "Openings which the contractor proposes to fill pursuant to a customary and traditional employer-union hiring arrangement" means employment openings which the contractor proposes to fill from union halls, which is part of the customary and traditional hiring relationship which exists between the contractor and representatives of his employees.

(i) The contractor agrees to comply with the rules, regulations, and relevant orders of the Secretary of Labor issued pursuant to the Act.

(j) In the event of the contractor's noncompliance with the requirements of this clause, actions for noncompliance may be taken in accordance with the rules, regulations, and relevant orders of the Secretary of Labor issued pursuant to the Act.

(k) The contractor agrees to post in conspicuous places available to employees and applicants for employment notices in a form to be prescribed by the Director, provided by or through the Contracting Officer. Such notice shall state the contractor's obligation under the law to take affirmative action to employ and advance in employment qualified disabled veterans and veterans of the Vietnam era for employment, and the rights of applicants and employees.

(l) The contractor will notify each labor union or representative of workers with which it has a collective bargaining agreement or other contract understanding that the contractor is bound by terms of the Vietnam Era Veteran's Readjustment Assistance Act and is committed to take affirmative action to employ and advance in employment qualified disabled veterans and veterans of the Vietnam era.

(m) The contractor will include the provisions of this clause in every subcontract or purchase order of $10,000 or more unless exempted by rules, regulations, or orders of the Secretary issued pursuant to the Act, so that such provisions will be binding upon each subcontractor or vendor. The contractor will take such action with respect to any subcontract or purchase order as the Director of the Office of Federal Contract Compliance Programs may direct to enforce such provisions, including action for noncompliance.

MINORITY BUSINESS ENTERPRISES SUBCONTRACTING PROGRAM

FPR 1-1.1310-2(b)

(This clause is applicable if this contract exceeds $500,000.00.)

(a) The Contractor agrees to establish and conduct a program which will enable minority business enterprises (as defined in the clause entitled "Utilization of Minority Business Enterprises") to be considered fairly as subcontractors and suppliers under this contract. In this connection, the Contractor shall:

(1) Designate a liaison officer who will administer the Contractor's minority business enterprises program.

(2) Provide adequate and timely consideration of the potentialities of known minority business enterprises in all "make-or-buy" decisions.

(3) Assure that known minority business enterprises will have an equitable opportunity to compete for subcontracts, particularly by arranging solicitations, time for the preparation of bids, quantities, specifications, and delivery schedules so as to facilitate the participation of minority business enterprises.

(4) Maintain records showing (i) procedures which have been adopted to comply with the policies set forth in this clause, including the establishment of a source list of minority business enterprises on the source list, and (iii) specific efforts to identify and award contracts to minority business enterprises.

(5) Include the Utilization of Minority Business Enterprises clause in subcontracts which offer substantial minority business enterprises subcontracting opportunities.

(6) Cooperate with the Contracting Officer in any studies and surveys of the Contractor's minority business enterprises procedures and practices that the Contracting Officer may from time to time conduct.

(7) Submit periodic reports of subcontracting to known minority business enterprises with respect to the records referred to in subparagraph (4), above, in such form and manner and at such time (not more often than quarterly) as the Contracting Officer may prescribe.

(b) The Contractor further agrees to insert, in any subcontract hereunder which may exceed $500,000, provisions which shall conform substantially to the language of this clause, including this paragraph (b), and to notify the Contracting Officer of the names of such subcontractors.

ALTERATION TO SF-32, General Provisions

UNSOLICITED SAMPLES, DESCRIPTIVE LITERATURE, OR BRAND NAME REFERENCES:

Where procurement is effected under specifications or purchase descriptions (other than "brand name or equal") and the Government does not specifically request bid samples, descriptive literature, or references to brand names, models, or part numbers as an integral part of the bid, bids which are accompanied by any of the foregoing will be rejected unless it is clear from the bid or accompanying papers that the samples, descriptive literature, or references to brand names, models, or part numbers are not intended to qualify the bid and that the bidder proposes to furnish items fully in accordance with the specifications or purchase descriptions. Where offers contain unsolicited material such as samples, descriptive literature, or references to brand names, models, or part numbers, the Government will not be responsible in any way for determining whether the items which are offered meet the Government's requirements set forth in the applicable specifications or purchase descriptions.

EXAMINATION OF RECORDS BY DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE:
(Applicable to negotiated contracts only.)

The provisions of the clause included herein, entitled "Examination of Records by the Comptroller General," are extended to provide equal rights to duly authorized representatives of the Secretary or of the Contracting Officer.

ALTERATIONS TO SP-32, GENERAL PROVISIONS (Supply Contract)

(See Federal Procurement Regulations, Subpart 1-11.4 Regarding Use.)

FEDERAL, STATE AND LOCAL TAXES

(a) Except as may be otherwise provided in this contract, the contract price includes all applicable Federal, State, and local taxes and duties.

(b) Nevertheless, with respect to any Federal excise tax or duty on the transactions or property covered by this contract, if a statute, court decision, written ruling, or regulation takes effect after the contract date, and–

(1) Results in the Contractor being required to pay or bear the burden of any such Federal excise tax or duty or increase in the rate thereof which would not otherwise have been payable on such transactions or property, the contract price shall be increased by the amount of such tax or duty or rate increase: *Provided*, That the Contractor if requested by the Contracting Officer, warrants in writing that no amount for such newly imposed Federal excise tax or duty or rate increase was included in the contract price as a contingency reserve or otherwise; or

(2) Results in the Contractor not being required to pay or bear the burden of, or in his obtaining a refund or drawback of, any such Federal excise tax or duty which would otherwise have been payable on such transactions or property or which was the basis of an increase in the contract price, the contract price shall be decreased by the amount of the relief, refund, or drawback, or that amount shall be paid to Government, as directed by the Contracting Officer. The contract price shall be similarly decreased if the Contractor, through his fault or negligence or his failure to follow instructions of the Contracting Officer, is required to pay or bear the burden of, or does not obtain a refund or drawback of, any such Federal excise tax or duty.

(c) No adjustment pursuant to paragraph (b) above will be made under this contract unless the aggregate amount thereof is or may reasonably be expected to be over $100.

(d) As used in paragraph (b) above, the term "contract date" means the date set for the bid opening, or if this is a negotiated contract, the date of this contract. As to additional supplies or services procured by modification to this contract, the term "contract date" means the date of such modification.

(e) Unless there does not exist any reasonable basis to sustain an exemption, the Government, upon request of the Contractor, without further liability, agrees, except as otherwise provided in this contract, to furnish evidence appropriate to establish exemption from any tax which the Contractor warrants in writing was excluded from the contract price. In addition, the Contracting Officer may furnish evidence to establish exemption from any tax that may, pursuant to this clause, give rise to either an increase or decrease in the contract price. Except as otherwise provided in this contract, evidence appropriate to establish exemption from duties will be furnished only at the direction of the Contracting Officer.

(f) The Contractor shall promptly notify the Contracting Officer of matters which will result in either an increase or decrease in the contract price, and shall take action with respect thereto as directed by the Contracting Officer.

ALTERATION TO SF-32, GENERAL PROVISIONS

EMPLOYMENT OF THE HANDICAPPED

(a) The contractor will not discriminate against any employee or applicant for employment because of physical or mental handicap in regard to any position for which the employee or applicant for employment is qualified. The contractor agrees to take affirmative action to employ, advance in employment and otherwise treat qualified handicapped individuals without discrimination based upon their physicial or mental handicap in all employment practices such as the following: employment, upgrading, demotion or transfer, recruitment, advertising, layoff or termination, rates of pay or other forms of compensation, and selection for training, including apprenticeship.

(b) The contractor agrees to comply with the rules, regulations, and relevant orders of the Secretary of Labor issued pursuant to the Act.

(c) In the event of the contractor's noncompliance with the requirements of this clause, actions for noncompliance may be taken in accordance with the rules, regulations and relevant orders of the Secretary of Labor issued pursuant to the Act.

(d) The contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices in a form to be prescribed by the Director, provided by or through the Contracting Officer. Such notices shall state the contractor's obligation under the law to take affirmative action to employ and advance in employment qualified handicapped employees and applicants for employment, and the rights of applicants and employees.

(e) The contractor will notify each labor union or representative of workers with which it has a collective bargaining agreement or other contract understanding, that the contractor is bound by the terms of section 503 of the Rehabilitation Act of 1973, and is committed to take affirmative action to employ and advance in employment physically and mentally handicapped individuals.

(f) The contractor will include the provisions of this clause in every subcontract or purchase order of $2,500 or more unless exempted by rules, regulations, or orders of the Secretary issued pursuant to section 503 of the Act, so that such provisions will be binding upon each subcontractor or vendor. The contractor will take such action with respect to any subcontract or purchase order as the Director of the Office of Federal Contract Compliance Programs may direct to enforce such provisions, including action for noncompliance.

Revised 6/8/76

TERMINATION FOR CONVENIENCE
OF THE GOVERNMENT

(a) The performance of work under this contract may be terminated by the Government in accordance with this clause in whole, or from time to time in part, whenever the Contracting Officer shall determine that such termination is in the best interest of the Government. Any such termination shall be effected by delivery to the Contractor of a Notice of Termination specifying the extent to which performance of work under the contract is terminated, and the dates upon which such termination becomes effective.

(b) After receipt of a Notice of Termination, and except as otherwise directed by the Contracting Officer, the Contractor shall:

(1) Stop work under the contract on the date and to the extent specified in the Notice of Termination;

(2) Place no further orders or subcontracts for materials, services, or facilities, except as may be necessary for completion of such portion of the work under the contract as is not terminated;

(3) Terminate all orders and subcontracts to the extent that they relate to the performance of work terminated by the Notice of Termination;

(4) Assign to the Government, in the manner, at the times, and to the extent directed by the Contracting Officer, all of the right, title, and interest of the Contractor under the orders and subcontracts so terminated, in which case the Government shall have the right, in its discretion, to settle or pay any or all claims arising out of the termination of such orders and subcontracts;

(5) Settle all outstanding liabilities and all claims arising out of such termination of orders and subcontracts, with the approval or ratification of the Contracting Officer, to the extent he may require, which approval or ratification shall be final for all the purposes of this clause;

(6) Transfer title to the Government and deliver in the manner, at the times, and to the extent, if any, directed by the Contracting Officer, (i) the fabricated or unfabricated parts, work in process, completed work, supplies, and other material produced as a part of, or acquired in connection with the performance of, the work terminated by the Notice of Termination, and (ii) the completed or partially completed plans, drawings, information and other property which, if the contract had been completed, would have been required to be furnished to the Government;

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(7) Use his best efforts to sell, in the manner, at the times, to the extent, and at the price or prices directed or authorized by the Contracting Officer, any property of the types referred to in (6) above: Provided, however, that the Contractor (i) shall not be required to extend credit to any purchaser, and (ii) may acquire any such property under the conditions prescribed by and at a price or prices approved by the Contracting Officer: And provided further, that the proceeds of any such transfer or disposition shall be applied in reduction of any payments to be made by the Government to the Contractor under this contract or shall otherwise be credited to the price or cost of the work covered by this contract or paid in such other manner as the Contracting Officer may direct;

(8) Complete performance of such part of the work as shall not have been terminated by the Notice of Termination; and

(9) Take such action as may be necessary, or as the Contracting Officer may direct, for the protection and preservation of the property related to this contract which is in the possession of the Contractor and in which the Government has or may acquire an interest.

At any time after expiration of the plant clearance period, as defined in Subpart 1-8.1 of the Federal Procurement Regulations (41 CFR 1-8.1), as the definition may be amended from time to time, the Contractor may submit to the Contracting Officer a list, certified as to quantity and quality, of any or all items of termination inventory not previously disposed of, exclusive of items the disposition of which has been directed or authorized by the Contracting Officer, and may request the Government to remove such items or enter into a storage agreement covering them. Not later than fifteen (15) days thereafter, the Government will accept title to such items and remove them or enter into a storage agreement covering the same: Provided, that the list submitted shall be subject to verification by the Contracting Officer upon removal of the items or, if the items are stored, within forty-five (45) days from the date of submission of the list, and any necessary adjustment to correct the list as submitted shall be made prior to final settlement.

(c) After receipt of a Notice of Termination, the Contractor shall submit to the Contracting Officer his termination claim, in the form and with certification prescribed by the Contracting Officer. Such claim shall be submitted promptly but in no event later than one year from the effective date of termination, unless one or more extensions in writing are granted by the Contracting Officer upon request of the Contractor made in writing within such one-year period or authorized extensiton thereof. However, if the Contracting Officer determines that the facts justify such action, he may receive and act upon any such termination claim at any time after such one-year period or any extension thereof. Upon failure of the Contractor to submit his termination claim within the time allowed, the Contracting Officer may, subject to any review

required by the contracting agency's procedures in effect as of the date of execution of this contract, determine, on the basis of information available to him, the amount, if any, due to the Contractor by reason of the termination and shall thereupon pay to the Contractor the amount so determined.

(d) Subject to the provisions of paragraph (c), and subject to any review required by the contracting agency's procedures in effect as of the date of execution of this contract, the Contractor and the Contracting Officer may agree upon the whole or any part of the amount or amount to be paid to the Contractor by reason of the total or partial termination of work pursuant to this clause, which amount or amounts may include a reasonable allowance for profit on work done: Provided, that such agreed amount or amounts, exclusive of settlement costs, shall not exceed the total contract price as reduced by the amount of payments otherwise made and as further reduced by the contract price of work not terminated. The contract shall be amended accordingly, and the Contractor shall be paid the agreed amount. Nothing in paragraph (e) of this clause, prescribing the amount to be paid to the Contractor in the event of failure of the Contractor and the Contracting Officer to agree upon the whole amount to be paid to the Contractor by reason of the termination of work pursuant to this clause, shall be deemed to limit, restrict, or otherwise determine or affect the amount or amounts which may be agreed upon to be paid to the Contractor pursuant to this paragraph (d).

(e) In the event of the failure of the Contractor and the Contracting Officer to agree as provided in paragraph (d) upon the whole amount to be paid to the Contractor by reason of the termination of work pursuant to this clause, the Contracting Officer shall, subject to any review required by the contracting agency's procedures in effect as of the date of execution of this contract, determine, on the basis of information available to him, the amount, if any, due to the Contractor by reason of the termination and shall pay to the Contractor the amounts determined as follows:

(1) For completed supplies accepted by the Government (or sold or acquired as provided in paragraph (b)(7) above) and not theretofore paid for, a sum equivalent to the aggregate price for such supplies computed in accordance with the price or prices specified in the contract, appropriately adjusted for any saving of freight or other charges;

(2) The total of --

(i) The costs incurred in the performance of the work terminated, including initial costs and preparatory expense allocable thereto, but exclusive of any costs attributable to supplies paid or to be paid for under paragraph (e)(1) hereof;

(ii) The cost of settling and paying claims arising out of the termination of work under subcontracts or orders, as provided in paragraph (b)(5) above, which are properly chargeable to the terminated portion of the contract (exclusive of amounts paid or payable on account of supplies or materials delivered or services furnished by subcontractors or vendors prior to the effective date of the Notice of Termination, which amounts shall be included in the costs payable under (i) above); and

(iii) A sum, as a profit, equal to 2 percent of that part of the amout determined under (i) above which represents the cost of articles and materials not processed by the Contractor, plus a sum equal to 8 percent of the remainder of such amount, but the aggregate of such sums shall not exceed 6 percent of the whole of the amount determined under (i) above: Provided, however, that if it appears that the Contractor would have sustained a loss on the entire contract had it been completed, no profit shall be included or allowed under this subdivision (iii) and an appropriate adjustment shall be made reducing the amount of the settlement to reflect the indicated rate of loss; and

(3) The reasonable costs of settlement, including accounting, legal, clerical, and other expenses reasonably necessary for the preparation of settlement claims and supporting data with respect to the terminated portion of the contract and for the termination and settlement of subcontracts thereunder, together with reasonable storage, transportation, and other costs incurred in connection with the protection or disposition of property allocable to this contract.

The total sum to be paid to the Contractor under (1) and (2) of this paragraph (e) shall not exceed the total contract price as reduced by the amount of payments otherwise made and as further reduced by the contract price of work not terminated. Except for normal spoilage, and except to the extent that the Government shall have otherwise expressly assumed the risk of loss, there shall be excluded from the amounts payable to the Contractor as provided in (e)(1) and (2)(i) above, the fair value, as determined by the Contracting Officer, of property which is destroyed, lost, stolen, or damaged so as to become undeliverable to the Government, or to a buyer pursuant to paragraph (b)(7).

(f) Costs claimed, agreed to, or determined pursuant to paragraphs (c), (d), and (e) of this clause shall be in accordance with the contract cost principles and procedures in Part 1-15 of the Federal Procurement Regulations (41 CFR 1-15) in effect on the date of this contract.

(g) The Contractor shall have the right to appeal, under the clause of this contract entitled "Disputes," from any determination made by the Contracting Officer under paragraph (c) or (e) above, except that, if the Contractor has failed to submit his claim within the time provided in paragraph (c) above and has failed to request extension of such time, he shall have no such right of appeal. In any case where the Contracting Officer has made a determination of the amount due under paragraph (c) or (e) above, the Government shall pay to the Contractor the following: (1) if there is no right of appeal hereunder or if no timely appeal has been taken, the amount so determined by the Contracting Officer; or (2) if an appeal has been taken, the amount finally determined on such appeal.

(h) In arriving at the amount due the Contractor under this clause there shall be deducted (1) all unliquidated advance or other payments on account theretofore made to the Contractor, applicable to the terminated portion of this contract; (2) any claim which the Government may have against the Contractor in connection with this contract; and (3) the agreed price for, or the proceeds of sale of, any materials, supplies, or other things acquired by the Contractor or sold, pursuant to the provisions of this clause, and not otherwise recovered by or credited to the Government.

(i) If the termination hereunder be partial, prior to the settlement of the terminated portion of this contract, the Contractor may file with the Contracting Officer a request in writing for an equitable adjustment of the price or prices specified in the contract relating to the continued portion of the contract (the portion not terminated by the Notice of Termination), and such equitable adjustment as may be agreed upon shall be made in such price or prices.

(j) The Government may from time to time, under such terms and conditions as it may prescribe, make partial payments and payments on account against costs incurred by the Contractor in connection with the terminated portion of this contract whenever in the opinion of the Contracting Officer the aggregate of such payments shall be within the amount to which the Contractor will be entitled hereunder. If the total of such payments is in excess of the amount finally agreed or determined to be due under this clause, such excess shall be payable by the Contractor to the Government upon demand, together with interest computed at the rate of 6 percent per annum for the period from the date such excess payment is received by the Contractor to the date on which such excess is repaid to the Government: Provided, however, that no interest shall be charged with respect to any such excess payment attributable to a reduction in the Contractor's claim by reason of retention or other disposition of termination inventory until ten days after the date of such retention or disposition, or such later date as determined by the Contracting Officer by reason of the circumstances.

(k) Unless otherwise provided for in this contract, or by applicable statute, the Contractor, from the effective date of termination and for a period of three years after final settlement under this contract, shall

preserve and make available to the Government at all reasonable times at the office of the Contractor but without direct charge to the Government, all his books, records, documents, and other evidence bearing on the costs and expenses of the Contractor under this contract and relating to the work terminated hereunder, or, to the extent approved by the Contracting Officer, photographs, microphotographs, or other authentic reproductions thereof.

FPR 1-8.701

ALTERATIONS (Continued) January 1975

PRICE REDUCTION FOR DEFECTIVE COST OR PRICING DATA (FPR 1-3.814-1(a))

If any price, including profit or fee, negotiated in connection with this contract or any cost reimbursable under this contract was increased by any significant sums because:

(a) The Contractor furnished cost or pricing data which was not accurate, complete and current as certified in the Contractor's Certificate of Current Cost or Pricing Data;

(b) A subcontractor, pursuant to the clause of this contract entitled "Subcontractor Cost or Pricing Data" or "Subcontractor Cost or Pricing Data -Price Adjustments" or any subcontract clause therein required, furnished cost of pricing data which was not accurate, complete and current as certified in the subcontractor's Certificate of Current Cost or Pricing Data;

(c) A subcontractor or prospective subcontractor furnished cost of pricing data which was required to be accurate, complete and current and to be submitted to support a subcontract cost estimate furnished by the Contractor but which was not accurate, complete and current as of the date certified in the Contractor's Certificate of Current Cost or Pricing Data; or

(d) The Contractor or a subcontractor or prospective subcontractor furnished any data, not within (a), (b), or (c) above, which was not accurate as submitted; the price or cost shall be reduced accordingly and the contract shall be modified in writing as may be necessary to reflect such reduction. However, any reduction in the contract price due to defective subcontract data of a prospective subcontractor when the subcontract was not subsequently awarded to such subcontractor, will be limited to the amount (plus applicable overhead and profit markup) by which the actual subcontract, or actual cost to the Contractor if there was no subcontract, was less than the prospective subcontract cost estimate submitted by the Contractor: PROVIDED, The actual subcontract price was not affected by defective cost or pricing data.

(NOTE: Since the contract is subject to reduction under this clause by reason of defective cost or pricing data submitted in connection with certain subcontracts, it is expected that the Contractor may wish to include a clause in each such subcontract requiring the subcontractor to appropriately indemnify the Contractor. It is also expected that any subcontractor subject to such indemnification will generally require substantially similar indemnification for defective cost or pricing data required to be submitted by his lower tier subcontractors.)

SUBCONTRACTOR COST OR PRICING DATA (FPR 1-3.814-3)

(a) The Contractor shall require subcontractors hereunder to submit, actually or by specific indentification in writing, cost or pricing data under the following circumstances:

(1) Prior to the award of any subcontract the amount of which is expected to exceed $100,000 when entered into;

(2) Prior to the pricing of any subcontract modification which involves aggregate increases and/or decreases in costs plus applicable profits expected to exceed $100,000; except where the price is based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation.

(b) The Contractor shall require subcontractors to certify, in substantially the same form as that used in the certificate by the Prime Contractor to the Government, that to the best of their knowledge and belief, the cost and pricing data submited under (a) above is accurate, complete, and current as of the date of agreement on the negotiated price of the subcontract or subcontract change or modification.

(c) The Contractor shall insert the substance of this clause including this paragraph (c) in each subcontract hereunder which exceeds $100,000 when entered into except where the price thereof is based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation. In each such excepted subcontract hereunder in excess of $100,000, the Contractor shall insert the substances of the following clause:

SUBCONTRACTOR COST OR PRICING DATA -
PRICE ADJUSTMENTS

(a) Paragraphs (b) and (c) of this clause shall become operative only with respect to any modification made pursuant to one or more provisions of this contract which involves aggregate increases and/or decreases in costs plus applicable profits expected to exceed $100,000. The requirements of this clause shall be limited to such contract modifications.

(b) The Contractor shall require subcontractors hereunder to submit, actually or by specific identification in writing, cost or pricing data under the following circumstances.

(1) Prior to award of any subcontract, the amount of which is expected to exceed $100,000 when entered into;

(2) Prior to the pricing of any subcontract modification which involves aggregate increases and/or decreases in costs plus applicable profits expected to exceed $100,000; except where the price is based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation.

(c) The Contractor shall require subcontractors to certify, in substantially the same form as that used in the certificate by the Prime Contractor to the Government, that to the best of their knowledge and belief the cost and pricing data submitted under (b) above is accurate, complete, and current as of the date of agreement on the negotiated price of the subcontract or subcontract change or modification.

(d) The Contractor shall insert the substance of this clause including this paragraph (d) in each subcontract hereunder which exceeds $100,000 when entered into.

ALTERATIONS (Continued)

AUDIT (FPR 1-3.814-2)

(a) GENERAL. The Contracting Officer or his representatives shall have the audit and inspection rights described in the applicable paragraphs (b), (c), and (d) below.

(b) EXAMINATION OF COSTS: If this is a cost-reimbursement type, incentive, time and materials, labor hour, or price redeterminable contract, or any combination thereof, the Contractor shall maintain, and the Contracting Officer or his representatives shall have the right to examine books, records, documents, and other evidence and accounting procedures and practices, sufficient to reflect properly all direct and indirect costs of whatever nature claimed to have been incurred and anticipated to be incurred for the performance of this contract. Such right of examination shall include inspection at all reasonable times of the Contractor's plants, or such parts thereof, as may be engaged in the performance of this contract.

(c) COST OR PRICING DATA. If the Contractor submitted cost or pricing data in connection with the pricing of this contract or any change or modification thereto, unless such pricing was based on adequate price competition, established catalog or market prices of commercial items sold in substantial quantities to the general public, or prices set by law or regulation, the Contracting Officer or his representatives who are employees of the United States Government shall have the right to examine all books, records, documents and other data of the Contractor related to the negotiation, pricing or performance of such contract, change or modification, for the purpose of evaluating the accuracy, completeness and currency of the cost or pricing data submitted. Additionally, in the case of pricing any change or modification exceeding $100,000 to formally advertised contracts, the Comptroller General of the United States or his representatives who are employees of the United States Government shall have such rights. The right of examination shall extend to all documents necessary to permit adequate evaluation of the cost or pricing data submitted, along with the computations and projections used therein.

(d) AVAILABILITY. The materials described in (b) and (c) above, shall be made available at the office of the Contractor, at all reasonable times, for inspection, audit or reproduction, until the expiration of 3 years from the date of final payment under this contract or such lesser time specified in Part 1-20 of the Federal Procurement Regulations (41 CFR Part 1-20) and for such longer period, if any, as is required by applicable statute, or by other clauses of this contract, or by (1) and (2) below:

(1) If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for a period of 3 years from the date of any resulting final settlement.

(2) Records which relate to appeals under the "Disputes" clause of this contract, or litigation or the settlement of claims arising out of the performance of this contract, shall be made available until such appeals, litigation, or claims have been disposed of.

(e) The Contractor shall insert a clause containing all the provisions of this clause, including this paragraph (e), in all subcontracts hereunder except altered as necessary for proper identification of the contracting parties and the Contracting Officer under the Government prime contract.

July 1974

ACCOUNTS, AUDITS, AND RECORDS

(a) The Contractor shall maintain books, records, documents, and other evidence, accounting procedures and practices sufficient to reflect properly all direct and indirect costs of whatever nature claimed to have been incurred for the performance of this contract. The foregoing constitutes "records" for the purpose of this clause.

(b) The Contractor's facility(ies) or such part thereof as may be engaged in the performance of this contract, and his records shall be subject at all reasonable time to inspection and audit by the Secretary or his authorized representatives.

(c) The Contractor shall preserve and make available his records (1) until the expiration of 3 years from the date of final payment under this contract, or the time periods for particular records specified in 41 CFR Part 1-20, whichever expires earlier, and (2) for such longer period, if any, as is required by applicable statute, or by other clauses of this contract, or by (i) or (ii) below:

(i) If this contract is completely or partially terminated, the records relating to the work terminated shall be preserved and made available for a period of 3 years from the date of any resulting final payment.

(ii) Records which relate to (A) appeals under the "Disputes" clause of this contract, (B) litigation or the settlement of claims arising out of the performance of this contract, or (C) costs and expenses of this contract to which exception has been taken by the Contracting Officer or any of his duly authorized representatives, shall be retained until such appeals, litigation, claims, or exceptions have been disposed of.

(d) The Contractor shall insert the substance of this clause, including this paragraph (d) in each subcontract hereunder with the exceptions of (1) purchase orders not exceeding $2,500 and (2) subcontracts or purchase orders for public utility services at rates established for uniform applicability to the general public. When so inserted, changes shall be made to designate the higher-tier subcontractor at this level involved in place of the Contractor; to add "of the Government prime contract," in place of "this contract" in (B) of subparagraph (c)(ii) above.

PREAWARD EQUAL OPPORTUNITY COMPLIANCE REVIEWS

Where the bid of the apparent low responsible bidder is in the amount of $1 million or more, the bidder and his known first-tier subcontractors which will be awarded subcontracts of $1 million or more will be subject to full, preaward equal opportunity compliance reviews before the award of the contract for the purpose of determining whether the bidder and his subcontractors are able to comply with the provisions of the Equal Opportunity clause.

ALTERATION TO SF-32, General Provisions

CLEAN AIR AND WATER CLAUSE

(Applicable only if the contract exceeds $100,000, or the contracting officer has determined that the orders under an indefinite quantity contract in any one year will exceed $100,000, or a facility to be used has been the subject of a conviction under the Clean Air Act (42 U.S.C. 1857C-8(C)(1)) or the Federal Water Pollution Control Act (33 U.S.C. 1319 (C)) and is listed by EPA, or the contract is not otherwise exempt.)

(A) The contractor agrees as follows:

(I) To comply with all the requirements of Section 114 of the Clean Air Act, as amended (42 U.S.C. 1857, et seq., as amended by Public Law 91-604 and Section 308 of the Federal Water Pollution Control Act (33 U.S.C. 1251, as amended by Public Law 92-500), respectively, relating to inspection, monitoring, entry, reports, and information, as well as other requirements specified in Section 114 and Section 308 of the Air Act and the Water Act, respectively, and all regulation and guidelines issued thereunder before the award of this contract.

(II) That no portion of the work required by this prime contract will be performed in a facility listed on the Environmental Protection Agency list of violating facilities on the date when this contract was awarded unless and until the EPA eliminates the name of such facility or facilities from listing.

(III) To use his best efforts to comply with Clean Air Standards and Clean Water Standards at the facilities in which the contract is being performed.

(IV) To insert the substance of the provisions of this clause in any nonexempt subcontract, including this paragraph (IV).

(B) The terms used in this clause have the following meanings:

(I) The term "Air Act" means the Clean Air Act, as amended (42 U.S.C. 1857 et seq., as amended by Public Law 91-604).

(II) The term "Water Act" means Federal Water Pollution Control Act, as amended (33 U.S.C. 1251 et seq., as amended by Public Law 92-500).

(III) The term "Clean Air Standards" means any enforceable rules, regulations, guidelines, standards, limitations, orders, controls, prohibitions, or other requirements which are contained in, issued under, or otherwise adopted pursuant to the Air Act or Executive Order 11738, an applicable implementation plan as described in Section 110(D) of the Clean Air Act (42 U.S.C. 1857C-5(D)), an approved implementation procedure or plan under Section 111(C) or Section 111(D), respectively, of the Air Act (42 U.S.C. 1857C-6(C) or (D)), or an approved implementation procedure under Section 112(D) of the Air Act (42 U.S.C. 1857C-7(D)).

ALTERATION TO SF-32, General Provisions

Clean Air and Water Clause **(Continued)**

(IV) The term "Clean Water Standards" means any enforceable limitation, control, condition, prohibition, standard, or other requirement which is promulgated pursuant to the Water Act or contained in a permit issued to a discharger by the Environmental Protection Agency or by a State under an approved program, as authorized by Section 402 of the Water Act (33 U.S.C. 1342), or by a local government to ensure compliance with pretreatment regulations as required by Section 307 of the Water Act (33 U.S.C. 1317).

(V) The term "compliance" means compliance with Clean Air or Water Standards. Compliance shall also mean compliance with a schedule or plan ordered or approved by a court of competent jurisdiction, The Environmental Protection Agency or an Air or Water Pollution Control Agency in accordance with the requirement of the Air Act or Water Act and regulations issued pursuant thereto.

(VI) The term "Facility" means any building, plant, installation, structure, mine, vessel or other floating craft, location, or site of operations, owned, leased, or supervised by a contractor, subcontractor, to be utilized in the performance of a contract or subcontract. Where a location or site of operations contains or includes more than one building, plant, installation, or structure, the entire location shall be deemed to be a facility except where the Director, Office of Federal Activities, Environmental Protection Agency, determines that independent facilities are colocated in one geographical area.

EQUAL OPPORTUNITY (July 1976)

(The following clause is applicable unless this contract is exempt under the rules, regulations, and relevant orders of the Secretary of Labor (41 CFR ch. 60).)

During the performance of this contract, the Contractor agrees as follows:

(a) The Contractor will not discriminate against any employee or applicant for employment because of race, color, religion, sex, or national origin. The Contractor will take affirmative action to ensure that applicants are employed, and that employees are treated during employment, without regard to their race, color, religion, sex, or national origin. Such action shall include, but not be limited to, the following: Employment, upgrading, demotion, or transfer; recruitment or recruitment advertising; layoff or termination; rates of pay or other forms of compensation; and selection for training, including apprenticeship.

The Contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices to be provided by the Contracting Officer setting forth the provisions of this Equal Opportunity clause.

(b) The Contractor will, in all solicitations or advertisements for employees placed by or on behalf of the Contractor, state that all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, or national origin.

(c) The Contractor will send to each labor union or representative of workers with which he has a collective bargaining agreement or other contract or understanding, a notice, to be provided by the agency Contracting Officer, advising the labor union or workers' representative of the Contractor's commitments under this Equal Opportunity clause, and shall post copies of the notice in conspicuous places available to employees and applicants for employment.

(d) The Contractor will comply with all provisions of Executive Order No. 11246 of September 24, 1965, and of the rules, regulations, and relevant orders of the Secretary of Labor.

(e) The Contractor will furnish all information and reports required by Executive Order No. 11246 of September 24, 1965, and by the rules, regulations, and orders of the Secretary of Labor, or pursuant thereto, and will permit access to his books, records, and accounts by the contracting agency and the Secretary of Labor for purposes of investigation to ascertain compliance with such rules, regulations, and orders.

(f) In the event of the Contractor's noncompliance with the Equal Opportunity clause of this contract or with any of the said rules, regulations, or orders, this contract may be canceled, terminated, or suspended, in whole or in part, and the Contractor may be declared ineligible for further Government contracts in accordance with procedures authorized in Executive Order No. 11246 of September 24, 1965, and such other sanctions may be imposed and remedies invoked as provided in Executive Order No. 11246 of September 24, 1965, or by rule, regulation, or order of the Secretary of Labor, or as otherwise provided by law.

(g) The Contractor will include the provisions of paragraphs (a) through (g) in every subcontract or purchase order unless exempted by rules, regulations, or orders of the Secretary of Labor issued pursuant to section 204 of Executive Order No. 11246 of September 24, 1965, so that such provisions will be binding upon each subcontractor or vendor. The Contractor will take such action with respect to any subcontract or purchase order as the contracting agency may direct as a means of enforcing such provisions, including sanctions for noncompliance: *Provided, however,* That in the event the Contractor becomes involved in, or is threatened with, litigation with a subcontractor or vendor as a result of such direction by the contracting agency, the Contractor may request the United States to enter into such litigation to protect the interests of the United States.

Mr. WAXMAN. Was it the intention of HEW and the vaccine manufacturers to, at some point, enter into written contracts, which they did do in August of this year, with at least three of the four companies. Is that correct?

Dr. MILLAR. That is true.

Mr. WAXMAN. Why was it such a long delay between the letter contracts and reducing it into a written contract?

Dr. MILLAR. As the GAO people mentioned earlier, one of the major issues involved was whether or not the Federal Government would waive the usual requirement for cost accounting standards. This strikes me as a very serious matter, which was pondered for a rather considerable period of time, largely because of its implications.

I would venture that this consideration of whether or not to waive the cost accounting standards is, in fact, the reason for most of the delay.

Mr. WAXMAN. Tell us what the serious implications are.

Dr. MILLAR. I think that we referred to them earlier, and I am not competent to comment on the special ramifications of waiving those procedures. I would presume that any time a company asks the Government to waive a standing set of standards that this should require some significant pondering. But I do not feel that I personally have the competence to respond as to what the implications of those waivers really are.

Mr. WAXMAN. GAO said that it was inappropriate to contract with the vaccine manufacturers, and to have that kind of language in it. This generally applies to Defense people. You seem to indicate that there would be some serious consequencies in having waived that provision, which caused HEW to ponder on it for over 1 year.

Dr. MILLAR. It took a rather considerable period to deal with that. I wonder if I might ask Mr. Bradford to offer some help on this point.

Mr. BRADFORD. I think it took an awful long time, clearly, to decide the issue of whether this should be waived or not. Obviously, the Department has come down on the position that this will not jeopardize the Government's interest in signing the contract. But, yes, it took a long time.

Mr. WAXMAN. Tell me more about it. What did the Government decide to give up?

Mr. BRADFORD. Again, I apologize, Mr. Waxman, because I am not a contractual expert. As I understand the issue, the manufacturers' normal accounting systems were not set up to directly relate each item of cost to a specific, or to one specific product.

What was done, in fact, initially when the letter contracts were signed in September 1976, was to establish cost criteria which both the Government and the contractors could agree upon. This was the basis for the contracts which were signed in September.

The issue of whether the normal standards would apply in allocating costs in the audit could not be agreed upon by the parties, and so this was a major reason why the final contracts went unsigned.

Mr. WAXMAN. You are talking about allocating costs. In other words, the party contracted with by the Government would have to

allocate the costs to show where each dollar went. Is that what the accounting system requires?

Mr. BRADFORD. That is the general idea, but I cannot speak to the specifics.

Mr. WAXMAN. Would it be fair for one to conclude that it would have been a way for the U.S. Government to know what the costs were for the manufacturers of the vaccine by way of a clear-cut audit, as opposed to just taking their word for what the costs would be?

Mr. BRADFORD. This does not take the place of an audit. Again, the Department determined, after reviewing the issue, that these accounting standards could be waived, and the final determination of what it cost the manufacturers to produce the vaccine could still be obtained through audit. So the audit process still takes place.

Mr. WAXMAN. Tell me about the audit. Would the audit go into every part of the cost incurred by the vaccine manufacturers, to know what their costs were; or would it be taking certain assumptions to furnish the Government by the vaccine manufacturers?

Mr. BRADFORD. Agreements have been reached with the manufacturers that the records of cost, and other records, will be open to the HEW auditors for this purpose.

Mr. WAXMAN. I want to know what we gave away that took such a long time, and that HEW pondered over so greatly before deciding to give the signed contracts. After all, we gave up the normal liability that is placed on the vaccine manufacturers because we were threatened with adverse effects.

So HEW came to Congress, and said: "You have to pass a new law." HEW made an administrative decision that they were going to waive some provision that is in the law, and I imagine that it is in the law for some purpose. Could HEW give us some information on that.

Mr. BRADFORD. I think that we could provide the detailed information about each of the standards included, what was the difficulty with them, and why the decision was made. There are procedures, as you indicated, for the granting of waivers of these types of clauses in contracts, when there is deemed to be good reason.

Mr. WAXMAN. I am not questioning whether you have the right to make a waiver. I am not sure that you have the right to make the waiver, but it is a decision that HEW made to give the waiver to the vaccine manufacturers after a year of negotiations as to the cost.

Evidently, this was something important enough for the vaccine manufacturers to want that out, and which finally the Government felt they could not press any longer. What did we give up?

Mr. BRADFORD. I cannot answer that question. The audits will turn that up, and, of course, GAO will continue to look at this process.

Mr. WAXMAN. GAO only talks to you. It does not talk to anybody else.

I would like, Mr. Chairman, that the record be held open for a detailed account. I wonder why we do not have a person from HEW who negotiated this. This is a very important part of the negotiations with the manufacturers. I find it inexcusable that we do not

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have somebody here to give us this detailed information of what we gave up.

I would like to have the record held open for that information to be provided to us.

Mr. ROGERS. Without objection, it is so ordered.

[A detailed description of the waiver of cost accounting standards granted by the Department is included in the information provided on page 110 of the Hearings.]

Do you have anyone here who negotiated the contracts, or is a contract person from HEW?

Dr. MILLAR. No.

Mr. WAXMAN. How many people were involved in the negotiations?

Mr. BRADFORD. The contracting officer at CDC in Atlanta. Some of these determinations, I might add, had to be made elsewhere in the Department, particularly the waiver question.

Mr. WAXMAN. Did HEW object to the item for $8 million that the vaccine manufacturers asked for their insurance coverage in light of the liability?

Mr. BRADFORD. I believe HEW would have been happy to sign the contract that would have assured the delivery of vaccine at the lowest possible price.

The agreement was reached as a result of Public Law 94-380. While no profit would be allowed, the manufacturers were also interested in seeing that no losses would be incurred. I think that this is the basis for that agreement.

Mr. WAXMAN. HEW failed to monitor the use of informed consent forms. Use of the forms was haphazard. Those who contracted Guillain-Barre had difficulty making a case because they never signed a form, or cannot prove that they did or did not. That is a conclusion of the GAO. Do you have any comment to make about that?

Dr. MILLAR. That has to be viewed in the context of the national use of informed consent procedures. In fact, surveys that have been done with recipients of the vaccine have indicated that approximately 89 to 90 percent of the people who got the swine flu vaccine did, in fact, receive informed consent forms, and did, in fact, execute those. Almost universally, they claimed that they understood what they were signing.

This means that there were approximately 10 percent who received the shot who did not receive the informed consent procedure. Constructed in the very narrow sense, one would have to say that the system was imperfect because these people did not receive the informed consent materials. However, when looked at in the broader sense of doing such an activity for the first time on a national basis, there is considerable reason for thinking that 90-percent performance is pretty good performance.

Mr. WAXMAN. How many forms of the warning did you have? How many different forms of the warning did you have?

Dr. MILLAR. We had two basic forms. One form for the monovalent vaccine, and one form for the bivalent vaccine. Both forms consisted of two pages, the front page of which was an introduction which was identical in each instance, and the second page provided

specific information about the specific vaccine, whether it was monovalent or bivalent.

Mr. WAXMAN. Did each form advise the person that there was a possibility of Guillain-Barre syndrome?

Dr. MILLAR. The form did not contain any reference to the Guillain-Barre syndrome. At the time the forms were constructed, and indeed up until December of last year, the experience with Guillain-Barre and vaccine was as follows: there was a report published of some 1,100 cases of Guillain-Barre syndrome, essentially comprising the published experience with that syndrome. Among those 1,100 cases, there was one person who had been vaccinated with influenza vaccine prior to onset of Guillain-Barre.

I hasten to add that there were 150 or so other such conditions that were also listed, including some fairly bizarre ones; four people in that group had even been struck by lightning. We did not feel that the available information at the beginning of the program, in fact, warranted any conclusion that there was an association between flu vaccine and the Guillain-Barre syndrome.

Mr. WAXMAN. Were patients informed on either form that there was a potential danger for pregnant women to have the vaccine?

Dr. MILLAR. The section on pregnancy was obviously one that produced a certain amount of controversy. The matter was taken to the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research. Afterward, there was never an adequate resolution to the issue because of the fact that there is a substantial historical amount of information on the use of flu vaccines which does not indicate specific problems between the vaccine and pregnancy.

On the other hand, the sort of well-controlled studies that we are coming to expect nowadays, evaluating women who have been vaccinated and then having children, with women who have not been vaccinated who have children, these studies simply have not been done. So the data do not exist to say, with 100-percent clarity, that there is absolutely no risk.

Trying to balance these risks and benefits for pregnant women was a real problem. But the pregnancy section that eventually became a part of the form was drawn from the recommendations of the Advisory Committee on Immunization Practices and did, in fact, note that there was some ambiguity.

Mr. WAXMAN. It later became part of the form, but it was not part of the form initially.

Dr. MILLAR. The first forms that were sent out, dated July 15, 1976, and the introduction to the vaccine forms, said:

> Many people ask questions about flu vaccination during pregnancy. An advisory committee of the Public Health Service examined this question and reported that "there are no data specifically to contraindicate vaccination with the available killed virus vaccine in pregnancy. Women who are pregnant should be considered as having essentially the same balance of benefits and risks regarding influenza vaccination and influenza as the general population."

That was in the forms that were in use when the program began.

Mr. WAXMAN. Later you changed that.

Dr. MILLAR. After the Guillain-Barre episode, forms were produced that changed the language of that to the following:

Many people ask about the risks of flu vaccination during pregnancy. There is not now any specific data on whether the risks are the same or different from what they are for the general population. For this reason, a pregnant woman should be advised by a doctor on the benefits and risks for her or her offspring.

It does not say how the doctors should be advised about the benefits and risks, and that illustrates the ambiguity.

Mr. WAXMAN. If you were a pregnant woman, would you feel that you got any information from that form?

Dr. MILLAR. I would say that from the form that we were using in July, as far as I am concerned, the statement, "the same balance of benefits and risks regarding influenza vaccination and influenza as the general population," is a significant message.

Mr. WAXMAN. That was changed.

I want to ask about some contradiction in your testimony. As I understood your testimony earlier, you talked about 36 cents per dose for monovalent as the cost, and 42 cents per dose if there was some self-insurance. I did not understand what that meant.

Then later you came back and testified that it was a range of 15 to 30 cents per dose. Could you explain that difference?

Dr. MILLAR. The discrepancy arose in our scrambling to get the information that we did not have in front of us. It was confused, and I would appreciate it if you would ignore what I said on costs just before the break, because we developed that as quickly as we could from the information at hand.

Mr. WAXMAN. Are you sure that I should ignore what was said before the break?

Dr. MILLAR. On that point.

Mr. WAXMAN. You are willing to give us figures. Are you satisfied that that represents cost and not profit?

Dr. MILLAR. For the two companies, there is no profit even sought for the bivalent vaccine. For the other two companies, I would presume their figures do include some profit for the A-Victoria vaccine.

Mr. WAXMAN. Are you accepting the fact that they are not asking for profit, and that they are not getting profit?

Dr. MILLAR. I am accepting the fact that to date we have three contracts concluded and audits are or soon will be underway. At this point in time, I am not prepared to say specifically, without having seen the audits, one way or the other. I don't think that I have the information at hand to really respond.

Mr. ROGERS. Would you have those audit reports presented to the committee at the conclusion of those audits?

Dr. MILLAR. We will.

[The following information was received for the record:]

AUDIT REPORTS

Audits by the HEW Audit Agency could not commence until the manufacturers accumulated the final costs and closed their accounting periods. Currently, HEW audits of Merck Sharp and Dohme and Wyeth are in progress. An audit of Merrell-National is scheduled to begin in the near future. The audit of Parke-Davis will be delayed pending final determination of the Shope influenza virus vaccine production cost issue. Copies of these audits will be provided to the subcommittee as they become available.

Mr. ROGERS. Mr. Maguire?

Mr. MAGUIRE. Thank you, Mr. Chairman.

In the July 1976 hearing that was conducted by this committee, there was an exchange between Dr. Cooper and myself, just prior to the meetings that were to take place between HEW, the manufacturers and the insurers, to try to hammer out the details.

This is the frame of reference:

> If we are going to become involved, that is the Government, in the sharing of the risk in some fashion, above a certain level, I would hope that those doing the negotiating might also keep in mind that it would be nice for the Government, to the extent that we find we do not end up with a problem—I meant by that a situation where there would not be an incredible number of claims and the costs associated with those claims—that we also be able to share in whatever reduction of cost might result from that fact, just as we would equally share the risk.

Dr. Cooper answered, "Yes, sir. We would adhere to those principles."

Now it is my understanding that among other alternatives that were considered, or proposed, there were some that were proposed by the insurance companies, which involved a retrospective adjustment of premium payments. What became of those proposals?

Dr. MILLAR. I don't have any information on that.

Mr. BRADFORD. I am not sure of the specific question, but the contracts do not now require retrospective reimbursement.

Mr. MAGUIRE. I am aware of that, sir. But what I am trying to find out is, what happened to that idea which was discussed in the hearings. It seemed to me at the time and it seems to me now, if that had been properly negotiated, surely there could be ways to negotiate it that would be satisfactory, so that in a situation where there are very few claims compared to the projections we would not have had to pay enormous amounts of money. If we had a retrospective arrangement, it would seem to me that we would not be in a better position. Alternatively, if the costs had exceeded those that were anticipated, and it had been necessary to consider how to cover that, the agreement would have concerned itself with that.

Some assumption of Government responsibility beyond the ceiling might have made some sense. We discussed that at great length at the hearings as well.

Mr. Chairman, it appears to me as though once again the representatives of HEW are not prepared to answer the questions of the committee. I think that it is very surprising that HEW's delegation to these hearings does not contain someone who participated in the negotiations a year ago.

Apparently, we will have to leave the record open at this point for a written response to the committee, or the committee will have to call further HEW witnesses to find what, in fact, occurred during those negotiations.

Mr. ROGERS. I think that it may be that the committee will want to hear from the people who actually participated in those negotiations, and we will leave the record open and make that judgment.

Mr. MAGUIRE. Thank you, Mr. Chairman.

Mr. ROGERS. Dr. Carter?

Mr. CARTER. Thank you, Mr. Chairman.

Is the risk of a swine flu epidemic any greater, or less, or about the same this year?

Dr. MILLAR. Dr. Carter, I wish I could answer that question with some precision. The experts are very quiet on that particular point.

But I cannot escape my own common sense as an epidemiologist that since there have not been many cases, or any outbreaks of swine flu in the interim, I cannot believe that the risks of swine flu in the future are as great as they were when we dealt with this problem in February and March of 1976. But this is based on epidemiologic intuition.

We still don't know influenza viruses well enough to know whether we have seen the last of the swine flu virus. We do know that we are still due for a major pandemic change within the next few years.

Dr. Jordan is perhaps more expert in these matters.

Would you care to comment on that, Dr. Jordan?

Dr. JORDAN. I would agree with Dr. Millar's comment. The unpredictability of influenza is one of the greatest plagues to the epidemiologists and physicians, as you know. There is a cyclical behavior that recurs and produces pandemics, and that is why it is expected, and was expected when this new variant arose, that we are due for a new pandemic within the next few years.

Mr. CARTER. If a new virus were to be located and isolated, this year in a similar experience to Fort Dix, what steps would you take to assess the risk of the outbreak? How would you go about evaluating such a situation?

Would you do it differently than was done with the swine flu threat?

Dr. JORDAN. We are beginning now to discuss this question. We have been thinking about it for some time, since last year. The Secretary's Office has created within the agency a working group that involves the Bureau of Biologics, National Institutes of Allergy and Infectious Diseases and CDC, to discuss what preparations should be made to control future pandemics.

Hopefully, we will learn from the swine flu experience something about the decisionmaking process and how to improve our performance. If a new variant arises, we will face the same questions that we faced in February when the swine flu arose. We will have to address the same issues: how different is the new strain from previous strains, how different is it from strains currently in today's vaccine, and how susceptible is the population.

Mr. CARTER. GAO has stated that before another mass immunization program is conducted, that total Federal assumption of the liability coverage of vaccine production should be considered. Would you comment on these recommendations?

Dr. MILLAR. I think, Dr. Carter, that the Department is, at this point, giving very careful consideration to issues relating to liability and to compensation. As I indicated in my statement, the two are, in fact, inter-digitated in the sense that until there is some means found to compensate the rare, but finite victims of an immunization procedure, one will have chronically to deal with problems of liability.

A preliminary draft of the departmental position on this has been sent to the Congress. We are promising that in October, a final report, hopefully incorporating very specific recommendations, will be forwarded to you. So rather than commenting on the GAO recommendation, I would prefer to say that the Department's position on this, I think, is spelled out in the draft, and also

hopefully will come to you with some recommendations for a program in October.

Mr. CARTER. Do you think there is relation between the Guillain-Barre syndrome and the swine flu virus vaccine, or the Victoria-A strain, or any other particular influenza virus?

Dr. MILLAR. We saw cass of Guillain-Barre syndrome in recipients not only of the 2–A vaccine, the swine vaccine and A-Victoria, but also in recipients of the B-virus vaccine. Because we do not have a clear fix on exactly how many doses of B vaccine were administered to people, that not being part of the national program, we cannot come up with a rate for Guillain-Barre in recipients of only B influenza vaccine.

My own personal opinion is that the association such as it is applies to all the flu vaccines, but that is based on a presumption, because we do not have the necessary data on the distribution of B-influenza vaccine to make a firm conclusion about those rates.

Mr. CARTER. Have you read that the Guillain-Barre syndrome may be related to, or precipitated by the type of injection, and not just influenza?

Dr. MILLAR. I realize that that opinion exists, but at this point I do not agree with it. I don't think that there are data to suggest that Guillain-Barre syndrome is associated with other vaccines.

Mr. CARTER. How do you account for the approximately equal number of Guillain-Barre cases that did occur without being injected with the virus?

Dr. MILLAR. We know that there is a background occurrence of the Guillain-Barre syndrome that has been going on for as long as the syndrome has been described, which is a century now. But we did not have a good fix on the prevalence before this past winter.

It is quite obvious that there are cases occurring all the time from a variety of causative factors, which are not clear.

Mr. ROGERS. May I ask you to answer, for the record, number of additional questions. I want additional information about the number of people who may have been injured as a result of the swine flu immunization program. What methods the Department are employing to review actual costs of the program, and to predict other future program costs.

I think the committee is also interested in how the Bureau of Biologics plans to go into a future program, and what would be the possibility, if we find, as the General Accounting Office has stated we might, that a manufacturer does not want to produce a vaccine. What steps should we take?

I think that we should have the recommendations of the Department, as to whether or not we should get into the business ourselves. These and other additional questions will be submitted to the Department; their response will be a part of the record.

Thank you for your presence today.

[Testimony resumes on p. 378.]

[The following correspondence was received for the record:]

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Congress of the United States
House of Representatives
Subcommittee on Health and the Environment
of the
Committee on Interstate and Foreign Commerce
Washington, D.C. 20515

October 4, 1977

Honorable Joseph A. Califano, Jr.
Secretary
Department of Health, Education,
and Welfare
Washington, D.C. 20201

Dear Mr. Secretary:

At the conclusion of HEW's testimony on September 16, 1977, before the Subcommittee's oversight hearing on swine flu, I indicated that additional written questions would be submitted to the Department for your response.

The Subcommittee has been polled, and Congressman Henry Waxman, Congressman Andrew Maguire and I now pose the accompanying questions with the request that the Department's response be submitted for the hearing record no later than October 21, 1977.

Your attention to this request is most appreciated.

Kind regards.

Sincerely yours,

Paul G. Rogers

PAUL G. ROGERS, M.C.
Chairman, Subcommittee on
Health and the Environment

PGR:rd
Enclosures

ADDITIONAL QUESTIONS
SWINE FLU

1. Why has one vaccine manufacturer still not signed a contract with the federal government in the Swine Flu Program?

2. Why did the other vaccine manufacturers finally sign contracts about a month ago with the federal government? Was there a quid pro quo for their signing the contracts?

3. Exactly why was there a waiver granted from standard government accounting standards?

4. Why have HEW's audits of the manufacturers' cost been so delayed and what have the findings of these audits been?

5. What is the status of negotiations between HEW and Parke-Davis with respect to who will bear the costs of producing the wrong flu vaccine?

6. What steps have been taken to assure smooth organizational management (i.e. a defined 'chain of command') for future immunization programs?

7. What new research and testing procedures, specifically related to vaccine development and assessment of effectiveness and safety, are being developed by the Department?

8. What methods is the Department employing to review actual costs of the program and better predict future program costs?

9. Why was the decision made to accept the fixed liability insurance premium rather than opting for a retrospective rate adjustment? What options were proposed, and why were the various other options rejected?

10. What effort, if any, has the Department made to locate individuals who may have been injured as a result of the swine flu immunization program?

11. Please respond to each of the twenty specific recommendations made by the Association of State and Territorial Health Officials' spokesmen, Dr. Lloyd, in his testimony,(a copy of that testimony is enclosed for your use).

12. What new national liability policies has HEW developed to prevent the government from bearing the cost of indemnifying the pharmaceutical manufacturers?

13. What initiatives has HEW taken to develop a patient compensation scheme?

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

October 27, 1977

The 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. Chairman:

Secretary Califano has asked that I respond to your letter concerning questions which arose during the Subcommittee's oversight hearings on September 16 regarding the swine flu immunization program.

The enclosure responds to the questions raised by the Subcommittee, with the exception of question number 11 requesting comments on the 20 recommendations of the Association of State and Territorial Health Officers. Because of delay in our receipt of these recommendations, adequate responses have not yet been developed. They will be forwarded to you as expediously as possible.

We hope that the enclosed information will assist in your efforts to utilize the lessons from the swine flu experience in the construction of a workable immunization policy.

Sincerely yours,

Dick Warden
Assistant Secretary
for Legislation

Enclosure

Subcommittee Question

1. Why has one vaccine manufacturer still not signed a contract with the Federal Government in the Swine Flu Program?

Department Response

A finalized contract with Parke-Davis is being delayed pending resolution of the issue on the allowability of production costs of approximately 6 million doses of vaccine produced from a laboratory strain of the influenza virus (Shope) which was not approved for use in the 1976-1977 program. These costs have been disallowed by HEW and Parke-Davis has appealed the HEW decision to the Armed Services Board of Contract Appeals (ASBCA) which has been designated by the Secretary to hear appeals of this nature. The ASBCA will review the facts and circumstances surrounding the Parke-Davis claim for payment and the HEW decision and will render a final opinion of the allowability of the production cost. Once the final judgment has been rendered, a "definitized contract" can be signed with Parke-Davis replacing the existing "letter contract" presently binding the Government and this vaccine manufacturer.

Subcommittee Question

2. Why did the other vaccine manufacturers finally sign contracts about a month ago with the federal government? Was there a quid pro quo for their signing the contracts?

Department Response

Three issues prevented the signing of definitized contracts in September 1976: (1) The need for a ruling on the tax status of the self insurance retention fund; (2) a ruling on whether the cost of producing approximately six million doses of the wrong vaccine by one manufacturer would be paid; and (3) the need for a decision on waiving the normal cost accounting standards which are applied to contracts of this type.

The second issue, affecting only Parke-Davis, is discussed in the answer to question number one. It has not been resolved. The resolution of the first and third issues permitted the signing of final contracts with three of the manufacturers in August 1977.

The issue related to the waiver of normal cost accounting standards is discussed in response to question number three. With reference to the tax status of the self insurance retention fund, the manufacturers were concerned that if this payment of $2.5 million was taxable in the year it was received (1976), most of it would be required to meet the tax imposed. HEW agreed to seek a ruling on this from the Internal Revenue Service. This ruling was requested on November 17, 1976, and a decision was received on April 8, 1977. In essence, IRS ruled that the fund was taxable in the year it was used and not the year it was received. Since this fund could only be used to meet certain legal expenses as specified by Public Law 94-380 and the provisions of each contract, the effect of this ruling was that the fund would always be offset by expenses resulting in a "tax wash-out." A copy of this ruling will be supplied to the Committee with the transcript for inclusion in the record.

There was no "quid pro quo."

Subcommittee Question

3. Exactly why was there a waiver granted from standard government cost accounting standards?

Department Response

The normal procedure for procuring vaccine is to negotiate a price based on established catalogue or market prices. A supply contract is then awarded on a firm, fixed price basis. The cost accounting standards are not applicable when this procedure is used.

Enactment of Public Law 94-380 required the cost of swine flu vaccine to be determined on a retrospective basis through audit to preclude (or in the case of A/Victoria/75 antigens, to limit) payment of profit. Because of this requirement, the contracts could not be awarded on a firm, fixed price basis, but rather a cost-reimbursement contract was called for. In this type of contract, the price is not established based upon catalogue or market price, and the cost accounting standards become applicable. For reasons discussed below, application of the cost accounting standards was ultimately considered inappropriate.

Significant standards normally included in cost type contracts are:

- Consistency in estimating, accumulating, and reporting costs.
- Consistency in allocating costs incurred for the same purpose.
- Allocation of home office expenses to segments.
- Capitalization of tangible assets.
- Accounting for unallowable costs.
- Cost accounting period.
- Use of standard costs for direct material and direct labor.

The use of many of those standards is generally predicated on accumulating and reporting costs consistent with the manufacturers' normal cost accounting practices. The vaccine manufacturers, prior to the swine flu program, did not accumulate or report costs on a product-by-product basis. Therefore, their normal accounting practices did not lend themselves to the kind of cost accounting generally associated with these unusual cost type contracts. Although the manufacturers did take steps to establish accounting systems to be able to isolate and report costs of producing swine flu vaccine, in order to use the actual cost accounting standards, they would have had to reestablish their entire accounting system. In addition, it is important to understand that those standards are only a way to calculate costs, not the only way.

The Department, therefore, elected to permit the manufacturers to establish special cost accounting procedures for the swine flu program without modifying their cost accounting system on a company-wide basis. Such a step would have been excessively costly to the manufacturers and the Government, and was not justified for this one-time special procurement.

In conducting the audits referred to in the answer to question number 4, the Department will, of course, verify that costs have been accounted for in accordance with generally accepted accounting principles and practices.

Subcommittee Question

4. Why have HEW's audits of the manufacturers' cost been so delayed and what have the findings of these audits been?

Department Response

The HEW audits of cost could not commence until the manufacturers accumulated the final costs and closed their accounting periods. Currently, HEW audits of Merck Sharp and Dohme and Wyeth are in progress. An audit of Merrell-National is scheduled to begin in the near future. The audit of Parke-Davis will be delayed pending final determination of the "Shope" virus vaccine production cost issue. Copies of these audits will be provided to the Subcommittee as they become available.

Subcommittee Question

5. What is the status of negotiations between HEW and Parke-Davis with respect to who will bear the costs of producing the wrong flu vaccine?

Department Response

As indicated in the response to question number one, Parke-Davis is appealing HEW's decision not to permit reimbursement of the costs associated with the production of this vaccine. The determination of the Armed Services Board of Contract Appeals will be final if it is adverse to the Government. If the Government should prevail, however, Parke-Davis could appeal the Board's decision to the Court of Claims.

Subcommittee Question

6. What steps have been taken to assure smooth organizational management (i.e., a defined 'chain of command') for future immunization programs?

Department Response

The Department has taken a number of steps toward improving its organizational structure relative to future immunization programs:

1. The Assistant Secretary for Health has established a special group within the Department (designated the Pandemic Influenza Planning Committee) comprised of representatives from the Bureau of Biologics (FDA), the Center for Disease Control, and the National Institute of Alergy and Infectious Diseases (NIH). Among the issues being addressed by the group are:

   (a) Time-tables regarding decision making and program implementation.

   (b) Immediate needs in the areas of surveillance, vaccine production, administration, and research.

   (c) The decision making process, including organizational structures.

   Their report, which is due November 1, will summarize past and present activities, include options for the future, and make specific recommendations.

2. The Secretary has appointed a project manager for the Secretary's Immunization Initiative who is reporting directly to the Secretary and the Assistant Secretary for Health.

3. The Secretary obtained the services of Professor Richard Neustadt to carry out a study of the decision making process in the swine flu program. It is anticipated that the study will be helpful in developing the best organizational scheme possible.

Subcommittee Question

7. What new research and testing procedures for flu vaccines have been initiated relating to developments in the safety and efficacy area?

Department Response

As you know, the Department has an ongoing program for the development and improvement of controlled test procedures to ascertain the safety and efficacy of influenza vaccines.

Of particular significance are the recently developed procedures employing immunoelectrophoresis for direct quantitation of viral content of vaccines which appear to provide a more reliable index for determining influenza vaccine potency than the currently used agglutination tests. These newer immunological techniques currently are being evaluated in an international collaborative test sponsored by the Bureau of Biologics of the Food and Drug Administration, the National Institute of Biological Standardization and Control in England, and the World Health Organization.

In addition, the extensive clinical trials carried out as a result of the swine flu campaign provided us with a unique opportunity to study the effect that vaccines have on man, both in terms of potency and adverse effects. For example, it was determined that there was a correlation between whole virus vaccines and the incidence of short-term reactions, e.g., aches and fever. It was also noted that in older populations, which may have been exposed to influenza earlier, split virus vaccines produced good antibody responses without the systemic reactions produced by the whole virus vaccine.

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Subcommittee Question

8. What methods are the Department employing to review actual costs of the program and better predict future program costs?

Department Response

As indicated in the answers to questions 3 and 4, the Department is in the process of auditing actual production costs of the manufacturers. As you are aware, costs for the swine flu program were originally estimated to be $135 million, based upon estimates of the per unit cost and the cost of distributing and administering the vaccine. No estimate was included for the cost of liability since there was no experience upon which such an estimate could be made.

To date, the program has cost $102 million, approximately $33 million less than estimated, primarily because unit costs were less than estimated (43¢ versus 50¢) and the number of units produced was fewer. In addition, a survey of State and local projects revealed that considerable resources were devoted to the program over and above Federal funds. A summary of these data is enclosed.

Findings from the present audit and the actual experience of State and local governments should contribute to our capacity to estimate the costs of future programs.

NATIONAL INFLUENZA IMMUNIZATION PROGRAM
ESTIMATE OF TOTAL RESOURCES USED,
BY TIME PERIOD, FOR 61 OF 63 GRANTEES

SOURCES OF RESOURCES USED	TOTAL APRIL 1976 TO MAY 1977	APRIL - SEPT. 1976	OCT. - DEC. 1976	JAN. - MAY 1977
TOTAL	43,983,653	12,364,640	27,392,204	4,226,809
TOTAL FEDERAL FUNDS	20,044,865	6,327,075	11,081,590	2,636,200
SWINE FLU GRANT	17,420,150	5,302,989	9,803,321	2,313,840
OTHER FEDERAL FUNDS	2,624,715	1,024,086	1,278,269	322,360
VALUE OF HEALTH AGENCY (GRANTEE) RESOURCES	12,011,318	2,994,054	8,111,323	905,941
VALUE OF RESOURCES PROVIDED BY OTHER OFFICIAL AGENCIES	11,927,470	3,043,511	8,199,291	684,668
STATE AGENCIES	1,568,402	746,035	659,567	162,800
LOCAL AGENCIES	10,359,068	2,297,476	7,539,724	521,868

SOURCE: NATIONAL PUBLIC HEALTH PROGRAM REPORTING SYSTEM, ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS

Subcommittee Question

9. Why was the decision made to accept the fixed liability insurance premium rather than opting for a retrospective rate adjustment? What options were proposed, and why were the various other options rejected?

Department Response

As you know, pursuant to P.L. 94-380, the Federal government was authorized through subrogation to sue program participants, including manufacturers, for their negligent acts in the manufacture of the swine flu vaccine. This provision made it necessary for the manufacturers to obtain insurance against the possibility that they might produce a faulty batch of vaccine. Although the legislation did provide "...that any insurance premium amount which is included in the price of such procurement contract and which is refunded to the manufacturer under any retrospective, experience-rating plan or similar rating plan shall in turn be refunded to the United States...", it did not mandate that the insurance premium be subjected to a retrospective adjustment. It is our understanding that in the negotiations between the manufacturers and the insurance companies various options were not discussed because the insurers refused to offer any retrospective adjustment. The possibility of significant profits to insurance companies was recognized (see in particular the comments of Congressman Eckhardt, Congressional Record, August 10, 1977, H8653). Under less extreme circumstances, the Department might have entered the negotiations between the manufacturers and the insurers. However, with the flu season imminent and negotiations otherwise faltering, it did not do so.

Subcommittee Question

10. What effort, if any, has the Department made to locate individuals who may have been injured as a result of the swine flu immunization program?

Department Response

The standard consent documents, which were provided to each vaccinee, summarized the types of side effects which might be experienced after vaccination. Each federally assisted State or local project developed procedures (generally a note attached to the consent documents) which informed vaccine recipients about the mild side effects which might be expected and listed a place to call if anything more serious occurred.

Reports of illnesses which occurred following vaccination were reviewed by State or local project personnel and sent to CDC for analysis if the illness required a visit or call to a physician or clinic or resulted in the need for bed care. Over 4,500 reports have been received by CDC.

The standard consent documents also provided specific information on how to file a claim if a person felt that their injury or illness was related to the vaccination.

In addition, on a retrospective basis, the Department, in an attempt to identify victims of Guillain-Barre Syndrome, requested all States to conduct surveys which included directly contacting all neurologists within the State.

Subcommittee Question

12. What new national liability policies has HEW developed to prevent the Government from bearing the cost of indemnifying the pharmaceutical manufacturers?

Department Response

The liability issue has been under study since prior to the swine flu program. As required by Public Law 94-380, the Department has developed a preliminary draft document outlining options for a national liability policy and strategy. The initial draft was submitted to the House Subcommittee on Health and the Environment on September 15, 1977. To review more carefully all available options and to obtain better estimates of the costs of the various options, the Department requested a delay in the submission of the final report.

Subcommittee Question

13. What initiatives has HEW taken to develop a patient compensation scheme?

Department Response

In November 1976, HEW convened a National Immunization Conference which addressed six different problems associated with immunization. One of these was the question of liability, including the issue of compensation of persons injured in the course of immunization programs. A work group was appointed to develop recommendations for addressing each problem. The final report and recommendations regarding liability options were reviewed in a public forum on April 5, 1977.

Since the compensation issue is so closely related to the liability issue, it will be dealt with comprehensively in the report discussed in the answer to question number 12.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

December 13, 1977

The 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. Chairman:

As noted in my letter of October 27, delayed transmittal of the 20 recommendations of the Association of State and Territorial Health Officers regarding the swine flu program necessitated additional time to prepare adequate responses. I hope that the enclosed responses will be helpful in your continuing review of the swine flu experience.

Sincerely yours,

Dick Warden
Assistant Secretary
for Legislation

Enclosure

Subcommittee Question

1. Please respond to each of the twenty specific recommendations made by the Association of State and Territorial Health Officers' spokesman, Dr. Lloyd, in his testimony (a copy of that testimony is enclosed for your use).

Department Response

The conclusions and recommendations of the Association of State and Territorial Health Officers (ASTHO) touch on several aspects of the swine flu program which must be addressed carefully before another nationwide mass immunization program is undertaken. As such, they will receive careful attention during the next few months as the Department completes its own evaluation of the decision-making, organizational, and operational aspects of the swine flu program in order to better manage similar programs in the future. Professor Richard Neustadt of Harvard University has been asked by the Secretary to prepare an independent analysis of the program, focusing especially on the decision-making process. His analysis is due in March 1978. In addition, a work group made up of a number of agencies within the Public Health Service, established by the Assistant Secretary for Health, will develop options for preparing for the next influenza pandemic. The Department will therefore be carefully assessing the weaknesses and the successes of the 1976-77 experience in order to establish an improved approach for meeting future threats.

Comments on each of the specific recommendations of the ASTHO follow:

ASTHO Recommendation

1. State health departments should have input at two levels, i.e., policy decisions and implementation decisions, in any future program.

Department Comment

The Department concurs. While there was representation from State health departments in all formal and almost all informal policy meetings and discussions throughout the duration of the swine flu program, the perception of many State health officers that their involvement was minimal must be recognized and addressed in future programs. In the final analysis, it is these officials who are charged with carrying out such programs. The matter of consultation with State officials is receiving attention as the process of decision-making during the swine flu program is evaluated and as plans are made for future Departmental responses to similar health threats.

ASTHO Recommendation

2. There should be a rational, detailed discussion of the medical facts bearing on the decisions in the medical press.

20. More publication of clinical trials data is needed in medical journals.

Department Comment

The Department concurs. During the swine flu program, the results of the first phase of the field trials were published in the Journal of Infectious Diseases within 20 days after the data were accumulated and analyzed in an open meeting at the Bureau of Biologics (BoB). Publication of the second phase of the field trials in this journal occured 60 days after their collection and analysis. Additional articles on the swine flu program also appeared in the medical press. While the Department agrees that more could be done to disseminate information to the medical press, including information regarding the medical decision-making process, it must be noted that the Department cannot control what independent medical journals publish.

The Department believes that means other than the dissemination of information to the medical press must also be used to provide technical information to the medical community, including distribution through State and local medical societies and through health department and Public Health Service publications. All possible avenues must be utilized in order to provide the medical community with better information about pandemic influenza and the options available for preventing illness and death prior to the time when major national decisions must be made.

ASTHO Recommendation

3. There should be a clearly delineated focal point within HEW for such a program, rather than a variety of leaders.

Department Comment

The Department concurs. During the swine flu program the Assistant Secretary for Health functioned as the focal point for directing the entire Public Health Service's influenza immunization activity. The Center for Disease Control (CDC) was designated as the lead agency for carrying out the program. Clarification of the chain of command is receiving attention as plans are developed for future immunization programs. Recently, to facilitate the coordination and management of the new Childhood Immunization Initiative, Secretary Califano has established a special work group in his immediate office.

ASTHO Recommendation

4. Immunization programs should be aimed at high risk groups, not at the total population of the country.

Department Comment

The response to this question depends on the circumstances. If the nation is faced with the threat of pandemic influenza, in which excess mortality has been observed in young, apparently healthy individuals, and the vaccine supply is adequate to immunize the entire population, it would be improper to exclude persons not at high risk from an influenza immunization program. If the influenza threat is of such a nature that it is expected to cause excess mortality primarily in high risk groups, or if vaccine supplies are inadequate to immunize the entire population, then aiming an influenza immunization program at high risk groups may be appropriate. During inter-pandemic periods, the Department's only recommendation is that high risk individuals be given influenza vaccinations. No recommendations are currently made for other groups.

ASTHO Recommendation

5. All State health departments should have teletype or reactive computer terminal capability in order to receive rapid communication from CDC.

6. More teletype and postal communications should emanate from CDC; all telephonic communications should be followed by written confirmation.

Department Comment

One of the most persistent problems encountered during the swine flu program was that of communication. At the present time a number of measures are under consideration, including improved telecommunication systems. The cost of various alternatives remains a major concern, however. The Center for Disease Control (CDC) is presently conducting a formal, structural evaluation of methods to improve communications with each State. Similar systems are needed within States to complete the network of communication to local areas. The CDC has discussed these alternative approaches with the ASTHO at its meeting on November 3, 1977 and is taking their suggestions under consideration. The determination of which systems will be most cost effective in improving rapid, two-way communications is expected in the near future.

ASTHO Recommendation

7. CDC should develop a mechanism to obtain input from State and local health departments.

Department Comment

The Department concurs. The CDC carries out much of its overall mission through State and local health departments and is committed to remedying any remaining weaknesses in obtaining advice from these groups. The CDC maintains an informal line of communication with State health officers, and collaborates with State and local health departments through the day-to-day implementation of disease control grant programs, the epidemic assistance provided by the CDC to State and local agencies, and the diagnostic reference and other laboratory improvement services offered by the CDC.

In addition, there are more formal means by which the CDC receives advice from State and local health departments, including: (1) membership on the Advisory Committee on Immunization Practices; (2) meetings with the ASTHO as a whole and with its Executive Committee; (3) annual meetings with the Association of State and Territorial Epidemologists--particularly with respect to determining which diseases shall be notifiable on a weekly basis; and (4) annual meetings with the Association of State and Territorial Public Health Laboratory Directors.

ASTHO Recommendation

8. If CDC is going to use its regional offices to transmit or handle requests for information, such offices need to be better informed.

Department Comment

The Department concurs in the need to assure good two-way communication with the States. One of the earliest problems encountered in the swine flu program was the need to improve the exchange of information between the CDC and the State and local health officials through the Regional Offices. Because of this problem, in June, 1976 CDC designated 5 staff members to serve as liaison to each Regional Office which resulted in improvements in the exchange of information. Future programs would, of course, be conducted with this experience in mind. In addition, the Department has recently reorganized the Regional Offices to enhance their ability to serve as an effective first line of communication.

ASTHO Recommendation

9. When considerable amounts of State and local resources will be required for a program, the program should not be hailed as a "federal program."

Department Comment

The Department concurs. The swine flu program was appropriately designated as a "national" program, but unfortunately this was sometimes translated by the media and the public as being a "Federal government" program. In most States, however, the role of the State and local governments was properly perceived. Naturally, in programs such as these the Department is anxious that the cooperative aspects be recognized.

ASTHO Recommendation

10. An estimate of State and local costs should be considered in the initial decision-making process.

Department Comments

State and local costs were considered in the initial swine flu decision-making process. The original estimates of State and local costs were based on previous experience in carrying out immunization programs, although there was no completely adequate prototype since no program comparable in scope had ever been carried out.

Several key assumptions were made. First, it was thought that significant numbers of volunteers would be available to assist State and local agencies in doing many needed jobs. This assumption was apparently valid until delays in vaccine availability forced State and local health officers to continually reschedule their programs. Many volunteers were lost in that process.

Second, it was assumed that existing State and local personnel resources would be available for use in the program. Even if Federal funds had been made available to support all paid personnel needed for the program, State and local officials would not have been able to hire new personnel to do many of the tasks. Personnel loaned from existing programs were required because special expertise, found only in existing health department staffs, was necessary. The Federal budget estimates did not include reimbursement for such personnel if they were already budgeted for ongoing health department programs. While the provision of funds for this purpose might have eased some of the financial pressure on State and local health agencies, it would not have prevented the temporary diversion of health department personnel to the swine flu program.

The Department is aware of these problems and anticipates that the swine flu experience will be valuable in anticipating personnel dislocations and in estimating costs of similar programs in the future.

ASTHO Recommendations

11. Funds should be made available for State and local public information efforts since these were generally more effective than the Federal efforts.

Department Comment

The Department concurs. Funds were in fact provided for State and local public immunization efforts during the swine flu program and should be provided in any future effort.

ASTHO Recommendation

12. The public should be provided at the start of a program with information on potential side effects.

Department Comment

The Department concurs. Known side effects from influenza immunization were widely publicized from the beginning of the program as were the results of the field trials on the particular vaccines which were used in the swine flu program. Furthermore, the Department made continuing efforts to apprise individuals of risks as they became known to the Department.

A related problem which has been raised by State and local health officers is that the public was not prepared for the expected coincidental illnesses which were bound to occur but which had no relationship to the swine flu vaccine. While it was common knowledge among Federal and State health officials that there would be coincidental deaths and illnesses, the expected incidence of those events was not thoroughly quantified nor were adequate efforts undertaken to make the public aware of such expected coincidental occurences. The need for greater public education is not confined to the swine flu program, but should be extended to all immunization programs. While it will be very difficult to counter the impact of "crisis" media coverage of events where vaccine associated illness or death is alleged, an active effort must be made to provide a balanced picture of the true risks and benefits of vaccination in order to help the public place such reports in proper perspective.

ASTHO Recommendation

13. More realistic dates for vaccine delivery should be given with recognition that delays will occur.

Department Comment

The Department agrees that the changing vaccine availability schedules during the period July-September 1976, were a major source of frustration and lost opportunity during the early stages of the swine flu program. In establishing schedules, the Department tended to focus on production and distribution capacities and might not have sufficiently emphasized the disruptive effect that ancillary events might have.

In the swine flu program, the liability issue significantly disrupted distribution schedules when the manufacturers delayed release of produced vaccine until adequate protection against liability was in place. While it is often difficult to foresee that kind of eventuality, the swine flu experience has taught the Department to be more wary of the many complicating factors that can impede the delivery of vaccine. Present review of that experience by the Department and Congress should produce more reliable production and delivery schedules.

ASTHO Recommendation

14. Normal distribution channels should be used for vaccine with availability through commercial channels.

Department Comment

The Department will give consideration to this recommendation, although past experience with reliance on normal distribution channels in national programs has not been favorable. When production of vaccine was left to voluntary action by the manufacturers during the 1957 influenza pandemic, supplies were inadequate and maldistributed.

During the swine flu program the four vaccine manufacturers honored the Department's request that the Federal government's needs be met before the vaccine was provided through normal commercial channels. This request was made in an effort to achieve an equitable distribution of vaccine throughout the country. In any future mass immunization program, so long as timely and adequate supplies of vaccine are assured to the Federal government for its distribution, the manufacturers would be encouraged to provide supplies through whatever commercial channels are available to them.

While overall delays in the distribution of the swine flu vaccine were a major problem in 1976, the Department feels that the ability of CDC to direct early supplies of vaccine to areas of the country with confirmed clinic schedules facilitated the best use of the supplies which were available. This was particularly true during the month of October, the critical first month of the vaccination phase of the program.

ASTHO Recommendation

15. Immunization schedules should be kept simple.

Department Comment

The Department concurs with this recommendation in principle. However, the type of antibody response produced by a given vaccine, previous experience with the target virus, and the fact that reaction rates vary according to age, are factors which must be considered in making vaccine recommendations. To the extent that there are uniform reaction and antibody responses to a single vaccine formulation throughout the population, influenza immunization schedules will be kept simple.

ASTHO Recommendation

16. HEW should develop a national policy on informed consent with substantial planning around the issue of informed consent before the next program requires immediate action.

17. Input on form preparation should be obtained from public health professionals and lay persons.

Department Comment

The Department concurs. During the swine flu program, informed consent procedures and forms were developed and implemented under very stringent time constraints. While the response from State and local project directors to the original drafts of the swine flu consent forms was very useful, subsequent developments, including delays in vaccination recommendations for young people and the special requirements for consent forms authorized by Pub. L. 94-380, such as review by the National Commission for the Protection of Human Subjects, required revisions of forms and procedures with minimal advice or recommendations from State and local health authorities.

The Department is currently attempting to improve its procedures for developing informed consent forms to provide an easily comprehended and balanced statement of the risks and benefits of vaccination. The recent development of new forms to be used in immunization programs for the vaccine preventable diseases of childhood included: (1) review by State and local health authorities, and (2) a field trial of their effectiveness in adequately informing the potential vaccinee's parent or guardian about the risks and benefits of vaccination. Naturally, we are aware of the need to review consent forms on a continuing basis not only to reflect developments in the medical and scientific areas but also to improve them as a means of communication.

ASTHO Recommendation

18. HEW should develop a mechanism for involving national, State, and local medical societies in medical policy-making at an earlier stage.

19. The role of private medicine in such a program should be enhanced and encouraged.

Department Comment

The Department concurs. No national immunization program can succeed without the active participation of private medicine. Unfortunately, the cooperation and participation of private medicine in the swine flu program of 1976 was generally less than expected.

With respect to the decisions made during the swine flu program, national medical groups were represented on the Advisory Committee on Immunization Practices and through participation in national meetings held at the White House on March 24, 1976, and at the CDC on April 2, 1976. On a continuing basis the CDC attempts to involve medical societies through the Advisory Committee on Immunization Practices and other Departmental advisory committees. In addition, the general issue of the involvement of all elements of the health care delivery system in the decision-making process is being studied both retrospectively, with respect to the swine flu program, and prospectively, with respect to future immunization programs.

Mr. ROGERS. The committee will have to stand in recess for 10 minutes. I know that there are some of you who have to catch planes, and I apologize, but we are running behind schedule. We will try to get to you as soon as possible.

The committee stands in recess for 10 minutes.

[Brief recess.]

Mr. ROGERS. The subcommittee will come to order, please.

We will now have the testimony from the official health agencies, Dr. Douglas S. Lloyd, Connecticut Department of Health on behalf of the Association of State and Territorial Health Officials; Dr. William Elsea, Health Officer and Director of the Fulton County, Ga., Department of Health, on behalf of the National Association of County Health Officials; and Dr. Richard M. Biery, Director of Health, Kansas City, Mo., Director of Health, Kansas City, Mo., Department of Health, on behalf of the U.S. Conference of City Health Officers.

All of you are welcome. Your statements will be made part of the record, and at this point, we will hear from Dr. Lloyd.

STATEMENT OF DOUGLAS S. LLOYD, M.D., ON BEHALF OF THE ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS (ASTHO)

Dr. Lloyd. Thank you, Mr. Chairman.

My name is Dr. Douglas Seward Lloyd. I am Commissioner of Health for the State of Connecticut. I appear before you today representing the Association of State and Territorial Health Officers (ASTHO) to give testimony concerning the 1976–77 A/New Jersey-A/Victoria national influenza immunization program—Public Law 94–380.

The information contained herein represents the combined response of the State and Territorial Health Officers who participated in a nationwide survey conducted by ASTHO at the conclusion of the swine influenza program

ASTHO members were asked to characterize the way in which the decision to immunize the nation's population against the A/New Jersey/76 virus was made. The vast majority felt that the decision was correct, given the facts available at the time, and not politically motivated. It was a mistake, however, to have the program announced by the President, as such endorsement prevented any later attempt to modify the program, and it cast a political overtone on the decision.

A major weakness of the decisionmaking process was the lack of input from State and local health departments. Opposition to the decision to launch the program should have been presented forthrightly at the time the decision was announced. The apparent HEW philosophy to "move forward at all costs," rather than to modify the program as problems developed, was another major weakness.

Of communication between the Center for Disease Control (CDC) and the States, the State and territorial health officials felt that all too often the press received information before the health officials I can relate a personal example of this particular situation, Mr. Chairman. When the conference call to halt the program was to come from CDC, local television camera crews had already been alerted through their news wires and were in my office filming me answering the phone. Their abilities with communications far exceeded the Federal capability to relay information concerning health expeditiously.

It was quickly found that conference calls cannot be used as a forum for discussion. It was often difficult, if not impossible, to find an appropriate person at CDC to answer questions when the pres-

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sure for those answer were upon State and local officials and the data on which to base the answer were in Federal hands. Communication did improve as the program progressed, but never reached satisfactory levels.

On the issue of funding of the program, the answers were almost unanimous. There was a definite drain on State and local resources to administer and implement the program, so that other public health programs suffered from diversion of staff to the influenza program. In some States, there was no possibility to obtain additional State or local funds, since appropriating legislative bodies were not in session.

A cost analysis of Connecticut's program clearly demonstrated that municipal governments had to bear the brunt of the costs of the program. At 50 cents per dose for the vaccine and 13 cents per dose for its delivery, the Federal expenditure per inoculation was 63 cents. The Connecticut State Health Department added another 11 cents per dose. This brought the total expenditure by the Federal and State Governments to 74 cents per dose. On the average, a town in Connecticut which immunized 30,000 people spent an additional 73 cents per vaccination. There were no extra State or Federal moneys available to offset these costs to the towns.

Public information and public awareness efforts can be characterized as too little, too late and reactive after the fact rather than anticipatory. The national public information effort through the mass media was inadequate and did not really educate the public. Materials provided by CDC for local use were received too late to be of much value. Although the quality of materials was generally good, some were too technical for the general public. Professional education was almost totally lacking, but an interesting finding was that the public can appreciate basic data on relative risks.

When ASTHO members were asked to comment on vaccines and supplies, the following answers were recorded: The Vaccine supply was adequate, only because the program was curtailed. The greatest problem encountered in implementation of the program was the late, delayed and fluctuating delivery of vaccines, which resulted in cancellation of clinics and strained credibility with the public and volunteers.

National campaigns should be as simple as possible; the complexity of immunization schedules and the use of four vaccines unnecessarily complicated the program. Jet injector guns were of inferior quality; the breakdown rate exceeded previous experience.

Perhaps the most controversial issue of the program centered about the informed consent procedures. The most typical problems voiced by respondents were as follows:

Frequent changes in the form added to the confusion surrounding the program and wasted large amounts of paper and money.

No provisions were made for handling informed consent forms from those who do not have a written language, such as Indians, or speak a less common foreign language, the foreign translation of the form was generally poor.

Problems in form distribution were similar to those with vaccine distribution. Forms were designed by lawyers to fulfill liability problems and, accordingly, did not serve as a tool to inform or educate the vaccine recipients.

The form was too long and was not read or understood.

A major oversight in the planning and funding of this immunization program was the failure to provide for orderly recordkeeping systems. If we are to carry out public health service programs on a mass scale we must keep retrievable individual records of those served just as would be expected in routine medical delivery.

Because of CDC's inability to fund computerized data systems, Connecticut now has 1,700 lineal feet of 3 by 5 catalog cards which are yet to be alphabetized by hand. The result is difficulty in tracing consent records on individuals who have sued the Federal Government for vaccine reactions, and inability to conduct evaluations of these data which could expand our knowledge of flu vaccine.

Opinions of ASTHO members varied considerable when the question of relationships with private medicine was posed, but several points were universal. The program fared better in those locations where the relationship with private medicine was good. Like State and local health departments, private medicine in general was not included in the decisionmaking process. Private medicine never really understood the program or the rationale behind it. There was little discussion of the medical issues in the medical journals.

Lack of a position on the program by the American Medical Association, we felt, also detracted from the support of the program by private medicine. Problems with vaccine distribution and the lack of availability of vaccine through normal commercial channels particularly irritated the private medical community.

All but one respondent felt that Federal public health advisers and Epidemic Intelligence Service Officers employed by CDC and assigned to the States were invaluable in the planning, coordination, and implementation of the program.

Medical complications were the issue that led to the final demise of the program. Health professionals were extremely critical in this area. The general feeling was that more advance warning on the possibility of coincidental mortality was needed. The media were at times overly negative in reporting deaths and complications because they had not been previously desensitized. CDC handled the Guillian-Barre Syndrome issue well. However, unfortunately, knowledge that this syndrome may follow other immunizations may detract from future immunization programs. CDC could have provided more information to the States regarding the complications and deaths.

Finally, on the question of the clinical trails of the vaccine, the information was thought by some to be misleading and overly optimistic. Data provided to the States did not entirely support the recommendations. Most, however, felt the data were adequate but were not shared sufficiently early.

The recommendations were:

One: State health departments should have input at two levels, that is, policy decisions and implementation decisions, in any future program.

Two: There should be a rational, detailed discussion of the medical facts bearing on the decisions in the medical press.

Three: There should be a clearly delineated focal point within HEW for such a program, rather than a variety of leaders.

Four: Immunization programs should be aimed at high-risk groups, not at the total population of the country.

Five: All State health departments should have teletype or reactive computer terminal capability in order to receive rapid communication from CDC.

Six: More teletype and postal communications should emanate from CDC; all telephonic communications should be followed by written confirmation.

Seven: CDC should develop a mechanism to obtain input from State and local health departments.

Eight: If CDC is going to use its regional offices to transmit or handle requests for information, such offices need to be better informed.

Nine: When considerable amounts of State and local resources will be required for such a program, the program should not be hailed as a Federal program.

Ten: An estimate of State and local costs should be considered in the initial decisionmaking process.

Eleven: Funds should be made available for State and local public information efforts, since these were generally more effective than the Federal efforts.

Twelve: The public should be provided at the start of a program with information on potential side effects.

Thirteen: More realistic dates for vaccine delivery should be given with recognition that delays will occur.

Fourteen: Normal distribution channels should be used for vaccine, with availability through commercial outlets, where possible.

Fifteen: Immunization schedules should be kept simple.

Sixteen: HEW should develop a national policy on informed consent with substantial planning around the issue of informed consent before the next program requires immediate action.

Seventeen: Input on form preparation should be obtained from public health professionals and lay persons.

Eighteen: HEW should develop a mechanism for involving national, State, and local medical societies in medical policymaking at an earlier stage.

Nineteen: The role of private medicine in such a program should be enhanced and encouraged.

Twenty: More publication of clinical trials data is needed in medical journals.

Almost all of these criticisms and recommendations bear on CDC's handling of this program. This is inevitable, given CDC's key role in coordinating the program and communicating with the States. The State health officers do not mean to impugn CDC. On the contrary, the Center is held in high regard as an indispensable source of aid and expertise in preventive medicine, especially in communicable disease control. It is, in fact, the Federal agency most adept at providing public health services, working through State and local health departments. Our hope is that through CDC the Federal capability to pursue all sorts of preventive medical programs on a mass scale may be refined and expanded.

If one were asked to make an overall assessment or draw conclusions from the multitude of responses from the health department heads throughout the country, the following would be the product:

First: The swine influenza immunization program of 1976–77 indicated that State health departments are not slow-moving bureaucracies. State and local health departments can rapidly launch a massive effort in response to demonstrated need.

Second: The swine influenza immunization program has enabled health departments to refine their skills in community organization, to improve relationships with the media, and to develop a cadre of health-oriented volunteers. Our fear is that the program may have harmed the credibility of health departments in some areas due to the many problems which appeared to develop unexpectedly.

If I may, I would like to add a personal note. Connecticut achieved one of the highest levels of immunization of its population in the country, almost 58 percent of the target population and more than 95 percent of the high-risk population was immunized in less than 2½ months. These achievements were the direct result of the extraordinary hard work and dedication of the health professionals of the State. It was those individual efforts and the outstanding cooperation from the news media which were the cornerstone of the Connecticut's successful program.

I would like to thank you for your kind attention and will be most happy to answer any questions either at this time, or at any future date of your choosing.

Mr. ROGERS. Do you feel that we will have this type of liability problem in future immunization programs?

Dr. LLOYD. It was a major headache for us in the State of Connecticut. We constantly had to deal with problems of liability. We found, for instance, that many of the private doctors did avoid the program because of the liability. There was a lot of unnecessary expense. I would think that the Congress needs to look very seriously at some sort of no-fault situation in the future for untoward effects.

Mr. ROGERS. You mean a better system of keeping records on the persons receiving immunization. What could have been done to improve this?

Dr. LLOYD. We spend roughly 13 cents per dose for delivery. We think as much should be spent for records. The reason is that if we are going to learn from massive health programs like this, we have to have better data. We need access in the event of reaction, death, or legal complications.

Many of the points that were brought in the testimony before the committee this morning show that we need better records. Absolutely, it is going to be necessary to evaluate effectiveness in the future, so that we can do the job better.

Mr. ROGERS. What about communications being improved. I think you have a good point there.

Dr. LLOYD. We would agree that communication, and CDC also agrees, is extremely important. It was somewhat embarrassing that the press very often had answers to questions that were being asked before we did. We feel that some sort of almost instantaneous communication between the CDC and the State health departments is going to be extremely important, some sort of interactive computer or teletype system. We feel that it is going to be very important.

Since the swine flu program, other problems that we have had, whether it be with measles, and other issues that we have had to respond to, have required some sort of better communication.

Mr. ROGERS. I thought that you might like to know that the American Medical Association did endorse the program, the entire program.

Dr. Lloyd, thank you for your presence. We appreciate your helpful testimony, and we will ask HEW to comment on your suggestions.

Dr. LLOYD. Thank you, sir.

Mr. ROGERS. Dr. Elsea, you may proceed.

STATEMENT OF WILLIAM R. ELSEA, M.D., VICE PRESIDENT, NATIONAL ASSOCIATION BY COUNTY HEALTH OFFICIALS (NACHO); ACCOMPANIED BY MIKE GEMMELL, LEGISLATIVE REPRESENTATIVE

Dr. ELSEA. Mr. Chairman, and members of the committee: I am Dr. William Elsea, health officer and director of the Fulton County, Ga., Health Department in Atlanta, and vice president of the National Association of County Health Officials—NACHO—on whose behalf I am appearing today. NACHO is the public health affiliate of the National Association of Counties.

I am also a member of the U.S. Public Health Service Advisory Committee on Immunization Practice which advised HEW on implementation of the national influenza immunization program. With me today is Mike Gemmell, legislative representative for both NACHO and NACO.

The purpose of my statement is to point out some of the successes and problems local government health officers faced during the implementation of the national immunization program last year.

In the interest of time, I will summarize my testimony. With your permission, I would like to have the attached survey of county agencies made a part of the record. The survey demonstrates the high level of county involvement of the national swine flu program.

Mr. ROGERS. Without objection, it will be made part of the record [see p. 392].

Dr. ELSEA. I would like to point out for the record that the National Association of County Health Officials and the National Association of Counties strongly supported the initial decision to launch the vaccination program against swine influenza. Both associations pledged their support and cooperation in carrying out the immunization program.

We did warn our county health officers about the potential problems they might face, such as problems in storage of the vaccine, lack of manpower, confusion over implied consent, public apathy, and most importantly, the lack of financial resources to get the job done.

On the last point, for example, Jefferson County, Ky., spent $140,000 of local money that was not reimbursed; Arlington County, Va., spent $16,000; Jefferson County, Ala., spent $54,000; Palm Beach County, Fla., spent $30,000, and large amounts of funds were spent in Los Angeles County, and that will be submitted on Monday.

Mr. Chairman, these do not sound like large amounts, perhaps, compared to the Federal budget, but these represent mainly local property taxes that are especially keenly felt by the local people.

In retrospect, and this does not include in general local resources, and we will go to that point in a moment, in restrospect we remain convinced that those Federal officials responsible for initiating the program acted in good faith. They made the hard decisions that circumstances required.

What concerns us now is the long range negative impact the swine flu program will have on other immunization programs conducted by county health agencies. Of the 52 million American children under 15 years of age, 20 million are not properly immunized against polio, measules, rubella, tetanus, diphtheria and whooping cough.

We have the vaccine, the public and private health care resources and the know-how to immunize these children, yet the experience with the swine flu program and the current immunization rates suggest a real danger of outbareaks of these preventable diseases.

The county health officers have strongly endorsed Secretary Califano's child disease immunization initiative. We want to be consulted during initial stages of the program. The feedback from the swine flu episode highlights the essential need to involve local health officers in program implementation.

During the swine flu program there was a definite drain on local resouces. We estimate that they probably nearly match the amounts spent on vaccine by the Federal Government. As a result, basic public health immunization programs suffered from the diversion of money, time and manpower to the national influenza program.

However, our failure to maintain proper immunization levels cannot be solely blamed on the swine flu episode. It is a result of inadequate knowledge on the part of the lay population, insufficient concern and vigilance on the part of the professional community, the fact that disease prevention has traditionally been the neglected part of Federal health care policy and, finally, the lack of Federal, State and local funds to improve the capacity of local health agencies to carry out their primary mission, that of protecting the public's health through disease prevention activities.

We concur with the Association of State and Territorial Health Officials' conclusions and recommendations just presented concerning the national influenza immunization program. Our own research found that the very nature of the emergency immunization program, including the preparation and administration of a new vaccine against a poorly understood virus, created problems that were to be expected and constituted a great majority of the complaints from the counties.

These included: Insufficient supplies of vaccine; time consuming informed consent forms; constantly changing guidelines creating numerous administrative problems, among others. But, many basic organizational problems could and should be avoided in any future mass immunization program.

More money allocated toward administration of the program, including personnel costs at the local level, better communication

and direct local agency involvement in the policymaking and implementation process were the most often cited suggestions for improvement of the national immunization program.

In summary, Mr. Chairman, the national swine flu program demonstrated that State and local health agencies have the capability to rapidly gear-up to carry out a national immunization program.

One final point needs to be made. Let it go on record, Mr. Chairman, that when the call went out to prepare for a possible influenza epidemic in the spring of 1976, county, State and city public health officials, at the expense of other public health endeavors, performed with distinction. They shouldered the burden. They faced the critical public and their local governments supported their immunization activities.

We thank you for giving us the opportunity to share our observations concerning county health agency involvement in the national influenza immunization program.

The National Association of County Health Officials' survey is attached to this testimony. This documentation will no doubt be of importance since HEW is launching a mass immunization program.

On a closing note, we wish to commend the chairman for his leadership under conditions that have been extremely volatile and mostly politically charged.

Thank you, Mr. Chairman. We will be happy to answer any questions.

[Testimony resumes on p. 397.]

[Dr. Elsea's prepared statement and attachment follows:]

STATEMENT ON WILLIAM ELSEA, M.D., HEALTH OFFICER, FULTON COUNTY, GEORGIA, ON BEHALF OF THE NATIONAL ASSOCIATION OF COUNTY HEALTH OFFICIALS (NACHO) BEFORE THE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE, SUBCOMMITTEE ON HEALTH AND ENVIRONMENT, ON THE NATIONAL INFLUENZA IMMUNIZATION PROGRAM, SEPTEMBER 16, 1977.

MR. CHAIRMAN, MEMBERS OF THE SUBCOMMITTEE, I AM DOCTOR WILLIAM ELSEA, HEALTH OFFICER AND DIRECTOR OF THE FULTON COUNTY, GEORGIA HEALTH DEPARTMENT AND VICE PRESIDENT OF THE NATIONAL ASSOCIATION OF COUNTY HEALTH OFFICIALS (NACHO) ON WHOSE BEHALF I AM APPEARING TODAY. NACHO IS THE PUBLIC HEALTH AFFILIATE OF THE NATIONAL ASSOCIATION OF COUNTIES (NACo)[1]. I AM ALSO A MEMBER OF THE U.S. PUBLIC HEALTH SERVICE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICE WHICH ADVISED HEW ON IMPLEMENTATION OF THE NATIONAL INFLUENZA IMMUNIZATION PROGRAM. WITH ME TODAY IS MIKE GEMMELL, LEGISLATIVE REPRESENTATIVE FOR BOTH NACHO AND NACo.

THE PURPOSE OF MY STATEMENT IS TO POINT OUT SOME OF THE SUCCESSES AND PROBLEMS LOCAL GOVERNMENT HEALTH AGENCIES FACED DURING THE IMPLEMENTATION OF THE NATIONAL INFLUENZA IMMUNIZATION PROGRAM LAST YEAR.

THE NATIONAL ASSOCIATION OF COUNTIES REPRESENTS OVER 1600 COUNTY GOVERNMENTS WHICH TOGETHER MAKE-UP OVER 90 PER CENT OF THE U.S. POPULATION. THE VAST MAJORITY OF THESE COUNTIES PROVIDE PUBLIC HEALTH AND MEDICAL CARE TO THOSE CITIZENS[2].

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[1]NACo is the only national organization representing county government in America. Its membership includes urban, suburban, and rural counties joined together for the common purpose of strengthening county government to meet the needs of all Americans. By virtue of a county's membership, all its elected and appointed officials become participants in an organization dedicated to the following goals: improving county government; serving as the national spokesman for county government; acting as a liaison between the nation's counties and other levels of government; and, achieving public understanding of the role of counties in the federal system.

[2]Over 75% of the 3000 counties are administratively responsible for providing community health services. Over 68% provide medical assistance, 60% provide mental health services, 30% operate hospitals (nearly half of public hospitals are county operated), 38% provide emergency medical services, and 26% operate long term care facilities. Counties also provide traditional public health services: immunization programs, sanitation, home health, school health, V.D. clinics, well-baby clinics, alcoholism and drug abuse prevention and treatment, family planning, etc. To a large extent, these services are financed by local funds. Census data shows that counties spent $3 billion for hospitals and $1 billion for community health services in 1975. In 1966, counties spent $1.3 billion and $311 million, respectively.

IN THE INTEREST OF TIME, I WILL SUMMARIZE MY STATEMENT. WITH YOUR PERMISSION, I WOULD LIKE TO HAVE THE ATTACHED SURVEY OF SELECTED COUNTY HEALTH AGENCIES BE MADE PART OF THE HEARING RECORD. THE SURVEY WAS CONDUCTED TO DEMONSTRATE THE HIGH LEVEL OF COUNTY INVOLVEMENT IN THE NATIONAL SWINE FLU PROGRAM.

I WOULD ALSO LIKE TO POINT OUT FOR THE RECORD THAT THE NATIONAL ASSOCIATION OF COUNTY HEALTH OFFICIALS AND THE NATIONAL ASSOCIATION OF COUNTIES STRONGLY SUPPORTED THE INITIAL DECISION TO LAUNCH THE VACCINATION PROGRAM AGAINST SWINE INFLUENZA. BOTH NACHO AND NACo PLEDGED THEIR SUPPORT AND COOPERATION IN CARRYING OUR THE IMMUNIZATION PROGRAM. WE DID WARN OUR COUNTY HEALTH OFFICERS ABOUT THE POTENTIAL PROBLEMS THEY MIGHT FACE — BASIC PROBLEMS LIKE STORAGE OF THE VACCINE, LACK OF MANPOWER, CONFUSION OVER IMPLIED CONSENT, PUBLIC APATHY, AND MOST IMPORTANTLY, THE LACK OF FINANCIAL RESOURCES TO GET THE JOB DONE. FOR EXAMPLE, JEFFERSON COUNTY, KENTUCKY SPENT $140,000 OF LOCAL MONEY THAT WAS NOT REIMBURSED; ARLINGTON COUNTY, VIRGINIA SPENT $16,000; JEFFERSON COUNTY, ALABAMA SPENT $54,000; PALM BEACH COUNTY, FLORIDA SPENT $30,000; GUILFORD COUNTY, NORTH CAROLINA SPENT $20,000. MOST COUNTIES REPORTED THAT NON-REIMBURSABLE LOCAL FUNDS WERE SPENT ON PERSONNEL, OVERTIME, PUBLIC RELATIONS, OUTREACH AND OTHER ADMINISTRATIVE COSTS. THESE FUNDS WERE LARGELY DIVERTED FROM OTHER BUDGETED PUBLIC HEALTH PROGRAMS.

IN RETROSPECT, WE STILL BELIEVE THOSE FEDERAL OFFICIALS RESPONSIBLE FOR INITIATING THE PROGRAM ACTED IN GOOD FAITH. WHAT CONCERNS US NOW IS THE LONG RANGE NEGATIVE IMPACT THE SWINE FLU EPISODE WILL HAVE ON OTHER IMMUNIZATION PROGRAMS CONDUCTED BY COUNTY HEALTH AGENCIES. OF THE 52 MILLION AMERICAN CHILDREN UNDER 15 YEARS OF AGE, 20 MILLION ARE NOT PROPERLY IMMUNIZED AGAINST POLIO, MEASLES, RUBELLA, TETANUS, DIPHTHERIA AND WHOOPING COUGH. WE HAVE THE VACCINES, THE PUBLIC AND PRIVATE HEALTH CARE RESOURCES AND THE KNOW HOW TO IMMUNIZE THESE CHILDREN, YET THE EXPERIENCE WITH THE SWINE FLU PROGRAM AND THE CURRENT IMMUNIZATION RATES

REPRESENT A REAL DANGER OF OUTBREAKS OF THESE PREVENTABLE DISEASES. THE COUNTY HEALTH OFFICERS HAVE STRONGLY ENDORSED SECRETARY CALIFANO'S CHILD DISEASE IMMUNIZATION INITIATIVE. WE WANT TO BE CONSULTED DURING INITIAL STAGES OF THE PROGRAM. THE FEED-BACK FROM THE SWINE FLU EPISODE HIGHLIGHTS THE ESSENTIAL NEED TO INVOLVE LOCAL HEALTH OFFICERS IN PROGRAM IMPLEMENTATION.

DURING THE SWINE FLU PROGRAM, THERE WAS A DEFINITE DRAIN ON LOCAL RESOURCES. AS A RESULT, BASIC PUBLIC HEALTH IMMUNIZATION PROGRAMS SUFFERED FROM THE DIVERSION OF MONEY, TIME AND MANPOWER TO THE NATIONAL INFLUENZA PROGRAM. HOWEVER, OUR FAILURE TO MAINTAIN PROPER IMMUNIZATION LEVELS CANNOT BE SOLELY BLAMED ON THE SWINE FLU EPISODE. IT IS A RESULT OF INADEAQUATE KNOWLEDGE ON THE PART OF THE LAY POPULATION, INSUFFICIENT CONCERN AND VIGILANCE ON THE PART OF THE PROFESSIONAL COMMUNITY, THE FACT THAT DISEASE PREVENTION HAS TRADITIONALLY BEEN THE NEGLECTED PART OF FEDERAL HEALTH CARE POLICY AND, FINALLY, THE LACK OF FEDERAL, STATE AND LOCAL FUNDS TO IMPROVE THE CAPACITY OF LOCAL HEALTH AGENCIES TO CARRY OUT THEIR PRIMARY MISSION -- TO PROTECT THE PUBLIC'S HEALTH THROUGH DISEASE PREVENTION ACTIVITIES.

WE CONCUR WITH THE ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS' (ASTHO) CONCLUSIONS AND RECOMMENDATIONS CONCERNING THE NATIONAL INFLUENZA IMMUNIZATION PROGRAM. OUR OWN RESEARCH FOUND THAT THE VERY NATURE OF THE EMERGENCY IMMUNIZATION PROGRAM CREATED PROBLEMS THAT WERE TO BE EXPECTED AND CONSTITUTED A GREAT MAJORITY OF THE COMPLAINTS FROM THE COUNTIES. THESE INCLUDED INSUFFICIENT SUPPLIES OF VACCINE, TIME CONSUMING INFORMED CONSENT FORMS, CONSTANTLY CHANGING GUIDELINES CREATING NUMEROUS ADMINISTRATIVE PROBLEMS,AMONG OTHERS. BUT, MANY BASIC ORGANIZATIONAL PROBLEMS COULD AND SHOULD BE AVOIDED IN ANY FUTURE MASS IMMUNIZATION PROGRAM. MORE MONEY ALLOCATED TOWARDS ADMINISTRATIVE ASPECTS OF THE PROGRAM, PERSONNEL COSTS, FOR EXAMPLE, MORE COMMUNICATION (SOME COUNTY HEALTH

OFFICIALS FOUND OUT FROM THEIR LOCAL NEWSPAPERS WHEN THE PROGRAM WAS TO BEGIN), AND DIRECT LOCAL HEALTH AGENCY INVOLVEMENT IN THE POLICYMAKING AND IMPLEMENTATION PROCESS, WERE THE MOST OFTEN CITED SUGGESTIONS FOR IMPROVEMENT OF A NATIONAL IMMUNIZATION PROGRAM. OTHER SUGGESTIONS FROM OUR COUNTY HEALTH OFFICERS INCLUDE:

* INCREASED MEDIA SUPPORT FOR THE PROGRAM.
* HIGH PRIORITY PROJECTS SHOULD BE THE ONLY ONES CONSIDERED.
* USE OF A TARGET POPULATION WOULD CUT DOWN ON CONFUSION AND INCREASE EFFECTIVENESS.
* INVOLVEMENT OF PRIVATE PHYSICIANS IN THE PROGRAM, AND INCLUDE THEM UNDER THE LIABILITY COVERAGE.
* LEAVE THE NORMAL DISTRIBUTION SYSTEM IN EFFECT IN ORDER TO AVOID TENSION BETWEEN PUBLIC AND PRIVATE PROVIDERS.
* BETTER ORGANIZATION AT THE FEDERAL LEVEL WOULD EASE IMPLEMENTATION AT THE COUNTY LEVEL.
* TIMELY DISTRIBUTION OF FUNDS AND VACCINES.
* IDENTIFICATION OF PRIORITY GROUPS AMONG THE POPULATION AT RISK AND MORE TECHNICAL ASSISTANCE TO DEVELOP EFFECTIVE STRATEGIES TO REACH INDIVIDUALS.
* EFFECTIVE AND EXPEDITIOUS IMPLEMENTATION OF CONSENT FORMS AND PROCEDURES.
* COORDINATION OF INFORMATION DISSEMINATION ACTIVITIES WITH OUTREACH AND DELIVERY SERVICES.
* INVOLVEMENT OF ALL SEGMENTS OF THE COMMUNITY.

IN SUMMARY, MR. CHAIRMAN, THE NATIONAL SWINE FLU PROGRAM DEMONSTRATED THAT STATE AND LOCAL HEALTH AGENCIES HAVE THE CAPABILITY TO RAPIDLY GEAR-UP TO CARRY OUT A NATIONAL IMMUNIZATION PROGRAM. ONE FINAL POINT NEEDS TO BE MADE. LET IT GO ON RECORD, MR. CHAIRMAN, THAT WHEN THE CALL WENT OUT TO PREPARE FOR A POSSIBLE INFLUENZA EPIDEMIC IN THE SPRING OF 1976, COUNTY, STATE AND CITY PUBLIC HEALTH

OFFICIALS, AT THE EXPENSE OF OTHER PUBLIC HEALTH ENDEAVORS, PERFORMED WITH DISTINCTION. THEY SHOULDERED THE BURDEN, THEY FACED THE CRITICAL PUBLIC AND THEIR LOCAL GOVERNMENTS SUPPORTED THEIR IMMUNIZATION ACTIVITIES.

WE THANK YOU FOR GIVING US THE OPPORTUNITY TO SHARE OUR OBSERVATIONS CONCERNING COUNTY HEALTH AGENCY INVOLVEMENT IN THE NATIONAL INFLUENZA IMMUNIZATION PROGRAM.

THE NACHO SURVEY OF SELECTED COUNTY HEALTH DEPARTMENTS IS ATTACHED TO THIS TESTIMONY. THE DOCUMENTATION WILL NO DOUBT BE OF IMPORTANCE SINCE HEW IS LAUNCHING A MASS IMMUNIZATION PROGRAM.

THANK YOU, MR. CHAIRMAN.

NACHO SURVEY OF SELECTED COUNTIES' EXPERIENCE WITH
THE NATIONAL INFLUENZA IMMUNIZATION PROGRAM*

GUILFORD COUNTY, NORTH CAROLINA vaccinated 62,750 people (22% of its population). Local money was spent mainly on overtime salaries ($20,000), but this has all been reimbursed. The special clinics and non-routine operating hours created problems in the beginning, but on the whole the program was viewed as "running smoothly." The informed consent form was too time consuming, very bulky, and required additional staff. There was a necessity to stockpile the informed consent forms as not enough were delivered at any one time. One suit was filed and turned over to the county attorney, which was subsequently handled by the U.S. Public Health service. A major fault with the swine flu program was the way publicity was handled. This particular county noted that very few blacks were vaccinated, and attributed this fact to the poor publicity.

Although AUGUSTA COUNTY, VIRGINIA, like most other counties, learned quickly how to adapt to mass immunization procedures, there lingers deep resentment against federal interference in what should have been a local program. The federal government publicized certain aspects of the program that never materialized at the local level (leading to certain embarrassment for county health officials as implementers of the program). Edicts were sent out to local health officials which complicated procedures rather than simplifying them. The county health staff was completely tied up with administering the swine flu vaccine, which set back many on going local programs (these constitute non-reimbursable costs to the county). Administrative problems occurred with site location of immunization centers (traffic tie-ups at schools). The county still has a large quantity of the vaccine and storing it is creating problems. The delay in receiving the vaccine also created problems. More publicity and support from the media was also suggested as a way to improve mass immunizations in the future. This county vaccinated 25% of its population.

JEFFERSON COUNTY, ALABAMA (which includes the city of Birmingham) vaccinated 199,614 persons (47% of its total population). Approximately $54,000 of local money was spent for supplies and wages that was not reimbursed by the state. Delays in receiving the vaccine created administrative problems. The informed consent form created mechancial and logistical problems (major back ups in lines). Jefferson County health officials feel not enough information about the program was disseminated. Any future program should take more precautions and be of a higher priority (unlike swine flu immunization turned out to be) in order to restore credibility in such programs. Using target populations was also suggested as a means of averting many of the problems that occurred under swine flu program.

PALM BEACH COUNTY, FLORIDA vaccinated 114,000 people (32%) and spent approximately $30,000 of local money that was not reimbursed. The program, as viewed from one county health official,was cumbersome,but with much effort they made it a workable program. A major problem was the inadequate funding for administration (this is where almost all of the non-reimbursable local money was spent). Suggestions for any future immunization project include more concrete planning,and involvement of private and public physicians.

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*Survey conducted in June 1977 by the National Association of County Health Officials, 1735 New York Avenue, N.W., Washington, D. C. 20006 (202) 785-9577

ARLINGTON COUNTY, VIRGINIA distributed 20,900 doses of swine flu vaccine and was able to immunize 60% of the high risk population (elderly, and chronically ill). Approximately $16,000 was spent by the county for personnel costs and was not reimbursable. Delays in receiving the vaccine, delays in settling the question of federal liability and the revised informed consent forms created administrative problems. Major mistakes made under the swine flu immunization program were the lack of a target population on a national level (Arlington itself chose to target vaccinations for high risk groups), and the inadequate dissemination of knowledge exacerbated by the media coverage of the Guillain-Barre episode. County health officials here also pointed out the danger that might occur in the future due to a diminished public acceptance of and response to all immunization programs.

HAMILTON COUNTY, TENNESSEE vaccinated 43,000 (17%) people and was reimbursed for all personnel costs from the state. The main problem that arose in handling the swine flu vaccination program was the distribution system imposed on county health officials. All vaccine was delivered to the county health department, whose duty was to distribute the vaccine to private physicians and local industry upon request. Due to the unpredictable delivery schedule of vaccine to the county, quantities requested by private physicians and industry were not readily available. This led to friction and tension between public and private providers, and embarrassment for the county health department (the county was accused of holding out). The informed consent forms required the hiring of extra clerks to explain the form to people who were already aware of the information. Hamilton County also received a surplus of supplies which were never requested by them, and are still creating storage problems.

FAYETTE COUNTY, KENTUCKY vaccinated 150,000 (33%) people. The program was said to have gone well until the adverse publicity appeared. Major problems were caused by the uncertain arrival of vaccine (rescheduling clinics, staff, etc.). The informed consent forms created a problem during the program (slowed line, and many did not understand what they were reading) and are still creating storage problems (the informed consent form for measles must be stored 20 years, rather than the 2 or 3 years for swine flu). Better organization at the federal and industry level (drug companies specifically) would make implementation of such programs at the county level much easier.

MECKLENBURG, NORTH CAROLINA vaccinated 25-30% of its population. Non-reimbursable money was spent on newspaper advertisements and staff. Administrative problems were created by diversion of time and effort of staff from their regular duties and projects. The informed consent forms were inadequate. The new forms including the provision for Guillain -Barre took time to process and review, and are still creating storage problems. County health officials here believe a major mistake made under swine flu was the announcement by the federal government that this was to be a cooperative program. In reality, it was neither a cooperative program nor a wholly federally run program. Enforceability of an immunization program should be under authority at the state and local level. Concern was also expressed for what the spin off effect from the outcome of the swine flu immunization will be onto other worthwhile immunization programs.

LOUISVILLE AND JEFFERSON COUNTY, KENTUCKY vaccinated 260,910 (32%) people. This county spent $140,000 of local money and has not been reimbursed for this cost for staff time. The problems with the program were all due to the changing guidelings - it made the program extremely difficult to administer and to justify.

ORLEANS COUNTY, LOUISIANA immunized 30,000 people (5%) and had large administrative costs that were not reimbursed by the state. This county also seemed to have in indirect problems with liability insurance - the private physicians did not readily volunteer their services due to fear of malpractice suits against them. The mass immunization program could work better if the vaccine was given directly to local health officials to administer.

ANNE ARUNDEL, MARYLAND vaccinated 67,573 (23%) people and spent local money for staff salary. Although this county received good local cooperation, the numerous unknowns (unreliability of receipt of vaccine, variabiliby of "walk-ins" at different centers which caused difficulty in scheduling volunteers) made it a nightmarish program to administer. The informed consent form was considered to be too long (the three page form was described as incomprehensible), too time consuming and ambiguous. The different dosages and different procedures created confusion. The problems with lack of adequate supply led to a lack of credibility and ill feelings from the public. Suggestions for any future program included more funding, a stronger mandate to physicians and public health officials, and more lead time for such a massive project.

WESTCHESTER COUNTY, NEW YORK vaccinated 100,000 people (10%). Political problems arose when each village wanted its own clinic (65 clinics were in operation; 6 of them were open 12 hours a day). The logistical problems in setting up these clinics and operating them were enormous. Future federal immunization programs should be better planned and apply better orientation and communication techniques for local health administrators. More notice would also alleviate many logistical problems.

ERIE COUNTY, NEW YORK immunized 84,000 people (8%) and spent a considerable amount for overtime salaries which has not been reimbursed. There was a problem in getting enough people to handle the program. Planning a budget for this program was difficult due to the reimbursement schedule of 5 cents for every shot. Since the number of shots given depended on the unknown factor of how many people would decide to be immunized, costs were minimized by skimping on staff. Many internal problems occurred with liability incidents (property damage, explosions, carelessness with syringes) all of which would not reoccur if another mass program were implemented. More money and more support would be required for any future immunization program to be more successful than the swine flu program.

BERGEN COUNTY, NEW JERSEY. This state administered its swine flu program by regions within the state rather than through county health departments . A county official believed any future immunization on a massive scale must use direct input from the counties, who are the ones that actually know what the problems are. Communication from the federal government should be much better organized and lines of responsibility should be clearly delineated.

MACOMB COUNTY, MICHIGAN vaccinated 170,000 people (27%) and all costs to the county were reimbursed by the state. The overall program ran smoothly, however, the unavailability of a vaccine supply created some problesm. Health officials here feel the federal government should not undertake another such program unless more time is allowed for planning,testing, and dissemination of information.

WAYNE COUNTY, MICHIGAN immunized 500,000 people (18%) and the staff costs were not reimbursed. All problems stemmed from the reliability and credibility of information at the national level. The vaccine delivery schedule created logistical problems as did the informed consent form (too difficult and too long). Any future program would need better cooperation by the news media, an informed public, and documented risks to be sucessful. The federal government's credibility, as far as another mass immunization program, was under question. Thus, any federal involvement must be done with low profile and administered directly through local government.

SACRAMENTO COUNTY, CALIFORNIA immunized 70,000 people (11%). Major problems arose due to the delay of arrival of the vaccine; scheduled clinics had to be cancelled and rescheduled numerous times. The informed consent form was too complicated to administer smoothly. The different kinds of vaccine and split populations also made administration difficult. The problem of liability insurance was common to all - from this time forth any time a county wants to administer a mass immunization effort on its own, it will be virtually impossible to get insurance due to the past experience with swine flu liability claims. This county suggests adoption of federal legislation to secure a permanent solution to this liability problem.

SAN DIEGO COUNTY, CALIFORNIA vaccinated 220,000 people (15%). While the state reimbursed counties for overtime personnel, many programs had to be dropped and these operational costs were considered as direct losses for the county. The informed consent forms created problems due to their late arrival, slowing down lines, and necessity of storage. A county health official believes that the federal approach is not the way to handle mass immunizations. The whole community should be involved if a program of this type is to be at all effective.

CLARK COUNTY, NEVADA vaccinated 38,000 (13%). Informed consent forms were never delivered in great enough supply and this created problems. The biggest mistake made under the swine flu immunization program was lack of communication with county health officials. During the swine flu program, the newspapers printed information before the county health officials knew anything about it. Any fast moving program, such as a mass immunization, must include the local administrators.

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WICHITA - SEDGEWICK COUNTY, KANSAS vaccinated 74,000 (21%) people and was reimbursed for overtime salaries for personnel. Administrative problems were created and exacerbated by the lack of uncertainty of vaccine arrival. This county had to scrap three plans due to delays and shortages of vaccine (this involved cancelling clinics, rearranging volunteer schedules). In order to avoid future embarrassment for local officials programs must render assurance that scheduled events will materialize and adequate supplies will be available when needed.

GALVESTON COUNTY, TEXAS vaccinated 18,000 people (10%). Administrative problems arose since no information was received about the arrival of vaccine. The informed consent forms required bilingual interpreters which created confusion. Suggestions for any future programs stress more flexibility achieved through more direct communication and information.

ALAMEDA COUNTY, CALIFORNIA immunized 100,000 (9%). Local money, which was spent on staff wages was not reimbursed. Administrative problems were created by the starting and restarting of programs every time a new vaccing was delivered. The informed consent forms were legnthy but manageable. One problem under swine flu immunization (due to the nature of the program) was the lack of any early long range planning.

ALLEGHENY COUNTY, PENNSYLVANIA vaccinated 498,900 people (31%). The cost of the program to the county is immeasurable. It was considered the number one priority program for four months, and as such demanded full staff attention. Administratively, programs had to be scrapped due to non-arrival of vaccine and changing guidelines created more problems. The informed consent form was not really considered to have served its purpose - senior citizens and others were not really informed. Better organization from the central authority (federal government) and a better documented program (adequate field research) would have alleviated many of the major problems.

Mr. ROGERS. Thank you, Dr. Elsea, for a very helpful statement. Here again, we will ask HEW to comment.

I think the participation of local government and local health authorities was outstanding. Do you have any other suggestions in order to make future national programs more effective?

Dr. ELSEA. I would like to add perhaps two or three suggestions to the ones that were presented by ASTHO. One is a quick analogy to the military situation. We were asked to gear up for a battle that was fairly unlikely, but nevertheless required preparation. There was a cry of "wolf," which went through our country, and the wolf, although threatening, never appeared. The longer the wolf never appeared, the more people became apathetic and, in fact, distrustful, so that gradually we lost their trust. We could see this happening each month as the program went forward.

We know that we were right to begin preparation, several studies have shown that. But we believe that we should have communicated better to the people, especially, and also to professionals, the kinds of risks that we were talking about. For example, what the guesstimate was of the probability of an epidemic.

We believe our communication was not good. We did not use the media too well, and we don't believe we had their understanding. We overkilled and oversold at some points, and I think especially the Federal Government got caught in the situation where it was not flexible enough to change in the middle of the stream.

We believe that local agencies were more flexible. We, in fact, did change several times. In fact, the people, of course, changed their response as the data came in, showing that the epidemic was less likely.

Two other specific suggestions, if I may. One is, I believe we will be better off if we can get a broader representation by particularly professional organizations, like the Advisory on Immunization Practices in the program. I was on this committeee. But we did not have important organizations like the AMA, and other important organizations, that should have been involved, learned from our deliberations, and supported the program more.

Finally, I believe that we need a well planned national liability policy with plans for payments of the vaccine caused disease, such as we have seen in this last endeavor.

This is the summary of my suggestions, Mr. Chairman.

Mr. ROGERS. Thank you so much, and your suggestions will be most helpful to the committee.

Dr. Biery, you may proceed.

STATEMENT OF RICHARD M. BIERY, M.D., ON BEHALF OF THE UNITED STATES CONFERENCE OF CITY HEALTH OFFICERS

Dr. BIERY. Mr. Chairman, I have curtailed my spoken remarks. If you wish, I can read them, but you have them.

Mr. ROGERS. Your complete statement will be made part of the record [see p. 400].

Dr. BIERY. Mr. Chairman, and members of the Subcommittee on Health and the Environment: I am Dr. Richard M. Biery, Director of Health, Kansas City, Mo., Department of Health, representing the United States Conference of City Health Officers, and I am an officer of that conference.

I am here to testify about my city's experience with the swine flu program, and provide some general observations. The swine flu vaccination program, generally, ran well in Kansas City. We vaccinated approximately 50 percent of the eligible population, approximately 70 percent of the significantly at risk population.

The city was basically receptive and supporting of the program. A large voluntary effort developed. Medical societies were supportive and cooperative. The local press was generally positive and noncynical.

I personally was on talk shows, and call-in shows, and discovered a remarkable degree of public trust and confidence, even in the face of adverse national publicity. For example, after one particular bad series of national events relating to the program, I was to be on a call show. So I braced myself for an anticipated storm of challenging calls from skeptics, or at least worried citizens, and we received not one such call, but instead calls from people who wanted to know whether they should take the shot because they had this or that ailment.

We also were impressed by the resiliency of people's basic positive attitudes against repeated publicity concerning the problems of the program; the public's ability to weigh the odds in their own mind, and decide where they were, personally, on the risk continuum.

Now, some words about the problems. From the local perspective, the technical foulups and the conflicts over resolving the liability question were unfortunate, and could only adversely affect the credibility of the program. But as I stated, in our part of the Nation, I was struck by the lack of cynicism, and the rather resilient and forgiving attitude toward these issues.

Furthermore, I feel philosophical about these problems. I hope that they are at least chalked up to experience, and I will return to them in a minute. I think that this committee is a reflection of that effort.

Locally, it created for us an on-again, off-again situation which certainly challenged our people in terms of planning. Again, the public was remarkably forgiving, and we pulled the program up.

The informed consent mechanism, or the warning system, also kept us guessing until late. But fortunately, developing that was not our responsibility. Part of the delay, which was not mentioned here today, was the fact that the State Attorneys General had to have input and/or approval, and this certainly added to the complexity of the decisionmaking process.

To assure ourselves of the maximum public information, we, and the Kansas City newspapers, published the entire consent form at the initiation of the program. Furthermore, our clinics were organized in such a way that people would have plenty of time to read the form prior to being vaccinated.

To my knowledge, the consent form changed no one's mind, once they had come to the clinic. I believed that in voluntary programs, either people come because they believe it to be in their interest, or they don't come. Informed consent is obviously signed by believers at the time, who are willing to take the risk of the known adverse effects against the risks of the disease.

The public willingness of the assumption of that risk, I believe, rests as much of the credibility of public health officials and epidemiologists as any other item of information the public may have concerning it, consent forms, or not.

It was our impression that the national press and media searched for and amplified conflict, differing opinions, whether or not informed, and the adversities mentioned earlier. Given that kind of national press coverage, I was surprised by the amount of local trust and support. I think that our ability to stay informed, answer the questions of the news agency was critical, and that gets to the issue of information transmissions and communication. I have a more positive view, perhaps, toward that than has been expressed.

Basically, we had no argument with the policy decisions nationally, based on what we found to be was well supplied information. In fact, we sent someone from our medical society to review the information personally, and concluded before our medical society took a position that they were founded on sound epidemiological principles, which not everyone understood.

Two decision analyses, including one at Chapel Hill, which I reviewed personally, done by the Management Systems people there, and one at Harvard, which I think has been published, and the retrospect of the discussions in the medical literature have borne those conclusions out.

Another benefit was that Kansas City had a B-strain outbreak this past winter, but while other cities were having A-Victoria outbreaks, because we had immunized 70 percent of our elderly population, we could feel fairly confident that we would not have an A-Victoria outbreak with mortality, and we did not.

In terms of dealing with Guillain-Barre sequel, we had one or two possible postimmunization cases. Our experience with this in Kansas City was well below the national average. That has not been a problem in terms of adverse publicity locally.

Our recordkeeping system was such that we have been able to pull informed consent and records when needed.

Turning to the indemnification device developed for the swine flu influenza program, it simply moved the liability back to Uncle Sam, but left the means of settling that liability in the same system. I am speaking now to the problem of liability.

It seemed to us that if Congress felt strongly enough about the swine flu, Congress should, at least, aggressively consider a similar device at minimum or, at most, total removal from the tort settlement mechanism in order to keep the established social process of protecting against exceedingly expensive disease in tact.

Finally, without a cooler and statesmanlike, I predict that we, as a Nation, will have serious difficulty in developing further the frontiers of preventive strategies for the benefit of all. The cost ratios are well documented, including immunizations. However, less threatening environment, public boldness, statesmanship, and mutual willingness to conquer these roadblocks are absolute necessities.

Thank you, Mr. Chairman.

[Dr. Biery's prepared statement follows:]

STATEMENT OF RICHARD M. BIERY, M.D., DIRECTOR OF HEALTH OF KANSAS CITY, MISSOURI, ON BEHALF OF THE UNITED STATES CONFERENCE OF CITY HEALTH OFFICERS

Mr. Chairman and members of the Subcommittee on Health and the Environment, I am Dr. Richard Biery, Director of Health of Kansas City, Missouri and representing the United States Conference of City Health Officers. I am here to testify about my City's experience with the Swine Flu Program and provide some general observations and note some growing serious threats to immunization programs.

The Swine Vaccination Program generally ran well in Kansas City. We succeeded in vaccinating approximately 50% of the eligible (adult) population and approximately 70% of the significantly at risk population. The City was basically accepting and supportive toward the program. A large volunteer effort developed, medical societies were supportive and cooperative and the local press was generally positive and non-cynical. I personally was on talk and call-in shows and discovered a remarkable degree of public trust and confidence even in the face of adverse national publicity and difficulties. For example, after one particular bad series of national events relating to the Program, I was to be on a call-in show and so I braced myself, anticipating a storm of challenging calls from skeptics and cynics or at least worried citizens. We received not one such call, but instead calls from people who wanted to know whether they should take the shot because they had this or that ailment! We also were impressed by the resiliency of

people's basic positive attitudes against repeated national publicity concerning the problems of the program and the public's ability to weigh the odds in their own mind and decide where they were personally on the risk continuum.

Now some words about the problems: From the local perspective, the technical foul-ups and the conflict over resolving the liability question was unfortunate and could only adversely affect the credibility of the Program but, as I stated, in our part of the nation I was struck by the lack of public cynicism and rather a resiliency and forgiving attitude.

Furthermore, I am sanguine enough personally to be fairly philosophical about those problems and tend to hope that they are, at least, chalked up to experience. I will return to them in a minute.

Locally, they created an off-again, on-again situation which certainly challenged our people in terms of planning - sort of a game of "keep-them-guessing" or "dodge-em" with target dates, facilities, manpower and equipment. Again, the public was remarkably forgiving.

The informed consent mechanism also kept us guessing until late, but fortunately developing that was not our responsibility. To assure ourselves of maximum public information we (and the Kansas City newspapers) published the entire consent form at the initiation of the program. Furthermore, our clinics were organized in such a way that people would have time to read the

form prior to being vaccinated. To my knowledge, the informed consent changed no one's mind once they had come to a clinic. It is my impression that, in a voluntary program, people believe or not and come or don't come. An informed consent is obviously signed by believers (at the time) who are willing to take the risk of the known adverse effects against the risk of the disease. The public willingness of the assumption of that risk, I believe, hangs as much on the credibility of public health officials and epidemiologists, as any other item of information the public may have, consent forms or not. One more comment on the national scene. It was our impression that the national press and media searched for and amplified conflict, differing opinions, whether informed or not, and the adversity mentioned earlier. If Dr. Salk disagreed with Dr. Sabin so much the better for the evening news. Given that kind of national coverage, I was surprised by the amount of our local trust and support. I think our ability to stay informed and answer the questions of the local news agencies was critical.

Policy:

Basically, we had no argument with the policy decisions nationally, and based on well supplied information, concluded they were founded on sound epidemiological principles (that not everyone necessarily understood).

At least two decision-analyses and retrospective discussions (even in spite of Guillian Barre' sequellae)

in the medical literature bear that out.

Although Kansas City had a B-strain outbreak this past winter, and while some other cities were having A-Victoria outbreaks, because we had immunized 70% of our elderly population to both A-New Jersey and A-Victoria, I could feel fairly confident we would not have an A-Victorian outbreak with mortality, and we did not.

In terms of Guillian Barre' sequellae, we had one possibly post-immunization case. This incidence was below the national average.

Substantial Issues Concerning Immunization Programs in General:

Waxing philosophical for a moment, we would like to point out the obvious, that those efforts of society to implement preventive strategies take corporate social action for significant public benefit to be achieved and also for the protection of those individuals handicapped in such a way that they cannot avail themselves of a particular strategy, e.g. the vaccination. In programs where individual responsibility is required to achieve such effects, a mutual responsibility as fellow human beings must be recognized and we as individuals must accept a corporate decision and its mechanism of implementation.

Parenthetically, we are no longer men to good will. The increasing litigenous spirit, skepticism, and adversarial mood of our society, coupled with the climate that as one health officer said, "you have to tell everyone everything..." but protect privacy, threatens the fabric of our public health and preventive capacity to solve problems under the old rules

of mutual good will.

Nowhere is that clearer than in the area of immunizations. To benefit as a society to this technology we need to maintain substantial immunization levels (in the face of an apathetic public) but we also maintain in our society a system that provides a means for individuals allegedly agrieved by a program to use society's tort system to hit us in the solar plexus. This is having a rapid and seriously threatening effect on immunizations as an important and critical part of our disease defense system. Probably, the most obvious and dramatic examples are the polio vaccine cases against 1.) Wyeth in Texas resulting in a substantial jury settlement (where the facts, I believe, are far from convincing) but more important Wyeth's withdrawal from the polio vaccine market and now, 2.) the recent two million dollar suit against Seattle and Lederle, the last remaining manufacturer. In that case, the plaintiff is suing in spite of having signed an up-to-date informed consent. No matter the outcome, which in these cases (in jury settings) is by no means benign, the effects on Seattle, its health department, dedicated community health workers and, I suspect, on Lederle is serious, demoralizing and damaging. The same would have been true, perhaps even more so, had this been a private medical sector incident.

Solution:

It seems to me that there may be public responsibility toward those rare situations in public health where an

untoward adverse effect occurs due to public policy (and state law in many cases) but such compensation needs to be removed, I believe, from a system where even one case can result in a disabling kick in the gut. Even governments are no longer immune; so exposure is essentially total. Kansas City has just been sued for 10 million dollars by a law student who maintains that Kansas City should have built its creeks and storm sewer systems to anticipate a 13" rain. I suspect that had he lived in Noah's day, he would have sued a skeptical mankind for not building more boats.

The indemnification device developed for the Swine Influenza Program simply moved the liability back to Uncle Sam but left the means of settling that liability in the same system. It seems to us that if Congress felt strongly enough about the Swine Influenza Program, a decision I am not critizing, but nevertheless a speculative but bold program against an "if-come" enemy, Congress should certainly agressively consider a similar device, at minimum, or at most, total removal from the tort (lay jury) settlement mechanism in order to keep the established social fabric of protective strategies against known and exceedingly expensive disease enemies intact.

Finally, without a cooler and statesman-like environment, I predict that we, as a nation, will have serious difficulty developing further the frontiers of preventive strategies where the benefit to cost ratios are substantial (removing entire disease categories from death certificates). However, a less threatening environment, public boldness, statesmanship and mutual willingness to conquer these roadblocks are absolute necessities.

Thank you.

Mr. ROGERS. Thank you very much.

I might say that we will have to look at the liability issue more closely. I think that the Federal Tort Claim Act, which was on the books, was used by the Congress in view of the fact that we had tort claims costing up to $23 billion. So we felt that there should be some no-fault.

Dr. BIERY. I commend Congress for that move. I think the rest of the immunization system is exposed to that same liability.

Mr. ROGERS. Thank you so much.

Are there any questions?

Mr. WAXMAN. Don't be too quick to congratulate Congress for taking on the liability. I don't think that it is a good move on our part. I appreciate your suggestion that we do have to address those questions in any future program.

Mr. ROGERS. I presume you would agree, that when the manufacturers said that they would not produce vaccine, or that they would not market vaccine without insurance, someone had to assume their liability.

Dr. BIERY. My reply would be that there would not have been a program, and polio is in the same situation right now.

Mr. ROGERS. Thank you so much for your presence.

Dr. J. Anthony Morris will be the next witness.

Dr. Morris, we welcome you before the committee.

STATEMENT OF J. ANTHONY MORRIS, Ph. D., GREENBELT, MD.

Dr. MORRIS. My name is Dr. J. A. Morris. I have been engaged in research on viral and rickettsial diseases and in study of vaccines to prevent these diseases since 1940 or for approximately 37 years. My work was done at Walter Reed Army Institute of Research, at the National Institutes of Health, and the Food and Drug Administration.

In the period 1966–72 I brought to the attention of the Director of the Division of Biologics Standards of the National Institutes of Health serious deficiencies in the regulation of vaccines for use in this country. The response to the receipt of this information on the part of the Director of the Division of Biologics Standards was first an attempt to fire me, and second to ignore the existence of serious deficiencies.

In 1972, these same deficiencies were brought to the attention of Senator Ribicoff including those deficiencies concerned with the potency and efficacy of influenza virus vaccine, one of the most widely used vaccines in this country. Senator Ribicoff requested a GAO investigation of the Division of Biologics Standards, and during the course of the investigation, found serious shortcomings concerned with vaccine regulation. As a result, hearings were held before the Subcommittee on Executive Reorganization and Government Research in 1972: following the hearings the vaccine regulatory agency was transferred from NIH to the FDA.

During the 1972 hearings it was noted that it was not possible to measure with accuracy the potency of influenza virus vaccine, yet the user and the recipient of this vaccine had no way of knowing this because the label indicated a precise measurement of potency.

What is the situation now? This is indicated by a quote from the GAO report of June 27, 1977, dealing with the swine flu program.

FDA and Manufacturers Differ in Potency Test Results

Three of the four swine flu vaccine manufacturers consistently reported potency test results which were higher than FDA test results for the same lots of vaccine submitted to FDA under the swine flu program. For example, one manufacturer's test results on 49 vaccine lots submitted during 1976 showed that 47 had a higher potency value than that shown by FDA's tests, 1 had the same test results, and the remaining lot scored lower. GAO report, June 27, 1977, page 34.

In addition, the tabular data provided in the GAO report show that one lot of swine flu vaccine with a designated CCA value of 800, when examined in the FDA's laboratory had a value of 696. This example and other examples given in tabular data in the GAO report clearly show that potency of swine flu vaccines was not indicated by the information on the label. In other words, the swine flu vaccine was mislabeled.

In 1972, it was brought to the attention of the Director of Division of Biologics Standards that there were no reliable data to measure the degree of protection afforded civilian populations by use of commercially available influenza vaccine.

This is indicated in by a quotation taken from the 1977 GAO report.

The Director of the Division of Biologics Standards questioned whether the use of flu vaccine had any detectable effect on the 1957 or 1968 pandemics. He stressed that priority be given to research into the problem of making sufficient vaccine available in time to counter a threatened flu epidemic.

A group of Government virologists who reviewed experience with flu between 1967 and 1972 concluded:

It is generally agreed that inactivated vaccine containing the appropriate antigenic concentration in suitable potency will provide a reasonable degree of immunity for a limited period of time. This statement simply means that on some occasions the vaccine has worked and on others it has not. * * * There is no doubt that properly constituted aqueous inactivated vaccines can provide some measure of protection. How much protection they afford is open to question. Protection rates are clearly influenced by many features peculiar to the vaccine, the virus, and the host—and by methods used by the investigators. GAO report, June 27, 1977, page 40.

In assessing the value obtained from use of the swine flu vaccine the GAO report concluded:

Previous efforts to combat pandemic flu have not been successful. The swine flu program differed from past vaccination efforts because the swine virus was isolated earlier and because the high-priority Federal mass vaccine delivery program was the first of its kind. Consequently, the potential protection provided by the swine flu vaccine is difficult to estimate based solely on previous experience. GAO report, June 27, 1977, page 38.

So, the situation now is as it was 5 years earlier: an assessment of the benefit derived from the use of influenza virus vaccine is not determined.

I would like to mention here the practice of administering influenza virus vaccine to pregnant women. In 1972 we wrote a memorandum to the director of the National Institutes of Health.

Not only has there been little or no benefit from the use of influenza vaccine in man, but harm has resulted. The vaccine contains a considerable concentration of virus material which, although inactivated, possesses toxic properties, and, if given in sufficient quantity, may cause illness in an appreciable percentage of people,

especially in children. Moreover, until recently, influenza vaccine contained (and still does in some instances) extraneous bacteria which could have been removed during the manufacturing process, but was not, because this was not required by the Division of Biologics Standards. These, too, when injected into man, cause illness. Further, the vaccine contains antigens of chicken-egg origin which may lead to sensitization, or, rarely, to marked reactions in persons already hypersensitive to such material. In addition, the egg protein contain blood group antigens which, when injected into man, induces the formation of specific antibody directed against that antigen. In pregnant women, this can be a dangerous event and result in fetal damage. It is for this reason that pregnant women were removed from the "high risk group" (CDC Report 1962 and compare with CDC Report 1969). It will never be known with certainty whether the recommended injection of influenza vaccine into pregnant women induced fetal damage, and if it did occur the degree and extent of the damage. What is inexcusable is that pregnant women were placed on, and removed from, the "high risk group" without first making these determinations. The risk might have been justifiable if the vaccinated women had been protected from contracting influenza during pregnancy, but the chances are that they were not.

In addition, every inactivated myxovirus vaccine—measles, parainfluenza, and mumps—that has been studied prospectively has been shown to hypersensitive a certain percentage of vaccinated people to subsequent exposure to natural disease induced by a virus of the same type. See S3419 April 20 and 21 and May 3 and 4, 1972, page 526.

What is the situation now? We learn now that after injecting swine flu vaccine into pregnant women who were told that:

"Flu vaccine can be taken safely during pregnancy,"—GAO report, June 27, 1977, Appendix I, page 87—that * * * the center for disease control is supporting two studies on women who received the swine flu vaccine to identify unfavorable pregnancy outcomes, such as spontaneous abortions, stillbirths, and congenital malformations. These studies will follow reactions in children up to 6 weeks beyond birth, born to women in the studies. Letter GAO to Congressman Waxman, June 27, 1977, page 7.

I might note here that if they stop the study at 6 weeks, I think that it would be very difficult to determine what definite results there are from these injections.

This series of events would, in my judgment, be serious endictments of vaccine regulation and of the Government's vaccine regulatory agency. In fact, Mr. Joseph Califano, Jr., Secretary of HEW on March 2, 1977, on Meet the Press, said:

The greatest damage the swine flu program has done, aside from the human tragedy of the individual paralyzed and killed, has been the impact on immunization programs, and a large part of that is attributable to the people's fear about immunization programs.

Mr. Califano said further: "We have got to restore confidence in immunization programs." I doubt that under the current managers of vaccine regulation in this country, this confidence is restorable and it is my judgment that the widespread skepticism that followed the swine flu fiasco is fully justified.

I thank you for your attention.

Mr. ROGERS. Thank you, Dr. Morris.

Mr. MAGUIRE. Mr. Chairman, the GAO witness this morning gave testimony that the vaccine which was released for the swine flu program met the Food and Drug Administration safety standards. They said that almost 30 percent of the vaccine was considered subpotent initially, and the agency did not permit its release to the public until the minimum potency requirement was met.

Now you are saying, I take it, that initially there was a problem. I think that it would be interesting to know why 30 percent of the

vaccine did not meet the potency requirements, but presumably that is a question we can address to the manufacturers.

The GAO said that when it was discovered that it did not meet the potency standards, that deficiency was corrected before it was used in the program. Now would you comment on that?

Dr. MORRIS. Yes. First of all, the GAO assumed that the CCA value, which is the measure, has meaning or is meaningful, when in fact the CCA value does not have meaning. I might mention parenthetically here that Dr. Hilleman in his comments made before one of the influenza vaccine workshops, said that he recognized that Dr. Hilleman is a virologist who works for Merck Sharp & Dohme, and he recognizes the inability to measure the potency of the vaccine by the CCA procedure.

Mr. MAGUIRE. The CCA procedure is completely unhelpful with respect to measuring the potency levels?

Dr. MORRIS. The CCA procedure is used to measure the agglutination of chicken red blood cells. There is no positive relationship whatsoever between that measurement and the ability of this vaccine to protect a person against influenza.

Therefore, I was interested in the comments made by Dr. Millar this morning, when he continuously stated that swine flu vaccine immunized its recipients. This vaccine induced the formation of swine antibodies, but Dr. Millar has yet to demonstrate that swine flu vaccine immunized anyone against anything.

Mr. MAGUIRE. Surely you recognize that there are other people in the field who disagree with you?

Dr. MORRIS. Let us take one, Dr. Sabin, before a congressional committee in June 1976, said, and I paraphrase: I am giving you a battery of reasons as to why I am withdrawing my support from this program. One of these reasons is the inability of anyone to measure with accuracy the potency of the influenza virus vaccine.

Mr. MAGUIRE. I think everyone has recognized that we are not as far along in developing the immunization potential and capacity of our inoculations with respect to influenza as well as some other things. Everybody has recognized that.

To move from that to the statement that it does not have any utility at all, does surprise me a bit. Are you saying, in effect, then, that all of the influenza immunization programs that we have had, whether it be the Hong Kong, the A-Victoria, or whatever, in recent years have been of no utility?

Dr. MORRIS. In my estimation, there is no substantial information in the medical literature which demonstrate satisfactorily that influenza virus vaccine has protected man against influenza.

Now this was brought to the attention of the speakers this morning. I think that it was Dr. Millar who said, in I paraphrase: Despite the use of 20 million doses of influenza virus vaccine, in 1957 the course of the 1957 epidemic was not altered. The same situation was true in 1968 despite the use of approximately 20 million doses or more of influenza virus vaccine, the course of the epidemic was not altered.

The reasons given by the Government in those two instances are that the vaccine was too little and too late.

Mr. MAGUIRE. There are examples, one can go over the data and say that the course of the epidemic was altered by timely application?

Dr. MORRIS. There is no record in the medical literature that indicates that the course of an influenza epidemic has ever been altered by the use of influenza virus vaccine.

Mr. MAGUIRE. Aside from your more general point, what would be the reason why tests by manufacturers and by the FDA would vary substantially with respect to the CCA factor, whatever that value may be?

Dr. MORRIS. There is a standard procedure, a set of measures that when applied by a manufacturer, or the FDA, or any other interested party, should result, in a series of measurements that approach similarity. If you measure with an inch, an inch is an inch, but when you measure the potency of influenza virus vaccine by the CCA test procedure, you get results which are shown, for example, in the GAO report, that in the test procedure the measurement unit—the CCA unit—may vary by approximately 100 percent.

You have figures given in my statement where the test results for a particular lot of swine vaccine was 690 in one laboratory and 1,008 in another laboratory by applying the same test procedure to the same lot of vaccine. These results should indicate the unreliability of the test procedure.

Mr. MAGUIRE. So we have in your mind a question about the value of the CCA value itself. You have questions about the test procedures and their accuracy.

Let me ask you whether you agree that the vaccines that were administered to the American public under the swine flu program met the minimum CCA standards as the GAO said they did, or whether you also doubt whether that was the fact or not?

Dr. MORRIS. That depends. The GAO has reported, if I remember correctly, that when certain lots of vaccine in rare instances did not meet the minimum requirement, in order to facilitate the passage of the vaccine lot, the requirement was lowered. It depends on what you mean by the requirement.

If you lower the requirement, then it is not that difficult to meet the requirement.

Mr. MAGUIRE. What about the ones that went out to the American public, did they meet whatever the requirements were that were in force at that time?

Dr. MORRIS. Each of these lots did meet the requirements which were standard at that particular time.

Mr. MAGUIRE. The implications in the witness's testimony go rather far, and I find myself unable at this point to pursue those various avenues. I yield back the balance of my time.

Mr. ROGERS. Mr. Waxman?

Mr. WAXMAN. Dr. Morris, if there were a rapidly growing epidemic and a clear national emergency, would you, then, favor mass immunization as long as any risk from the vaccine were disclosed?

Dr. MORRIS. There is no evidence in the medical literature which would suggest that an inactive influenza virus vaccine will alter the course of an epidemic of influenza. That fact is established.

There is evidence that a live influenza virus vaccine is capable of controlling influenza infections. You asked the question as to why a live influenza virus vaccine is not available. It is not available because of great shortcomings on the part of NIH in developing this vaccine.

When the NIH came before the Congress in 1972, if I remember correctly before Mr. Rogers, and said that there are serious shortcomings which characterized the activity of the virus vaccine. We would like to ask for an appropriation to develop a live influenza virus vaccine.

If I remember correctly, several million dollars were appropriated for that purpose to develop a lab to work on that virus. The reason for that development was the inadequate nature of the dead vaccine. There were serious problems encountered in the development of that vaccine, but there is no doubt that this vaccine does, in fact, protect you against influenza. That is the path that has to be followed in the future.

One has to abandon the hope that an inactive vaccine will ever protect man in an appreciable way against influenza. The avenue must be changed, and it should be changed toward the live influenza virus vaccine.

Mr. WAXMAN. Do you have any information as to the cost of the vaccine for swine flu, which would be helpful to us in developing that question?

Dr. MORRIS. The information I have, and I would rather not give it because it is not solid.

Mr. ROGERS. We very much appreciate your testimony. Thank you.

The next witnesses are a panel of vaccine manufacturers.

I would appreciate it if the witnesses would keep their testimony limited to 5 minutes. The statements will be included in their entirety in the record.

STATEMENTS OF ROBERT F. HENDRICKSON, VICE PRESIDENT, OPERATIONS, MERCK SHARP & DOHME DIVISION, MERCK & CO., INC.; ACCOMPANIED BY CLARENCE A. ABRAMSON, SENIOR COUNSEL; CHARLES F. HAGAN, GENERAL COUNSEL, AMERICAN HOME PRODUCTS CORP.; FRANK MARKOE, JR., VICE CHAIRMAN, BOARD OF DIRECTORS, WARNER-LAMBERT CO. (PARKE-DAVIS); AND FREDERIC D. LAMB, VICE PRESIDENT AND LEGAL COUNSEL, MERRELL-NATIONAL LABORATORIES

Mr. HENDRICKSON. My name is Robert F. Hendrickson, and I am Vice President for Operations of Merck Sharp & Dohme. I would like to make two brief points, and then we will be pleased to answer any questions.

I would like first to reaffirm that the vaccine manufacturers continue to be an important national resource for public health programs, able to tailor production rapidly to meet emerging needs when given a reasonable amount of advance warning and a reasonable degree of cooperation.

Second, I want to reemphasize that we could not be expected to participate effectively in public health programs if we were unable to obtain insurance, or otherwise be protected against liability from

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factors in the use of the vaccine that cannot realistically be considered our responsibility.

We are perfectly willing, and we believe able to accept that part of the liability burden that derives from factors over which we have control.

Contract arrangements between the Center for Disease Control and manufacturers are now including provisions stipulating the responsibility the Government assumes in carrying out public immunization programs, with specific attention to the duty to handle any necessary warnings to, or obtain any necessary informed consent from, recipients of vaccine in these programs.

These arrangements have helped to assure the continuation of the insurance coverage now in place. However, ill-defined liability risks continue to loom in the field of immunization, and we believe it is important to take a first legislative step now, in a non-crisis atmosphere, to help lessen the possibility of any jeopardy to immunization programs in the future. This might be in the form of legislative authority for HEW to indemnify manufacturers from costs resulting from HEW's breach of its duty to warn recipients of the vaccine of its risks.

The liability problem should not be permitted to distract us all from the principal job of assuring maximum protection of the health of American citizens. So we urge that interim action be taken now and future solutions of broad social significance be developed as rapidly as possible.

I will be happy to try and answer any questions that the committee may have, and I hope that my complete statement will be submitted as part of the record.

[Mr. Hendrickson's prepared statement follows:]

STATEMENT OF

ROBERT F. HENDRICKSON
VICE PRESIDENT, OPERATIONS
MERCK SHARP & DOHME DIVISION
MERCK & CO., INC.

Subcommittee on Health and the Environment
Committee on Interstate and Foreign Commerce

Friday, September 16, 1977

Mr. Chairman:

My name is Robert F. Hendrickson, and I am Vice President for Operations of Merck Sharp & Dohme. We were pleased to respond to your invitation and will be happy to be of any help we can in your review of immunization policy and procedure. I would first like to reaffirm that the vaccine manufacturers continue to be an important national resource for public health programs and second to urge that a modest but important legislative action be taken now to help lessen the likelihood that liability issues will complicate immunization programs in the months and years ahead.

When Secretary Califano announced the new initiative against pediatric diseases last April, Merck wrote to him to pledge our full support. We also expressed full confidence that private sector suppliers could meet the national need. We urged that this program, as with those in the past, recognize and encourage full participation by private sector health care resources in complementing the public health activity.

Given a reasonable amount of advance warning and a reasonable degree of cooperation, vaccine manufacturers are well equipped to make needed quantities of vaccine that reflect public interest. This ability was illustrated once again this past winter and spring, as outbreaks of measles occurred on the West Coast and in other areas of the country. We at Merck Sharp & Dohme were in a position to

scale up our production very rapidly because we maintain a substantial inventory of vaccine in a frozen-filled state. Thus we were able to escalate our deliveries by some 500% compared with the same period the previous year. To California alone, in the period of January through May we shipped a total of 800,000 doses of measles-containing vaccines to both the public and private sectors on what we believe was a very expeditious basis. It is a difficult situation for public health authorities when there is an outcry for tens of thousands of doses of vaccine and it does not materialize overnight, but it is generally impractical to maintain large inventories of dated vaccine ready for immediate shipment and a certain time-lag is required to scale up production. However, the capacity is there, and once again the ability to accelerate production to meet a need has been demonstrated.

The second point I want to reemphasize is that we could not be expected to participate if we were unable to obtain insurance or otherwise be protected against liability from factors in the use of the vaccine that cannot be realistically considered our responsibility. We are perfectly willing and we believe able to accept that part of the liability burden that derives from factors over which we have control.

We therefore urge that some interim measures on liability be adopted while a long-term solution is sought. It is admittedly difficult to focus attention on potential policy problems in the absence of a crisis. Yet, preventive measures now would save much difficulty when the crisis does arrive.

Last year this Committee and other members of the Congress found it necessary under crisis conditions to pass legislation radically altering the methods of handling liability problems for swine flu vaccine. We believe that action to have been very sound under the circumstances. We recognize the

reluctance of Congress to adopt a similar pattern for vaccines other than swine flu, and we are not at this point pressing for such a legislative move. However, we do believe it important to take a first legislative step now in a non-crisis atmosphere to help lessen the possibility of any jeopardy to further immunization programs. That step, simply, is to empower HEW to contractually indemnify manufacturers if courts make adverse judgments based on failure of the government to discharge responsibilities it bears in public health immunization programs.

As Dr. Foege of the CDC and others have noted, the Center for Disease Control and HEW have been working out specific arrangements with manufacturers in contracts for vaccine purchase. These stipulate the responsibility the government assumes in carrying out public immunization programs. A key element is the important duty to handle any necessary warnings to, or obtain any necessary informed consent from, recipients of vaccine in these programs.

These provisions are healthy. First, they clarify what appears to have been a confused picture in earlier years, whereby courts placed duties on manufacturers that would necessitate our intrusion deeply into the conduct of public health programs. Second, they help define and reaffirm the remaining areas of responsibility borne by us as manufacturers. These clarifications, we believe, materially aid in assessing potential risks, and have helped assure the continuation of the insurance coverage now in place.

Unfortunately, such provisions are not adequate to reduce the enormous amount of self-insurance built into our coverage nor to protect against the radical escalation in risk assessment that would follow any major new adverse judgment in this field. We and our carriers would bear the burden of handling any new avalanche of suits, regardless of merit. As you know, government estimates of its own costs for such handling of swine flu suits are huge. And, in the event

a court were to determine that the fault lay with the government, as defined in the contract, we then would face the possibility of relitigating this same issue against the government in order to recover.

Fortunately, the picture I paint is hypothetical at the moment, but it would become immediately real in the event of litigation of any magnitude.

The swine flu episode is instructive. Last year we heard much debate over potential liability risks in the swine flu program. Yet today many hundreds of citizens are seeking over a billion dollars in connection with the national program.

Ill-defined liability risks continue to loom in the field of immunization. A history of relative safety does not protect against an epidemic of litigation. A reasonable first step, in our opinion, is legislation empowering HEW simply to fulfill its contract commitments in the event of adverse court judgments against a manufacturer on matters within the government's accepted responsibility. This might be in the form of legislative authority for HEW to indemnify manufacturers from costs resulting from HEW's breach of its duty to warn recipients of the vaccine of its risks.

It would be gratifying to offer to the committee a definitive plan for some new form of compensation for those citizens unavoidably injured as a consequence of public health immunization programs. We have been intrigued as have been others by the concepts of a system that might parallel principles of workman's compensation. In face of the complexity of such a revolutionary plan, however, we have placed most of our hopes in the process that began last fall and winter with the National Immunization Conference, and the study report that I believe was then submitted to Congress. We recommend that this process be continued, so that consensus positions can be developed to underpin a specific legislative program for this committee to consider.

One final point: With the early termination of the swine flu program, there are millions of doses of both the bivalent and monovalent vaccines remaining on hand between the manufacturers' warehouses and the state and local distribution centers. We understand the CDC plans to stockpile the remaining vaccine until its final disposition has been decided. This vaccine had been dated to expire on August 1, 1977 (the date that the authority for the program expired under PL 94-380). Our concern is that sometime in the future it may be decided to use this vaccine, assuming the safety, purity and potency remain at their present levels. Since the government's responsibility for claims expired on August 1, 1977, we feel that it is important that no future use be made of this vaccine unless Congress has first authorized its use and has resolved the responsibility for liabilities arising out of the use of this vaccine after August 1, 1977.

To conclude: Despite the difficulties encountered last year, we remain optimistic that public health and private medical immunization efforts will be successful in reducing to a minimum the toll of communicable diseases. We are confident that national policies and practices will permit vaccine manufacturers to participate effectively and efficiently. The liability problem should not be permitted to distract us all from the principal job of assuring maximum protection of the health of American citizens. So we urge that interim action be taken now and future solutions of broad social significance be developed as rapidly as possible.

I will be happy to try to answer any questions you may have.

Mr. WAXMAN. [presiding]. Thank you very much for your abbreviated statement. Your complete statement will be made part of the record.

We will now hear from Mr. Charles Hagan.

STATEMENT OF CHARLES F. HAGAN

Mr. HAGAN. My name is Charles F. Hagan and I am general counsel of American Homes Products Corp., of which Wyeth Laboratories is a division.

We have been asked to comment on problems encountered in the swine influenza virus vaccine program. As other witnesses will undoubtedly affirm, by far the major problem in this program was the working out of satisfactory solution to the anticipated liability situation, especially because of the loss of the vast majority of insurance coverage for this vaccine in July of last year.

The Department of HEW and the manufacturers attempted to negotiate contractual provisions to deal with this problem, but adequate protection could not be worked out because of the Anti-Deficiencies Act.

With the passage of Public Law 94-380, and the cooperation of the insurance industry in providing coverage for any claim against the manufacturers by the Government in the event the Government is held liable because of the manufacturer's negligence, it appears that the liability problem has been adequately handled. However, the constitutionality of this law is being challenged in a number of suits. To date, two district courts have upheld the constitutionality of this law, and these decisions are being appealed.

The concerns expressed about liability before this subcommittee in the last session proved to be valid. As of August 5, we are told there were 743 administrative claims, totaling $1,334,463,319 pending against the Federal Government for injuries allegedly resulting from this vaccine. These suits were filed against the manufacturers, and are being handled by Government counsel under Public Law 94-380.

In any program of this magnitude, there are bound to be some technical and administrative problems, and that was so in this case. However, these problems were minor in comparison with the liability problem.

We appreciate the opportunity to appear before you today, and I will be pleased to try to answer any questions you may have.

Mr. ROGERS. Mr. Markoe.

STATEMENT OF FRANK MARKOE, JR.

Mr. MARKOE. My name is Frank Markoe, Jr., vice chairman of the board of directors of Warner-Lambert Co. I am appearing on behalf of Parke, Davis & Co., a subsidiary of Warner-Lambert and one of the four vaccine manufacturers that participated in the Government's national influenza immunization program last year and provided the swine flu vaccine at cost.

In the interest of time I will briefly summarize the longer statement which I have submitted for the record.

Parke-Davis wholeheartedly committed its total biological resources—including scientists, manufacturing facilities, and cap-

ital—to the swine flu program to provide the maximum possible number of doses within the time specified by the HEW for delivery. The company proceeded on a 7-day, around-the-clock program without a contract, without insurance and without knowledge of the final cost of the vaccine to try to meet an unrealistic timetable.

Prior to the announcement of the program there had been minimal consultation with the manufacturers on production scheduling, formulation, capacities, and administration of the vaccine. In our view any future Government mass immunization program must resolve these problems as well as deal with informed patient consent and the matter of liability except, of course, any issue of liability arising from a manufacturer's negligence. These problems, unless resolved, could be a serious limitation to future participation in the program.

On the matter of some of the vaccine produced by Parke-Davis at the beginning of the national program, which was prematurely and unscientifically highlighted in a press release by HEW, I think it is sufficient to say that this vaccine was produced from virus seed supplied by the Government and that the production, packaging, and quality control techniques used by Parke-Davis met every known scientific and manufacturing requirement.

It is most important to note that the investigation by outside, independent experts and by Government scientists immediately following identification of the problem indicated no evidence of negligence on the part of Parke-Davis in the manufacture of this vaccine.

It is further important to note that it has been determined by clinical studies that this particular vaccine met the criteria for the program and produced effective antibodies in the high-risk group against the New Jersey strain and could have been used in the program.

Despite the difficulties of last year's program and negative impact on our company, Parke-Davis would again work with the Government in a national effort, assuming we would be part of the decisionmaking process from the beginning and work together as a team.

Thank you, Mr. Chairman. If you have any specific questions, I should be happy to answer them.

[Mr. Markoe's prepared statement follows:]

Statement by
Frank Markoe, Jr.
Vice Chairman of the Board of Directors
Warner-Lambert Company (Parke-Davis)

Before the

Subcommittee on Health and Environment
House Interstate and Foreign Commerce Committee
Government Program on Swine Flu Immunization
September 16, 1977

Mr. Chairman:

I am Frank Markoe, Jr., Vice Chairman of the Board of Directors of Warner-Lambert Company. I am testifying on behalf of Parke, Davis & Company, a subsidiary of Warner-Lambert, which was one of the four vaccine manufacturers that participated in the Government's National Influenza Immunization Program last year.

On three previous occasions we have appeared before your Subcommittee detailing Parke-Davis' contributions to the immunization program. However, permit me to review briefly that participation.

Parke-Davis has been producing influenza vaccines for about 30 years, and has developed outstanding expertise in this field. Its experience in biological products dates back to the turn of the century, when the company was issued U.S. Biological License Number One.

In March of last year, Parke-Davis had nearly completed its normal influenza vaccine production requirements when swine flu virus was isolated at Fort Dix, New Jersey. At the request of the Government, the company immediately began the production of A/Swine influenza vaccine. Manufacturing

started on March 26, 1976, and continued on a seven-day-a-week, around-the-clock crash program until last fall. The company unreservedly committed its scientific and manufacturing resources to the project, even though it had no contract with the government, and with such matters as potency, dosage, packaging, consumer information, insurance and delivery of the vaccine still unresolved.

The manufacture by Parke-Davis and the other three companies of nearly 156 million doses of influenza vaccine was an unprecedented production achievement, especially when one considers that historically the industry produces only about 20 million doses in a normal year.

Even though we exerted almost superhuman efforts in providing the requested vaccine for the American public, the results for our company were disastrous.

We say this not in a spirit of animosity, but simply that the facts can be studied and sound plans can be made for closer, more effective cooperation between government and manufacturers so that the American people can best be served in any similar future public health undertaking.

As you know, the manufacturers provided the swine flu vaccine at cost -- as a social response to an anticipated national health emergency. Speaking only for Parke-Davis, the imposition of the swine flu program substantially reduced anticipated profit from our regular vaccine program. On balance, it appears we will lose money on the swine flu program, even though we were permitted by law to earn a small net profit, ultimately less than one cent per dose, on only the A/Victoria component of the bivalent vaccine.

Unfortunately, this hastily conceived program was launched in a turbulent political atmosphere, which, needless to say, did not add to its orderly accomplishment.

We are here today in the spirit of cooperation believing that our views will be helpful to your deliberative process. We have extreme concern for the maintenance of public health, and our company has strong recommendations that we believe should be considered prior to initiation of another major government-operated immunization program.

There is an absolute need for the manufacturers to be consulted in advance of any program, and to work as a team with the government, rather than just as a supplier receiving vague, often contradictory, orders.

Our concerns cover five areas -- timing, formulation, regulatory approvals, insurance and investment commitment.

Timing is essential in the production of vaccine, which is entirely dependent on the availability of fertile eggs. Crash programs during off production seasons increase the costs.

As part of the formulation, it is crucial that the potency requirement -- the stipulation of the CCA content -- be established at the earliest possible time. Knowledge of the potency requirement is critical, since it dictates the number of eggs that will be required, as well as the overall production time necessary to produce a given number of doses. Any delays in this orderly decision-making process greatly complicate production. In last year's program, there was a crucial delay of one month in confirming the potency requirements with the manufacturers.

The third area of concern is the regulatory approvals required. These include, among others, such elements as a license amendment, labeling guidelines, and production and lot releases. Not until the license amendment has been approved, can finished supplies of influenza vaccine be cleared for distribution. Last minute changes can delay the program. As you are aware, each vial of vaccine is individually labeled, and a package insert giving detailed product information must accompany the vaccine. I might add, however, that we have traditionally received excellent cooperation in these regulatory areas from the scientific professionals within the Bureau of Biologics.

A commitment of scientific resources and production facilities -- people and capital -- must be made at an absolute minimum of six months, and preferably nine months, before distribution of the vaccine to allow for orderly management of the program.

We believe that Parke-Davis fully complied with every government request in respect to the implementation of the national program -- including providing the number of doses committed for delivery at specified times, despite time consuming changes by the federal agency in package sizes, consumer information inserts and timing of distribution.

Much has been spoken and written about the vaccine produced by Parke-Davis at the beginning of the national program. I think it is sufficient to say at this point that the vaccine was produced from virus seed supplied by the government and that the production, packaging and quality control techniques used by Parke-Davis met -- as they always have -- every stipulated scientific and manufacturing requirement.

The exact reason why the vaccine lots in question exhibited some properties more closely associated with the Shope virus than the New Jersey virus is still not known, and in all probability will never be fully and scientifically understood.

Unfortunately, HEW seized upon this to announce prematurely and unscientifically that the program timetable would be delayed because of a "mistake" by Parke-Davis. In fact, the timetable was totally unrealistic to begin with.

However, it is of the utmost importance to recognize that, despite the most intensive scientific investigation, analysis and review by Parke-Davis, independent experts and representatives of the Bureau of Biologics, no evidence of negligence on the part of Parke-Davis has been identified. In fact, a report by the Bureau of Biologics, following their thorough investigations, stated, and I quote, ". . . we were not able to establish evidence of a break in technique that would have allowed mixing of the two viruses" end quote.

It is also important to note that this vaccine has been determined by clinical evidence, to have met the criteria for the program. It was an effective vaccine for the production of specific antibodies against the New Jersey strain and could have been used in the program for the high risk group.

The legal ramifications involving this particular vaccine are being reviewed by the attorneys for the government and Parke-Davis.

Turning now to the question of product liability: When we raised the issue six months before the mass program got underway, we were branded by some as "arrogant" and our attitude was termed by others to be "unconscionable." Subsequently, the Congress recognized the validity

of our position and enacted the essential legislation. The nearly 800 claims, totaling more than $1 billion, attest to the validity and the necessity of such action. In fact, yesterday's Wall Street Journal estimates 2500 eventual claims, totaling $2 billion. Any future government mass inoculation program must resolve this question and its corollary of informed consent by the recipients of the vaccine who fully understand the benefit-to-risk of an immunization program.

In retrospect, Parke-Davis committed for and did provide 30 million doses of swine flu vaccine which it volunteered to provide at cost, but still was accused of seeking windfall profits, though exactly the opposite was true.

One thing is clear -- our company's vaccine programs could simply not survive should the circumstances that prevailed during the swine flu program be repeated.

We appreciate that last year's program was conducted under very unusual circumstances. However, we believe that with sound planning, full cooperation between government and manufacturers and explicit and accurate information to the public on benefits and risks, the major problems that plagued the swine flu program can be sharply reduced, if not eliminated, in any future endeavors.

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STATEMENT OF FREDERIC D. LAMB

Mr. LAMB. Mr. Chairman, in the interest of time, I would submit my full statement and read only four short paragraphs from the statement. My name is Frederic Lamb, vice president and legal counsel of Merrell-National Laboratories.

While there were a number of problems understandably encountered in a program of this magnitude, I believe the main difficulty and time-consuming problem we all faced was dealing with the product liability situation, not only in terms of obtaining appropriate legislation but in terms of obtaining adequate specification and contractual language.

Had the product liability issue been worked out in advance, I believe the swine flu program could have proceeded more promptly and efficiently. The issue is not one of the manufacturer's attempting to avoid liability for its negligence in the production of vaccine; it is our belief that Federal legislation is required to resolve the product liability crisis since it seems virtually impossible, as perhaps suggested by others earlier in the day, to solve the matter on a State-by-State basis.

The method by which liability protection is accomplished is somewhat secondary in my judgment. More importantly, action of some type must be taken quickly to resolve the matter. It appears to our company that, unless the overall policy of the Federal Government is to resolve the product liability issue forthrightly and promptly, there is significant possibility of inadequate supplies of vaccine being available to the people of the United States.

[Mr. Lamb's prepared statement follows:]

STATEMENT ON BEHALF OF

MERRELL-NATIONAL LABORATORIES

I am Frederic D. Lamb, Vice President and Legal Counsel of Merrell-National Laboratories. My appearance today is through the invitation of the Committee's staff to review our experience with the Swine Flu Program and provide suggestions which may help strengthen future mass immunization programs.

Mr. Chairman, Merrell can point with pride to its record of cooperation in the Nationwide Immunization Program despite the critical problems that faced us and the Government:

1. Before the letter contract was signed, we took a substantial financial risk and proceeded at great expense to produce approximately 40 million doses of bulk vaccine even though, at the time, Congress had not passed legislation needed to provide adequate insurance protection.

2. Following passage of the necessary legislation we moved forward to pool, vial and package on a full capacity 7-day a week basis to provide the vaccine at the earliest possible time.

3. In September, when asked by the CDC to do so, we went back into production of additional quantities of bulk vaccine to help meet the then anticipated increased vaccine requirements. In fact, Merrell ultimately produced about 40% of the total vaccine supplied to the Government.

While there were a number of problems understandably encountered in a program of this magnitude, I believe the main difficulty and time-consuming problem we all faced was dealing with the product liability situation, not only in terms of obtaining the legislation but in terms of getting adequate specifications and contractual language. Had the product liability issue been worked out in advance, I believe that the Swine Flu Program could have proceeded more promptly and efficiently.

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As far as the future is concerned, we read with interest the "Reports and Recommendations of the National Immunization Work Groups" submitted to the office of the Assistant Secretary for Health, and presented at a public meeting in Washington, D.C. on April 4-6, 1977. The work groups recognized that a failure to solve the product liability issue could seriously affect the future of government immunization programs.

The product liability exposure created by the Reyes case, the high cost of defending spurious lawsuits, the notoriety of the swine flu program, the unpredictable nature of juries, and the lack of adequate insurance protection, is an unbearable risk to the vaccine manufacturer who might participate in a mass immunization program.

The recent Swine Flu Program points up the serious nature of the product liability issue. In the Reyes and subsequent cases the manufacturer was held to be responsible for assuring that the ultimate vaccinee in a mass immunization program is properly warned. In point of fact, it is impossible for the manufacturer to sustain this duty. Furthermore, it has been the experience that a number of groundless lawsuits have been brought alleging injury from the vaccine. Even if the lawsuits are spurious there is a high cost to their defense. In some cases the unpredictable nature of the jury's sympathy for the injured party and the consequent passion and prejudice leads to a money verdict for the plaintiff when one is not legally deserving. In most cases, the vaccine manufacturer has a substantial deductible before its product liability insurance becomes effective. These factors, together, appear to be economically unjustified and could lead to the bankruptcy of the producer.

The issue is not one of the manufacturer attempting to avoid liability for its negligence in the production of the vaccine.

It is our belief that federal legislation is required to resolve the product liability crisis, since it seems virtually impossible to solve it on a state-by-state basis. The exact means by which the liability protection is accomplished is, perhaps, secondary. More importantly, action of some type must be taken quickly to resolve the matter.

It appears to our Company that unless the overall policy of the federal government is to resolve the product liability issue forthrightly and promptly, there is a significant possibility of inadequate supplies of vaccine being available for the people of the United States.

Mr. ROGERS. Thank you very much.

Mr. WAXMAN. Were any of you gentlemen present or do you have any knowledge of what took place 1 month ago, when the manufacturers finally agreed to sign contracts with HEW? Were any of you involved in those negotiations?

Mr. ABRAMSON. Mr. Waxman, nothing happened 1 month ago. There was a series of communications for several months between the manufacturers and HEW, basically CDC. Last September we had a letter contract. It basically authorized CDC to purchase the vaccine and to be obligated to pay for it at some price that would be determined at a later date after certain audits were conducted.

The definitive contract was prepared about that time but we were waiting on several issues. One was determining the cost criteria that would apply to the contract as was mandated by the legislation last year. The second issue was over the tax treatment of the self-insurance retention funds. That would be the $2½ million that each manufacturer would have to maintain an escrow account. The resolution of this problem took, as I recall, until April of this year.

Then, after April of this year, the draft definitive contract was finalized. The various manufacturers, as I understand it, signed the contracts and submitted them to CDC. The contracts were not executed by CDC until after the question of the waiver of the cost accounting standards was satisfied; and then the next thing we knew, about 1 month ago the contracts were actually signed by CDC.

So that was really the sequence of events.

Mr. WAXMAN. Could you tell us why your clients wanted to change the terms of the cost accounting standards which otherwise have been part of the contract?

Mr. ABRAMSON. We did not want to change the terms. It was our financial adviser's view that the nature of the program was such, including nonprofit element, that having to crank up on short notice for the program, the cost accounting standards would not be applicable in this type of situation where so many unknowns existed for so long.

We discussed this with CDC and, under current Federal procurement regulations, there are provisions authorizing a waiver. We submitted a request for the waiver, I guess back in the spring of 1977. That never became a sticking issue. We requested it but we never took the position we would not execute the contract. It was a bargaining position.

We were audited both at a preaward stage by HEW and after the delivery of the vaccine and they were satisfied by examination of our records we met the generally accepted accounting principles. Thus they were satisfied, before they would grant the waiver, that there would be no variance between what would have been done under the cost accounting standards and how our books were actually kept.

Mr. WAXMAN. Could you tell us why you thought the cost accounting standards were not applicable in your case?

Mr. ABRAMSON. I am quoting what our financial people told me. It is a matter of restructuring the way we accounted for certain indirect costs. I can't explain it in detail; maybe one of these other

gentlemen can. But our costs were allocated under generally accepted accounting principles. I can't tell you under what cost accounting standards they might vary.

There is no difference in how we came out as far as numbers go. It is how we accounted for it on the books.

Mr. WAXMAN. Why, do you think, did it take so long before the definitive contracts were actually entered into and signed?

Mr. ABRAMSON. As I mentioned, the first thing was to determine what cost criteria would apply to the vaccine. This was something HEW, under Secretary Mathews, had to determine. They discussed it with the manufacturers and there were specific criteria determined which would govern what costs would be allocated. That had a bearing on the cost accounting standards and took several weeks to resolve.

The next thing was the IRS ruling on the tax treatment of the self-insurance retention funds. Until we knew what that tax treatment would be, we could not agree on final terms of that part of the contract. That took from November to April of 1977.

After that was resolved, we signed the definitive contract, which did not contain the cost accounting standards clause, and submitted it to the CDC. From April until August the contract was not signed by CDC until both we and they resolved the exclusion of cost accounting standards clause.

Mr. LAMB. Mr. Waxman, my wife asked me the same question and I tried to explain it this way: We had a letter contract the last time that this panel appeared before you. There is not much difference in the terms that are in the definitized contract and the terms that were in the letter contract—at least in our case—and I have reviewed the other contracts since I have received them under the Freedom of Information Act and I find that that is essentially true for the others.

So even though these questions have been raised, we have been operating essentially under the final contracts since September, when we testified, approximately 1 year ago.

Mr. WAXMAN. Even though there might be little difference in the terms of the contract, it was the desire on the part of the manufacturers to have that specific cost accounting requirement waived, isn't that correct?

Mr. LAMB. That, sir, is the only substantial difference in our contract between the one previously and that which was definitized—the waiver was decided by the new Secretary of HEW, since Mr. Califano is required by statute to make the waiver.

Second, we explained—I guess you understand Public Law 94-380 does contain the requirement that the Secretary of HEW must establish the cost data, the cost criteria. Those then became part of the contract and were established prior to the consideration of the fact that they were in conflict, in several instances, with the CASB.

Mr. WAXMAN. The Secretary established the criteria for the costs that the manufacturers would incur?

Mr. LAMB. According to Public Law 94-380 he was required to do so.

Mr. WAXMAN. And then he established that criteria which was at variance—I didn't understand what you said.

Mr. LAMB. With the Cost Accounting Standards Board.

Mr. WAXMAN. What is the Cost Accounting Standards Board?

Mr. LAMB. The Cost Accounting Standards Board, CASB, is the Board that establishes the CAS. These are the cost accounting standards that were waived by the Secretary, by Secretary Califano.

Mr. WAXMAN. But Secretary Califano still insisted on the criteria of the cost that his office had established being fulfilled.

Mr. LAMB. That is my understanding.

Mr. WAXMAN. What kinds of criteria?

Mr. LAMB. I am in the same spot as Mr. Abramson, I am a lawyer not an accounting man. I do know that most of the costs that were incurred in the performance of the swine flu program were incurred prior to the time we entered into the letter contract in September of last year. Those costs—and in our case they were quite substantial costs from producing 40 million doses of bulk vaccine—were done without regard to the cost accounting standards requirements. Consequently, the accounting records and the accounting procedures had to be changed at the time the contract was signed. The cost criteria that were established by the Secretary took into account the fact that there was a period of time when costs were being incurred and there was no contract, when there was no requirement that we proceed, and we later proceeded under a specified standard when they established the cost criteria that became part of the contract.

Mr. WAXMAN. The GAO study indicates that manufacturers' claims of potency in their vaccines were consistently at variance with the findings of the Government. I would like to know from you gentlemen were you deliberately trying to distribute vaccine that was ineffective, hoping to recoup your production costs or do you not test vaccine for potency before distribution?

Mr. HENDRICKSON. I will attempt to answer and start by saying that I am not a scientist. The CCA test is recognized as less than desirable by both the manufacturers and the BOB. It is not the best test we could have. Unfortunately it is the only one we have. It does have inherent in it a variance of test accuracy, and I think this is where the problem comes in. If we look at our own case, I think we submitted some 70-odd lots to the Bureau. There were a number of these lots where our results were higher than the Bureau's. there were a number where our results were lower.

So it is not unusual that you would get differences between laboratories. What we went through was a process of trying to establish what the relative gradation of this test was in the two laboratories so that we could achieve consistency of test results between the two laboratories. Now with regard to the potency, the only thing the CCA test really does for us is assure consistency between lots. What we determined through the clinical tests was what antibody levels would be achieved through a vaccine that contained 200 CCA units.

Then our job as manufacturers was to assure that we had at least 200 CCA units in our vaccine so that the same antibody level results would occur in human beings. We all recognize and you have heard other testimony to the effect that there are questions concerning whether this is really a measure of potency or not. The

only thing I can say is it is the best thing we have. It does assure consistency from batch to batch and that is really our concern.

Mr. WAXMAN. Nevertheless, GAO studies and the program indicates that 15.5 million doses were subpotent.

Mr. HENDRICKSON. The end result was that none of that vaccine was used by the public before it had been fortified with additional units. So what you have here is a normal process that goes on between the manufacturers and the Bureau to establish what is in fact the CCA level of the vaccine and this is firmly established and agreed to by both laboratories before anything is released to the public at large. We are only dealing with the bulk test. This is not a finished test so any variance at that stage can be corrected by adding or subtracting viral units.

It is really an in-process test and it is a test that is trying to establish what should be put into the final container.

Mr. WAXMAN. Let me ask a question about the relationship between the manufacturers, those of you before us, and your insurance carriers.

Is there an ongoing relationship with one particular carrier that each of you does business with or do you have various carriers insurance for various kinds of vaccines and drugs?

Mr. MARKOE. In our case we do business with I would estimate at least 20 to 30 carriers. However, they are all involved essentially in the same product liability program. Certain carriers carry more of the burden than others. But there are a multitude of companies that are involved.

Mr. WAXMAN. How much of a negotiation do you have on the setting of rates by the insurance companies for the various drugs and vaccines?

Mr. MARKOE. I don't personally do that, Mr. Waxman. I know there are extended discussions but I am not familiar with the precise nature of the discussions. It becomes more difficult every year subject to product liability. As the product becomes more difficult it takes longer to work out the negotiations.

Mr. WAXMAN. Are any of you other gentlemen familiar with the negotiations?

Mr. HAGAN. I can say this much. When this program began we had dollar one coverage. In other words, we were insured from the first dollar of exposure. The carrier who carried that risk no longer carries our risk and I don't believe is involved in this program at all.

Mr. WAXMAN. Which program?

Mr. HAGAN. The carriers that are backing up any claim by the Government against us. I don't believe it is one of the carriers that is involved.

Mr. WAXMAN. The carriers that have represented you for any liability as a result of the swine flu program have no other contracts with you for insurance coverage for other drugs and vaccines?

Mr. LAMB. They do not. That is essentially true, Mr. Waxman. In the case of our company we have a substantial deductible and there are a number of insurers and reinsurers.

Mr. ABRAMSON. That is also true with the primary carrier with which we do business and there are other insurance companies on top of the primary layer.

Mr. WAXMAN. How can you account for the fact that the cost of the bivalent vaccine was so much greater than the cost of the monovalent vaccine?

Mr. HENDRICKSON. The obvious answer is that there are two components to it so you would expect it to be higher. In our own case I can give you our prices if you lack them. For the monovalent we have it in two forms, 10 and 50 dose so on monovalent prices in 10 dose, 28 cents a dose. In 50 dose, 24 cents a dose. The bivalent in 10 dose was 45 cents a dose and in 50 dose it was 40 cents a dose.

Mr. WAXMAN. Almost twice as much.

Mr. HENDRICKSON. Slightly less than twice; yes.

Mr. WAXMAN. Why would it be so much more?

Mr. HENDRICKSON. Again you have two components in it.

Mr. WAXMAN. Don't you incur costs in developing bivalent that you would have with a monovalent that would change as additional doses are added?

Mr. HENDRICKSON. No, you are dealing with two different virus components. You have the same problems with the second component that you might with the first, variability of the yield, question of the amount per egg, the yield that you get as you go through your process. So each one is really a separate product and then combined at the end and as a separate product would, could carry entirely different costs throughout. I should say both of these components bear no profit margin in our case.

Mr. WAXMAN. Both bivalent and monovalent?

Mr. HENDRICKSON. Yes.

Mr. LAMB. In the case of Merrell we also agreed, for both the bivalent and the monovalent, to supply at cost. Our figures were 39 cents per dose on bivalent and 18 cents per dose on monovalent vaccine.

Mr. MARKOE. For Parke-Davis we believe our cost for monovalent will be about 20 cents and about 35 cents for the bivalent. Below some of the others. For an average of around 30 cents a dose.

Mr. WAXMAN. None of you gentlemen have the profit for your companies by virtue of the monovalent vaccine manufacture; is that correct?

Mr. MARKOE. Parke-Davis had no profit. We will suffer significant loss.

Mr. WAXMAN. Do any of you receive any benefit whatsoever from the $8 million that was paid for insurance coverage of what some people testified was only a remote possibility of liability?

Mr. HENDRICKSON. No benefit to Merck.

Mr. HAGAN. No benefit other than the insurance coverage that it bought.

Mr. MARKOE. Same for Parke-Davis.

Mr. LAMB. Same for Merrell.

Mr. WAXMAN. I thank you for your answers.

Mr. ROGERS. Do you have any arrangements with any insurance company for retroactive settlement if they don't have to pay out any of the premium you paid to them?

Mr. HENDRICKSON. Merck Sharp and Dohme does not.

Mr. ROGERS. How about the other companies?

Mr. HAGAN. No, sir.

Mr. ROGERS. No agreement to that.

Mr. HAGAN. No, sir.

Mr. ROGERS. So the payments made are made from the cost of the product. How much did each of the companies——

Mr. LAMB. Excuse me, Mr. Rogers, may I add one thing. No portion of the premium is refundable under our contract of insurance. I think they are identical to the others, nonrefundable to the companies; but the definitized contract that we entered into, as well as the letter contract, provided that if we receive, or any benefits are returned to us, they should be returned to the Government within 30 days after our receipt.

So that if for some reason there were refundable or retroactivity in any way applied, it would be refunded to the Government under the contract terms.

Mr. ROGERS. What about in any other insurance programs that would in any way be related to this? Would there be a refund at all?

Mr. LAMB. I know of no related insurance program.

Mr. ROGERS. In other words, in other vaccine programs there would be no relationship to what you are paying here with the adjustment?

Mr. LAMB. These are separate policies. This was a special policy.

Mr. ROGERS. No connection at all.

Mr. MARKOE. There is no connection.

Mr. ROGERS. What about your other vaccine programs? If you would just briefly give me an idea of the other vaccines you are currently producing?

Mr. HENDRICKSON. We are currently producing measles, mumps, and rubella vaccine and also have a meningococcal vaccine.

Mr. HAGAN. We produce a broad line of vaccines including the flu vaccine and tetanus vaccine and a great many others.

Mr. LAMB. Mr. Rogers, I did not come prepared to know exactly what vaccines we do produce. I know yellow fever vaccine is a vaccine we do produce and we are the only producer of that vaccine. Our other vaccines such as diphtheria, tetanus, meningococcus and diphtheria-tetanus vaccines are also produced by other manufacturers. We are not a single source of those, only yellow fever.

Mr. MARKOE. Parke-Davis produces DPT—diphtheria pertussis and tetanus.

Mr. ROGERS. Now what about your liability for these vaccines? Have you had any problem getting insurance for these biologicals?

Mr. MARKOE. In our case as you know it is handled through the private sector, the private distribution sector, administered in most cases by physicians so you have the physicians-patient relationship. So because of that reason, as I understand it, we have not had difficulty to date.

Mr. LAMB. In Merrell-National's case we have insurance coverage for biologicals this year but I think that is somewhat misleading unless I add that as most companies we have a substantial self deductible before the insurance protion applies.

Mr. ROGERS. I presume that is true with all the companies.

Mr. LAMB. I think it is true in most companies so that when you talk of insurance, the insurance starts after almost the catastrope level.

Mr. HAGAN. Above our self-insured level we have been able to maintain coverage. We perhaps could have gotten insurance from dollar one but the costs would have been prohibitive.

Mr. ROGERS. So you have self-insurance but you had no problem obtaining that coverage?

Mr. HAGAN. Well, it takes a good deal of effort but we have it for this current year.

Mr. ROGERS. What do you mean it takes a good deal of effort?

Mr. HAGAN. We have to look for it assiduously. We have been able to maintain an adequate layer of coverage for this current year. I can't predict next year yet.

Mr. HENDRICKSON. We have insurance coverage at the present time, but it is subject to a large deductible and that is a risk to which we are exposed.

Mr. ROGERS. How many suits or claims have you had filed against the company for these other vaccines that you manufacture?

Mr. MARKOE. I don't have the precise numbers but there have not been large numbers today in the case of Parke-Davis, but we have some.

Mr. ROGERS. As I recall it was generally less than 10.

Mr. MARKOE. I think that would be applicable to our company.

Mr. LAMB. It may be a few more than that for our company.

Mr. ROGERS. About how many more?

Mr. LAMB. A dozen, dozen and a half but it is not significantly more.

Mr. HAGAN. The last major attempt by the country to immunize on a national basis was in the polio campaign. In that instance the two companies I am familiar with had certainly better than 50 very serious product liability suits arising out of that program. In recent years, we have not had—apart from this swine flu effort—a national immunization program and our suits have been less. Certainly, within the past year, we have not had any more than 10 suits involving a vaccine.

Mr. HENDRICKSON. I don't have exact figures but I would estimate in the range of 10 to 20.

Mr. ROGERS. Have there been any recoveries in suits this year?

Mr. HENDRICKSON. Not for us.

Mr. HAGAN. None for us but that is because we have not proceeded to trial in any this year.

Mr. ROGERS. You must not have many suits if you have not even gotten to trial.

Mr. HAGAN. It takes an average from 2 to 7 years between the time a case is filed and the time that it is tried.

Mr. ROGERS. I understand, but I would think that if there were lots of suits you would constantly be in trial. Have any been dismissed?

Mr. HAGAN. Not this year in a vaccine case. We have been successful in some other cases.

Mr. ROGERS. How many are you in trial on now?

Mr. HAGAN. Today, we are in trial in two suits but neither one involved a vaccine.

Mr. ROGERS. I was trying to restrict this to vaccine.

Mr. HAGAN. We are not in trial at the moment on any vaccines.

Mr. ROGERS. Will you be next year?

Mr. HAGAN. We will be this year. But not at the moment.

Mr. ROGERS. How many do you anticipate in trial this year.

Mr. HAGAN. If they are not settled we should try two or three this year.

Mr. ROGERS. So the other vaccine products are not a very significan't cause of lawsuits?

Mr. HAGAN. No, the awards could be high because the type of thing you get involved with is encephalitis and that sort of thing and the injuries are severe. It had potential for a very high verdict.

Mr. ROGERS. What have been the payments for such suits? Could you supply that for the record for the last 5 years? I realize you would not have it with you.

Mr. HAGAN. We will be pleased to.

Mr. ROGERS. Let us know what that rate is. We went into some of this before, but I am trying to refresh my memory.

About how many doses are you now manufacturing of all your vaccines? Could you give us just a general estimate?

Mr. HENDRICKSON. We would rather not give those figures out here but we would be happy to supply them to you.

Mr. HAGAN. We are in the same position.

Mr. ROGERS. Why is that? Is this a trade secret?

Mr. HAGAN. In my case it is. In addition I don't know.

Mr. ROGERS. That is really a secret. If you would supply it for the record. I guess that I will get it eventually. I doubt if it would make much difference to your competitor. Does it really? Is that a great secret really?

Mr. MARKOE. I would be pleased to give you the information.

Mr. ROGERS. I am not pressing you for it.

Mr. MARKOE. I think it could be to the people responsible for the production and the marketing. They would consider this proprietary. It is highly competitive information. There are only four of us and it is a pretty tight group.

Mr. ROGERS. I would think everything would be known.

Mr. MARKOE. Surprisingly, it is not.

Mr. ROGERS. I won't press, but if you would let us know for the record. I think it would be helpful if you would also supply a statement for the record as to any suggestions you might have for future immunization programs, any criticisms you have on how the matter was handled before and what you think should be done in the future.

This would be helpful to the committee in trying to fashion some legislation. Thank you. We are grateful to you for your patience and for being here today.

The committee stands in recess for 5 minutes.

[The information requested was not available from all four of the manufacturers at the time of printing.]

[Brief recess.]

Mr. ROGERS. The subcommittee will come to order.

Our next panel is a panel of insurers. We have T. Lawrence Jones, president, American Insurance Association; William O.

Bailey, president, Aetna Life & Casualty; and Henry U. Harder, president, Chubb & Son, Inc.

Your statements will be made a part of the record in full and you may proceed.

STATEMENTS OF T. LAWRENCE JONES, PRESIDENT, AMERICAN INSURANCE ASSOCIATION; WILLIAM O. BAILEY, PRESIDENT, AETNA LIFE & CASUALTY; AND HENRY U. HARDER, PRESIDENT, CHUBB & SON, INC.

Mr. JONES. Thank you, Mr. Chairman, for this opportunity to appear before you. I am T. Lawrence Jones, president of the American Insurance Association. We have some attachments to our statements which I assume will be included in the record.

Mr. ROGERS. Without objection, they will be made part of the record following your statement [see p. 440].

Mr. JONES. In the interest of saving time, perhaps I can just simply open the discussion here by saying, with respect to the earlier testimony and the earlier questioning, that in the course of developing an insurance program for the manufacturers, working with the manufacturers and with the Department of Health, Education, and Welfare, we offered the Department three alternatives that contemplated enactment of the legislation then pending before your subcommittee. Two of those alternatives contemplated a retrospective premium.

The Department first chose alternative two, which included a retrospective premium arrangement, and we have virtually completed the commitments necessary to fill out that coverage when the Department advised us that they were changing their approach, that all the circumstances were changing, and that they did not want to go that way.

Mr. ROGERS. Do you recall when that judgment was made?

Mr. JONES. Yes. I believe it was July 30, 1976. You will find the discussion of this process at the top of page 5 of my statement, Mr. Chairman. Indeed, by the afternoon of Monday, August 2, commitments had been made to insure 90 percent of the $50 million primary insurance coverage which the initial program called for, but commitments to the additional or excess layer of coverage were proving hard to secure.

But at that time, HEW advised us that they were changing their approach, and they stated to us very frankly that they needed a fixed price. The reason was that they had an appropriation and they needed to know what the price would be. From then on, we approached their various proposals and needs from the standpoint of a fixed price, and we no longer brought up or developed any other retrospective rating proposal.

We felt that the retrospective plan was probably the best way to go under the circumstances, but we understood perfectly HEW's problem and the reason they made the decision, and we don't think they acted incorrectly under their circumstances and facts.

This was an entirely new program in our eyes, operating in a climate that was relatively new in terms of litigation and awards against pharmaceutical products on the part of juries and courts. These circumstances required the program that was actually enacted, and pursuant to the law, we developed an insurance pro-

gram, and were able to fulfill the commitment we made to it. We reported to you on that on September 13, 1976, and all the materials relating to it are here.

We think your committee made an appropriate decision under the circumstances. It was necessary to support the program, and we were glad to fulfill our responsibility. I must stress, however, that it was done with a great deal of difficulty and that we had to go into the world market to fill out the $220 million total insurance coverage over and about the 2½ million retention on the part of each manufacturer.

The choice of going with a fixed price approach was made by the client, HEW, on the basis of the limitations that they felt that they were governed by.

We would be perfectly willing to approach any future program on a retrospective basis or on a service basis. Certainly there is more experience at this point to justify approaching it on a retrospective basis than there was in the first instance, but still we think that the experience that has been put before this subcommittee confirms beyond any doubt that our concerns were not exaggerated about the different number and type of claims that would arise out of the swine flu program as distinguished from ongoing vaccination programs. In past immunization programs, people sought to get vaccinated, and we were not as concerned about informed consent or warnings, because they were actually seeking it and were going through the formal procedures with their own physicians. Moreover, time had been taken to properly develop the vaccine and distribute it in accordance with an unhurried program.

[Testimony resumes on p. 487.]

[Mr. Jones prepared statement and attachments follows:]

Statement of T. Lawrence Jones, President
American Insurance Association
Swine Flu Immunization Program
Oversight Hearings
Subcommittee on Health and the Environment of House
Interstate and Foreign Commerce Committee
September 16, 1977

My name is T. Lawrence Jones and I am president of the American Insurance Association, an organization of 145 insurance companies writing property and casualty insurance throughout this country. We appear today to report to the Subcommittee the events which took place between the Subcommittee hearings on July 23 and September 13, 1976 and thereafter. We will report the course of those events leading to the development of the final insurance program for the vaccine manufacturers and to the securing of the underwriting committments necessary to fill out the program, as insurance industry representatives observed and recollect them. We also describe subsequent preparation for claims handling.

On September 13, 1976, this Subcommittee heard Henry U. Harder, president of Chubb & Son Inc., and Kenneth A. Greiner, vice president of Johnson & Higgins, report on the actions of the insurance industry subsequent to the passage of Public Law 94-380 on August 10. Their report appears at pp. 329-340 of the subcommittee's published hearings on the Swine Flu Immunization Program. (Supplemental hearings before the Subcommittee on Health and the Environment of the House Committee on Interstate and Foreign Commerce, 94th Cong., 2nd Sess., Serial No. 94-113 (1976)).

As Mr. Harder informed the Subcommittee, each manufacturer would receive two policies, one for $5 million and one for $50 million, and that such insurance would be excess over what was understood to be a retention of $2.5 million of liability for each manufacturer's own account in accordance with its contract with the government. For the entire first layer of coverage ($20 million excess of such total retention) the premiums totalled $2.4 million. For the second layer of coverage, $200 million in all, the premiums totalled $6.25 million.

The coverage provided was, and is, basically for each manufacturer's liability imposed by law for personal injury or death arising out of the Swine Flu Program as such legal liability is limited by the manufacturer's contract with the government and by P.L. 94-380.

The hearing transcript contains copies of the two insurance policies and identifies the insurers who subscribed to either or both policies, setting forth the amounts of their subscriptions.

It shows that a substantial percentage (17.035%) of the second layer of coverage was subscribed by Lloyd's, London and various British and other foreign insurers.

In short, that report to this Subcommittee, simply describes the insurance program in its final form and annouces its successful completion.

The final form of the insurance program, however, only emerged after two weeks of intense discussions and negotiations involving representatives of HEW, of the vaccine manufacturers, and of insurance companies. The key meetings were attended by staff representatives of this Subcommittee, of the Federal Insurance Administration and of other government agencies.

In accordance with commitments made to this Subcommittee at its July 23 hearings, those two weeks of discussion and negotiation began on Monday, July 26. On the next day, three basically different insurance proposals were outlined to HEW by the insurance industry task force. Copies of the outlines as given to HEW and generally distributed to those attending the meetings, dated July 27, 1976, are attached hereto as exhibits. Called respectively alternatives #1, #2 and #3, it is to be noted that alternatives #1 and #2, both proposed that the insurance costs involved be handled on a retrospectively rated basis, subject to a maximum and a minimum premium.

The Initial Insurance Program

By Wednesday, July 28, the initial insurance program - it was based on alternative #2 - which HEW asked the insurance

industry to consider, was in final form. Secretary Mathews requested the insurers to respond to him in Washington on Friday, July 30. A copy of one of the Secretary's telexes to insurance executives, sent July 29, is attached as an exhibit.

That initial insurance program is detailed in the documents which the insurers then considered and copies of those are attached as exhibits. One is entitled, "Swine Flu Vaccine Program" and the other, "Swine Flu Excess." Also attached is the July 28, 1976 draft of contract between the government and contractor. In summary: one primary insurance policy with an aggregate limit of $50 million, retrospectively rated with a minimum premium of $2 million and a maximum premium of $40 million, was to be provided and shared by the four manufacturers. Pursuant to a statute to be enacted, the government would indemnify the manufacturers for claims not covered by that primary insurance, while the manufacturers would reimburse the government for any such indemnity payments which resulted from a manufacturer's failure to carry out its contractual responsibilities or from its negligence. $50 million insurance coverage against that liability to the government would be provided each manufacturer for a fixed premium of $375,000 per policy.

Secretary Mathews was informed on Friday morning, July 30, that the insurers believed the program could be carried out

and were beginning their best efforts to do that with the essential help of the insurance brokers for the four manufacturers. Indeed, by the afternoon of Monday, August 2, commitments had been made to insure 90% of the $50 million primary insurance coverage which the initial program called for, but commitments to the additional or excess layer of coverage were proving hard to secure.

By that time, however, the premises of that program were already shifting and within a few days were completely changed.

The government agencies concerned were concluding that the nature of the Swine Flu Immunization Program required that legislation to deal with the program's special liability problems should protect all program participants, and not simply the manufacturers, against claims other than for their negligence and should bring the government in as the sole defendant for all claims, whatever the legal theory, using the procedures of the Federal Tort Claims Act. On Tuesday, August 3, this Subcommittee had approved the essential form of the bill, later enacted as S. 3735, (P.L. 94-380, the National Swine Immunization Program of 1976) carrying out that conclusion.

Moreover, by the end of that week the government agencies concerned had reconsidered and ruled out a retrospective premium determination, deciding that insurance costs should be fixed from the outset of the program.

The Final Insurance Program and Its Fulfillment

The insurance industry, meaning the insurance brokers for the four manufacturers, the handful of insurance company executives who were familiar with the risks involved because their companies were insuring those manufacturers or because they had participated in the efforts to put together the initial program, and the insurance trade association executives who participated in the formulation and negotiation of that program, began as early as Thursday, August 5, to put together the insurance commitments which the final program would require.

The details of that program were reported to this Subcommittee on September 13, by Mr. Harder and Mr. Greiner, and the efforts necessary to fulfill that program were simply described as carrying out what was "not an easy task". As Mr. Harder put it, "The underwriting community... took a great deal of teaching."

That was an understatement. Those teaching or selling efforts entailed explaining to as many of the hundreds of insurance underwriters as possible the details of the government's relationship to the development of the vaccine and to the manufacturing and distribution process, as well as its testing procedures and controls over the release of the vaccine, the details of the different methods of manufacture, shipment and delivery, of the nature of the warnings and other information

to be given to those innoculated and of the controls necessary to ascertain that such information and warnings were indeed given and that the vaccine given each person innoculated would be definitely identified. Underwriters frequently requested data which might enable them and their counsel to evaluate the expected legal consequences of the statute which Congress was then considering and of the contract which the manufacturers and HEW were then negotiating.

With the cooperation of HEW, this educational process was begun with a seminar to which all insurance underwriters who could be reached on short notice were invited and which was held on Monday, August 9, in the HEW auditorium. Representatives of the manufacturers explained their testing and production processes, representatives of the Bureau of Biologics reviewed the government's program of testing and controls as it related to those processes and representatives of HEW reviewed other aspects of the program including systems for distritubtion and deliveries of the vaccine.

The educational efforts there begun took more than a month to complete. A number of major insurers, including some who had agreed to take part in the initial insurance program, decided in their own good judgment that they should not participate at all. It was particularly difficult to complete the second layer of coverage, which called for a commitment of

capacity to liabilities which could total $200 million. A number of insurers, including some who finally agreed to commit their capacity, regarded the premium as inadequate. Others had unresolved doubts about the application, interpretation and validity of P.L. 94-380.

Many United States insurers undoubtedly made commitments which they might not have otherwise made to the program, because they were moved to demonstrate social and political commitment to an immunization program, believed to be vitally necessary to the public interest of the United States. Those seeking to complete the necessary underwriting commitments had to go not only to United States insurers, including the life insurance community as well as the property/casualty underwriters, but also to the foreign insurance market where there was naturally considerably less interest in motivations which it regarded as essentially political and peculiar to the United States. Nevertheless, it was necessary to have substantial participation by that market. Despite many rejections, a sufficient participation was obtained at virtually the last minute through the efforts of one of the lead underwriters at Lloyd's, London. That underwriter later commented, that even though he had eventually supported the vaccine insurance program, he thought that "the premium was too thin for the deal".

Preparation to Carry Out the Insurers' Responsibilities

Subsequently in September 1976, and almost as soon as the insurance underwriting commitments were certain, four of the principal subscribing insurers met to plan for the efficient and economical investigation, adjustment and defenses of claims or potential claims against their insureds. Each of the more than forty subscribing insurers is entitled to a voice in such matters should they arise and as they affect its interest. Consequently, it was essential to have in place in advance a common, indeed centralized, generally agreed upon procedure, so that expense and duplication of effort might be avoided in, and unified supervision provided for, claims servicing.

Those four insurers met on several occasions, discussed proposed procedures with Neil R. Petersen, Assistant Chief, Tort Section, Civil Division, Department of Justice, and during October prepared a Servicing Carrier Agreement which was distributed to the 19 insurers subscribing to the first layer of coverage. A transmittal memorandum dated November 10, 1976 outlined the claims administration procedures proposed. A copy of that memorandum and one of the Servicing Carrier Agreements are annexed as exhibits hereto.

Each of the 19 insurers subscribing to the first layer of coverage executed and returned the agreements to the insurers'

Claims Administration Committee. Several other insurers joined the Committee. The Committee, as then permanently organized under the Chairmanship of Aetna Casualty & Surety Company, retained the Hogan & Hartson law firm to maintain regular liaison on its behalf with Mr. Petersen's office at the Department of Justice and to assist the Committee in monitoring incidents which might give rise to claims against the manufacturers under P.L. 98-340.

While the Committee has not yet had any such incident called to its attention, close to a thousand claims, we are informed, have been filed so far under P.L. 98-340. The Committee continues, and expects to continue indefinitely, to perform its functions of oversight and readiness to respond as required by the agreements among the participating insurers.

Mr. Chairman, and members of the Subcommittee, we appreciate the opportunity to make this report today.

Respectfully submitted,

T. Lawrence Jones
President

/jdw
attachments

Alternative #1

1. Insurers issue $125 million products liability coverage to each manufacturer, including all claim expense in the $125 million aggregate limit.
2. Policy covers the manufacturer and anyone else other than the government who is legally liable for injury resulting from the vaccine and its administration. The policy is primary to all other applicable insurance.
3. The premium for the first $10 million is determined on a cost basis and paid by the manufacturer.
4. The premium for $40 million excess of $10 million is determined on a cost basis with a minimum premium of $2 million and a maximum premium of $30 million (again, paid by the manufacturer).
5. The government "reinsures" the policy 100 percent excess of $50 million aggregate.
6. The term "aggregate" includes indemnity, allocated loss expense, and unallocated loss expense.

Alternative #2

1. Aggregate limit of $50 million shared by the four manufacturers and protecting only the manufacturers from third party claims (subject to mutually acceptable HEW contract dividing all responsibilities). Government pays on behalf of the manufacturers in excess of the $50 million aggregate limit.
2. The premium for the $50 million coverage is determined as follows: $1.20 for each $1.00 of indemnity or expense subject to $2 million minimum and $40 million maximum.
3. Each manufacturer obtains its own excess insurance program protecting it from a government claim for "bench error." The suggested amount of coverage is $50 million for each manufacturer (including defense cost regardless of outcome) with a cost estimated to be $375,000 per manufacturer.
4. The term "aggregate" includes indemnity, allocated claim expense, and unallocated claim expense.

Alternative #3

1. Government restricts by contract and legislation the liability of manufacturers to failure to manufacture vaccine according to specifications.
2. Individual manufacturer purchases insurance to cover this retained liability only when government successfully asserts failure to perform. Coverage estimated at $75 million - can be layered - and price can be negotiated.
3. Industry offers to provide claim investigation service for third party claims if requested.

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WILLIAM M ROSS CHAIRMAN & CHIEF EXEC OFCR
GIBB & SON INC
NY
T A MEETING TUESDAY AFTERNOON, OFFICIALS OF THIS DEPARTMENT
ROPOSED TO CERTAIN MEMBERS OF THE INSURANCE INDUSTRY THAT THEY
ONSIDER AN ARRANGEMENT FOR PROVIDING INSURANCE TO MANUFACTURERS
F THE SWINE FLU VACCINE. IT WAS REQUESTED THAT ALL MEMBERS OF
HE INDUSTRY REVIEW THE PROPOSAL AND DECIDE WHETHER THEY WOULD
ARTICIPATE IN IT AND TO WHAT EXTENT. I AM WRITING TO UNDERSCORE
HE IMPORTANCE AND URGENCY OF THIS REQUEST. IT IS ESSENTIAL, IF
HE FLU IMMUNIZATION PROGRAM IS TO BE UNDERTAKEN AT ALL, NOT ONLY
HAT INSURANCE BE AVAILABLE FOR THE MANUFACTURERS BUT THAT THIS
ACT BE DEFINITELY KNOWN AT THE EARLIEST POSSIBLE DATE.
O YOU KNOW, THERE WILL BE A MEETING ON FRIDAY, MORNING, JULY 30,
T 9:30AM, IN ROOM 5051 OF THE DHEW NORTH BUILDING, 330
NDEPENDENCE AVENUE, S.W., WASHINGTON, D.C. TO WHICH YOU OR YOUR
EPRESENTATIVE IS INVITED, AT WHICH TIME I LOOK FORWARD TO HEARING
HE DECISIONS OF THE INDIVIDUAL COMPANIES CONCERNING THIS PROPOSAL.
NFORMATION ABOUT THE DETAILS OF THE PROPOSAL IS AVAILABLE FROM
OTH NATIONAL INSURANCE ASSOCIATION, FROM THE MANUFACTURERS, AND
ROM THE DEPARTMENT.
S CHAIRMAN ROGERS AND OTHER MEMBERS OF THE COMMITTEE MADE PLAIN AT
EARINGS ON THIS SUBJECT HELD LAST WEEK, THE FEDERAL GOVERNMENT
ANNOT BE THE INDUSTRY WILL BE ABLE TO PARTICIPATE IN PROVIDING
NSURANCE FOR THIS PROGRAM. WHILE THE COMMITTEE, OF COURSE, HAS NOT
AD AN OPPORTUNITY TO REVIEW THE SPECIFIC PROPOSAL MADE TO YOU,
KNOW THAT THE CHAIRMAN AGREES WITH ME THAT YOUR IMMEDIATE RESPONSE
O IT IS ESSENTIAL
DAVID MATHEWS SECRETARY DEPARTMENT OF HEALTH EDUCATION &
WELFARE

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RECEIVED
JUL 30 1976

The following modifications to the standard ISO policy will be made:

1. The definition of occurrence will be changed to provide that occurrence means an innoculation of swine flu vaccine (as defined) manufactured by a named insured.

2. A definition of swine flu vaccine will be provided.

These two changes when read in the light of the insuring agreement will restrict the policy to innoculation of swine flu vaccine.

3. The named insureds shall be the four (4) manufacturers and the policy will be endorsed to provide coverage for the employees of the four (4) manufacturers.

4. The definitions of bodily injury and property damage will be modified to delete the words "during the policy period." These changes are necessary because the policy is intended to provide coverage for bodily injury whenever occurring arising from an innoculation during the policy period.

5. A separate provision will be added to restrict the policy to occurrences (innoculations) within the policy period.

6. The limits of liability provisions will be deleted and the following substituted therefor: Regardless of the number of (1) insureds under this policy, (2) persons or organizations who sustain bodily injury or property damage, or (3) claims made or suits brought on account of bodily injury or property damage, the Company's liability is limited to loss in the amount of fifty million dollars ($50,000,000) in the aggregate. Loss shall include all sums paid as damages and all sums paid as cost charges and expenses of defense, including both allocated expenses and unallocated expenses.

7. The premium provision will be as follows:

   The premium for this policy shall be the deposit premium plus an amount equal to one hundred and twenty percent (120%) of that portion of loss which includes sums paid as damages and as allocated claim expense and one hundred percent (100%) of sums paid as unallocated claim expense. However, in no event shall such premium exceed $40,000,000. The deposit premium is $2,000.000. The minimum premium is $2,000,000.

   Additional premiums based on this formula shall be paid to the insurers by the 20th of the month following the loss and claim expense payments.

8. In the event premiums are not paid when due, this policy may be cancelled by the insurers by giving 30 days cancellation notice to the Insureds.

SWINE FLU VACCINE PROGRAM

We are enclosing a proposal for Insurance to provide coverage for the four manufacturers. This proposal differs as you will note from any previous forms, and it has been drafted to provide the underwriters with a profit potential for exposing their limits of liability. The policy will be on a quota share subscription form with each underwriter signing for their percentage of participation. It is contemplated using the standard ISO policy form with the attached modifications.

It is anticipated that many claims will be subject to subrogation against the government, relying upon the contract between HEW and the manufacturers delineating the responsibilities of each.

The rating formula is as follows:

$50,000,000 AGGREGATE LIMIT FOR THE PROGRAM

$2,000,000 DEPOSIT PREMIUM

The premium for the policy is the deposit premium ($2,000,000.) plus an amount equal to 120% of that portion of loss which includes sums paid as damages and as allocated claim expenses and 100% of sums paid as unallocated claim expenses. The premium so determined is subject to a minimum of $2,000,000. and up to a maximum of $40,000,000.

SWINE FLU EXCESS

Each manufacturer will also require a policy in the amount of $50,000,000 aggregate limit, including losses and loss expenses, in excess of the primary $50,000,000 aggregate policy issued to the four manufacturers jointly.

This excess policy will apply only for liability which may remain with the manufacturer under the attached contract which each manufacturer has with HEW. The specifications for manufacturing and distribution of the product are established by the government and the government's action against any manufacturer can only be for reimbursement of losses which the government has paid to third parties arising out of a manufacturer's failure to comply with such specifications.

The premium for each of these individual policies will be a flat charge of $375,000. The policy will be on a quota share subscription form with each underwriter signing for their percentage of participation. We expect each underwriter will participate in these excess contracts as well as the primary program.

ARTICLE 1. DELINEATION OF RESPONSIBILITIES OF THE GOVERNMENT AND THE CONTRACTOR

A. The parties recognize that the Government has initiated, planned, and is arranging for the implementation of the influenza immunization program. Because of the need to have the vaccine tested, manufactured, and delivered within a relatively short period of time in order that the population may be inoculated in an attempt to prevent an influenza epidemic, the Government has assumed certain responsibilities as specified herein which would ordinarily devolve upon the Contractor. It is the intention of the parties that the Contractor will be responsible solely for the performance of its obligations under Paragraph C herein. It is the purpose of this Article to delineate the separate responsibilities of the Government and the Contractor.

B. In the light of the circumstances described in Paragraph A hereof, the Government shall be responsible for:

(1) The adequacy of the standards and specifications for the vaccine required to be delivered under this contract, including their compliance with all applicable requirements of law and regulation.

(2) The safety and suitability of materials provided to the Contractor by the Government under or in connection with this contract.

(3) The investigation and determination of the safe and effective dosages and adequate directions for the use of the vaccine.

(4) The investigation and determination of the risks and benefits of inoculation with the vaccine.

(5) The development of an adequate statement of information respecting the risks and benefits referred to in subparagraph (4).

(6) The taking of all appropriate steps to assure that each individual to be inoculated (or, where appropriate, a parent or guardian of such individual) is adequately informed of such risks and benefits.

(7) The content of the labeling of the vaccine, including its compliance with all applicable requirements of law and regulation.

(8) The taking of all appropriate steps to assure that each person responsible for administering the vaccine has adequate notice of the labeling of the vaccine, provided that nothing herein shall limit the responsibility which the manufacturer otherwise has to assure that labeling is included in and delivered with each shipment of the vaccine.

(9) The arrangements for the implementation of the influenza immunization program, including the issuance of appropriate guidelines and information.

C. The Contractor shall use due care and comply with all applicable laws and regulations in the manufacture and handling of the vaccine in accordance with the specifications herein.

ARTICLE 2. RIGHT OF CONTRACTOR TO RECOVER LOSSES SUSTAINED BECAUSE OF THE GOVERNMENT'S BREACH OF CONTRACT

A. If any claim or action by a third party is asserted against the Contractor arising in whole or in part from an alleged failure properly to discharge the responsibilities assumed by the Government in Article 1, the Contractor shall promptly notify the contracting officer and furnish to him copies of all pertinent documents served upon or received by the Contractor. The Government shall, at its option, either defend against or assist in the defense or settlement of such claim or action. If such claim or action includes an allegation that the Contractor failed to exercise due care in the manufacture and handling of the vaccine in accordance with the contract specifications, the Contractor reserves the right to direct and control the defense or settlement of the claim or action with respect to such allegation. The Government shall not contest, in any subsequent litigation brought by the Contractor against the Government, any factual determination made in any prior litigation against the Contractor of which the Contractor has given the Government timely notice.

B. In the event of the Government's breach of, or failure to carry out, its responsibilities under Article 1, any measure of resulting damages to the Contractor shall include, but need not be limited to, damages (including money judgments, settlements approved by the Government, and reasonable attorneys' fees and associated costs) sustained in connection with claims against the Contractor caused by the breach or failure. This provision shall not limit any other right of the Contractor to obtain damages or other relief

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for any breach of this contract or for the settlement of any dispute arising under this contract.

C. All reasonable costs incurred by the Contractor in defending a claim based in whole or in part on the alleged failure of the Contractor to carry out any responsibility assumed by the Government under Article 1, and any recovery of damages by a third party against the Contractor on such a claim, shall be presumed to have been incurred by reason of a breach by the Government of such responsibility. Such presumption may be rebutted by the Government in any judicial or administrative proceeding if the Government proves by a preponderance of evidence that the Contractor's loss was not the result of a failure by the Government to carry out any of its responsibilities under Article 1.

ARTICLE 3. REQUIREMENT FOR CONTRACTOR'S LIABILITY INSURANCE

A. This contract is contingent on the Contractor's ability to obtain and participate in the liability insurance described in paragraphs B and C, the premiums for which shall be paid by the Contractor and included in the cost of the vaccine supplied under this contract.

B. The Contractor will share in pooled product liability insurance covering the influenza vaccine supplied to the Government under this program by all participating manufacturers. Such policy shall provide an aggregate limit of not less than $50 million for payment of all losses resulting from claims of third parties against such manufacturers, under terms approved by the Contractor and the Government.

C. The Contractor will obtain liability insurance in the amount of $50 million, covering all losses resulting from any claims against the Contractor for reimbursement of indemnification payments under Article 4.

ARTICLE 4. INDEMNIFICATION OF CONTRACTOR FOR LOSSES FROM THIRD PARTIES' CLAIMS NOT COMPENSABLE BY INSURANCE

A. Pursuant to the authority of Public Law 94-____, within ___ days after presentation of a claim the Government will indemnify the Contractor for losses sustained by the Contractor on account of claims or actions by third parties against the Contractor for injuries from inoculation with the vaccine, provided that (1) the Contractor has given the Government timely notice of such claims or actions and has otherwise complied with the provisions of Paragraph B hereof, and (2) the losses of the Contractor are not compensable by insurance described in Paragraph B of Article 3. Losses subject to indemnification under this Article include final money judgments; settlements and payments of claims approved in advance by the Government; and reasonable costs of investigating and settling claims and defending lawsuits, including reasonable attorneys' fees. The Contractor shall reimburse the Government for any portion of the amount paid by way of indemnification which the Government thereafter establishes to have resulted from the Contractor's failure to carry out its obligation under Paragraph C of Article 1. Such reimbursement shall be made with interest at the rate of six per cent per annum from the date of the indemnification payment by the Government to the Contractor.

B. The Contractor shall give immediate written notice to the Contracting Officer of any claim or action filed against the Contractor which might result in losses subject to indemnification under this Article. Except as otherwise directed by the Contracting Officer, the Contractor shall promptly furnish to the Contracting Officer copies of all pertinent documents served upon or received by the Contractor in connection with such claim or action. The Government may, at its election, direct, control, or assist in the defense of such claim or action. If the settlement or defense of such claim or action is undertaken by the Government, the Contractor shall furnish all reasonable assistance to the Government. Irrespective of whether the Government participates in the defense of a claim or action, no payment by the Contractor in settlement of a claim will be indemnified under this Article unless the Contracting Officer has approved such payment in advance. If any claim or action includes an allegation that the Contractor failed to exercise due care in the manufacture or handling of the vaccine in accordance with the contract specifications, the Contractor reserves the right to direct and control the defense or settlement of the claim or action with respect to such allegation.

C. The provisions of this Article shall not be subject to Article ___ of this contract entitled "Disputes."

D. The rights and obligations of the parties under this Article shall survive the termination or expiration of this contract.

November 10, 1976

TO: Each Subscribing Insurer - Special Liability Insurance and Special Excess Liability Insurance for Vaccine Manufacturers National Swine Flu Immunization Program of 1976

RE: Claims Administration Procedures
Proposed Implementation

* * * * * * * * * * *

As you may know, four of the subscribing insurers (or affiliates thereof) are now providing primary coverage and/or certain primary loss adjustment services for the four vaccine manufacturers in connection with their non-Swine Flu general liability or pharmaceutical products liability insurance or self insurance programs. Almost from the outset of the difficulty in placing suitable insurance coverage for the Swine Flu Immunization Program, there was a fairly general request from the subscribing insurers to those four companies to provide loss adjustment services for the Swine Flu Program. Those four companies have agreed to perform such loss adjustment services, each for its own manufacturer, and additionally agreed to form a committee with membership open to others of the subscribing insurers, to provide initial oversight of matters which might involve the vaccine manufacturers' insured liabilities and to plan for the defense and adjustment of any insured claims which might ensue.

Representatives of each of the four companies referred to have met and now outline here the elements of their proposal to accomplish those purposes, as well as to provide for liaison with the government offices, the subscribing insurers, and others involved.

Those companies (also sometimes called "servicing carriers") and the manufacturers they respectively serve are:

Aetna Casualty & Surety Co. - Richardson-Merrell

Continental Insurance Company - Warner Lambert - Parke Davis

ESIS Inc. (affiliated with INA) - American Home Products - Wyeth

Federal Insurance Company (Chubb) - Merck, Sharp & Dohme

1. National Swine Flu Program Insured Claims Administration Committee

This Committee will be composed of (1) a claims officer (and designated alternate) of each of the four companies referred to, and (2) a representative of any other subscribing insurer whose prorata share of either layer of coverage is at least 5% and which wishes to

participate in the Committee's work. It will be responsible for establishing a central office which will collect information from the Government Claims Office, from the manufacturers, from the subscribing insurers or others, which may be necessary, or desirable, in carrying out the Committee's responsibilities for oversight of matters involving potential claims. It has certain responsibilities under the Servicing Carrier Agreements referred to below.

2. The Committee's Administrative and Accounting Office

The Committee expects to establish and staff an office which will among other matters serve as focal point for liaison with the Government Claims Office, prepare regular reports to each of the subscribing insurers of the activities of the office, of occurrences which may involve insured liabilities, and the like - all under the supervision of the Committee. The office will also maintain accounts in connection with the functions of the servicing carriers under the agreements referred to below, and bill, collect and disburse funds therefor.

3. Initial Funding of the Committee's Administrative Expenses

The Committee proposes to have the amount of $100,000. withheld from the total premiums (net of commission) for the first layer of coverage which would otherwise be paid to the subscribing companies and to have that sum of money paid over to the Committee for deposit in a special account out of which the Committee would pay the expenses it incurs for the office and for other expenses (such as travel, etc.) which are incurred in connection with its functions.

In addition, the subscribing insurers which have incurred expenses on behalf of all participants, particularly in connection with policy form preparation, would be reimbursed for their actual expenses in that regard out of the same funds.

These expenses (and the $100,000. initial funding thereof) will be allocated to each of the subscribing insurers for the first layer coverage in direct proportion to dollars of premium payable to each such participant.

The Committee through its office will account to each of such insurers for the funds initially set aside for the expenses referred to. Unexpended funds will be returned to them.

4. Expenses Relating to Self-Insured Retention
(For the Manufacturer's Account)

To the extent that any or all of the four companies also provide administrative or supervisory services of an allocable nature in connection

with claims matters which are requested by the manufacturer in connection with its potential liabilities falling within the particular manufacturers' self-insured retention of $2,500,000., those expenses will be for the account of that particular manufacturer in accordance with the understanding between that manufacturer and the insurer providing the services referred to.

Other "non-allocable" expenses incurred by any or all of the four companies at the instigation of such company(ies) or the Administrative Committee will be charged to the subscribing insurers in the appropriate layer as set forth in Section 4.5 of the Servicing Carrier Agreements.

5. Claims Services and Expenses for the Subscribing Insurers

The Committee also believes that the efficient and economical investigation, adjustment and defense of claims or potential claims arising against each manufacturer would be promoted, if such claims handling is conducted by the Servicing Carrier for such manufacturer on behalf of all. The understanding among the subscribing companies, or some of them, about the conduct of such claims servicing on their behalf has, of course, not been spelled out in any detail.

The Committee therefore proposes and now asks that each of the subscribing insurers execute an agreement with each of the four Servicing Carriers.

Copies of such servicing carrier agreements are enclosed herewith. We request each such subscribing insurer to review the agreement, have it executed by a duly authorized officer, and return it as indicated below.

It should be noted, however, that the Committee does not now plan to pay out of its funds, or otherwise on behalf of the subscribing insurers, any amounts for indemnity or for allocated loss adjustment expenses, i.e., payments which will involve "loss" as the special liability policies define that term. When any such "loss" is payable by the subscribing insurers in either layer of coverage, each such insurer would be billed for its appropriate and proportionate share thereof, or otherwise pay in accordance with the enclosed agreements.

As set forth in the enclosed agreements, the subscribing insurers will be charged for the services of a servicing carrier and at the rate of $35. per hour of professional employee's time. This "unallocated loss adjustment expense" will be billed as incurred to the appropriate layer of coverage.

6. Prompt Indication of Any Objections Required
Return of Executed Agreements
Representation on the Administration Committee

A. To the 16 Companies in the First Layer of Coverage

It is essential that the Committee proceed with the utmost promptness to carry out its plans for claims administration oversight on behalf of the subscribing companies. Therefore, each of those companies should advise the Committee immediately upon receipt of this communication, if it has any objection to what is proposed, especially to the initial funding to defray the expenses of the Committee and the work already done on your behalf as described above. If the Committee does not receive notice of a significant objection on your part to its plans as described herein by the end of the business day, November 19, 1976, it will proceed as outlined.

B. To All Subscribing Companies

You will be kept fully informed of the Committee's work on your behalf and notified of the location of this office, as soon as that is established.

In any event, as soon as possible, please return executed copies of the four Servicing Carrier Agreements.

We need to keep the Committee to a manageable size. Nevertheless, each insurer subscribing to at least five per cent (5%) of either layer of coverage is invited to designate one of its officers to be on the Committee.

Pending establishment of the Committee's regular office, please address it in care of:

Edward T. Harris, Assistant Vice President
Continental Insurance Companies
13th Floor
80 Maiden Lane
New York, New York 10038

Mr. Harris will receive, and there should be sent him on the enclosed form:

1. Your objection, if any, to the Committee's proposals;

2. If you accept the invitation to be represented on the Committee, a designation of the person who will serve thereon;

3. The name, address, and telephone number of the person with whom the Committee should communicate in the course of its work for you.

Please enclose with the completed form an executed Servicing Carrier Agreement for each of the four carriers and manufacturers. A self-addressed envelope is provided for your convenience.

For the Administration Committee as initially constituted,

Very truly yours,

Eugene F. Brady, Director, Claims
Aetna Casualty & Surety Co.

Malcolm Burton, Vice President
Chubb & Son Inc.

George W. Eichler, Manager, Nat'l Accounts
ESIS Inc.

Edward T. Harris, Assistant Vice President
Continental Insurance Companies

NATIONAL SWINE FLU IMMUNIZATION PROGRAM OF 1976
SERVICING CARRIER AGREEMENT
FOR INSURERS OF THE MANUFACTURERS OF VACCINE

THIS AGREEMENT made and entered into effective as of the 12 day of August, 1976, by and between the undersigned insurance company(ies), and FEDERAL INSURANCE COMPANY, (hereinafter, the "Company").

WHEREAS, the Insurers listed in Attachment A (hereinafter the "Insurers") have agreed to provide Swine Flu Liability Insurance for the manufacturers of the swine flu vaccine provided pursuant to the National Swine Flu Immunization Program of 1976 and all as more specifically set forth and for the quota share percentages subscribed for in the various insurance policies, and

WHEREAS, the undersigned insurance company(ies) wish to appoint the Company as servicing carrier for one of the manufacturers for the purpose of servicing Swine Flu Liability Insurance claims on their behalf, and

WHEREAS, the companies listed in Attachment B have agreed to act as servicing carriers for the undersigned insurance companies and such insurance companies agreed to establish a National Swine Flu Program Insured Claims Administration Committee (hereinafter the "Administration Committee") to provide overall supervision and promote efficiency and avoid expense and duplication in claim servicing, and

WHEREAS, the Company is willing to accept appointment as servicing carrier for such purposes subject, nevertheless, to the terms and conditions hereinafter specified:

NOW THEREFORE, in consideration of the premises and of the mutual agreements hereinafter contained, the Company agrees and the undersigned insurance companies agree severally and not jointly as follows:

SECTION 1 - Appointment.

1.1 The undersigned insurance companies hereby appoint the Company as the exclusive servicing carrier for the Swine Flu Liability Insurance claims and losses of the undersigned insurance companies with Merck & Co. Inc. and all entities which it owns, controls or operates, (hereinafter, the "Manufacturer"), and the Company hereby accepts the said appointment, for such purposes and with such authority as are hereinafter set forth.

1.2 The Company agrees to conduct its duties hereunder in accordance with the National Swine Flu Immunization Program of 1976 and any regulations promulgated thereunder and with the directives of the Administration Committee.

1.3 As used in this Agreement, "Swine Flu Liability Insurance" means: the policies issued by the "Insurers" to the Manufacturer on policy forms numbered N.S.F. 1 Ed: 8/76 and N.S.F.2 Ed:8/76.

1.4 The undersigned insurance companies severally but not jointly agree that they will contribut and pay to the Company the losses, settlements, allocated, non-allocated, and other expenses or obligations in accordance with the terms of this Agreement for their respective quota share percentages as set forth on the policies described in 1.3 above and on Attachment A.

1.5 As used in this Agreement, Company shall include the named company and any subsidiary or affiliate thereof including any affiliated or subsidiary adjusting company.

SECTION 2 - Term.

2.1 This Agreement shall extend from August 12, 1976 up to and including the resolution of the last claim reported under said "Swine Flu Liability Insurance", unless earlier terminated as hereinafter provided.

SECTION 3 - General Powers and Duties of the Servicing Carrier.

3.1 The Company shall make available such of its own staffing, office space, facilities and equipment as are necessary for the performance of its duties hereunder; provided, however, that any separate staffing, office space, facilities or equipment which the undersigned insurance companies determine are necessary or desirable for the efficient administration of their business shall be provided at their cost and expense.

3.2 The Company shall examine and investigate claim or loss reports, shall determine coverages and shall adjust, settle, compromise, or have the right to defend or litigate, any claim or loss under the policies referred to in Section 1.3 above and shall have the right to hire attorneys, independent adjuster or others in those circumstances in which the use of staff regularly employed by the Company is impractical or imprudent as determined solely by the Company.

Affiliated or subsidiary adjusting companies shall not be considered independent adjusters. The Company shall perform its claim services in accordance with such guidelines as may be established for such services by the Administration Committee.

3.3 The Company shall determine the amount of such reported claims reserves as are reasonable and proper consistent with its judgment and standards for determining reserves for its own account. Reserves shall include allocated loss adjustment expense. The Company shall prepare, maintain and furnish to the undersigned insurance companies all statistical claim data and other records as they may reasonably require.

3.4 The Company may establish such agency or custodian bank accounts as in the Company's judgment are necessary to allow the Company to pay therefrom the losses and allocated or non-allocated loss adjustment expenses of the undersigned insurance companies incurred in connection with the purposes of this Agreement. In such event the undersigned insurance companies shall at the Company's request immediately advance funds for deposit in such an account in amounts estimated by the Company to be required to pay allocated and non-allocated expenses and losses during a period of no more than three (3) months from the date of any such request. Upon the termination of this Agreement, the Company shall submit a final accounting to the undersigned insurance companies of any funds so advanced and return to them any unexpended balance thereof.

3.5 The Company shall act generally in the name of the undersigned insurance companies.

3.6 Notice: It is agreed that notice of a claim, or of an occurrence likely to give rise to a claim, given by the Insured or (by the U.S. Government) to the Company, as required under the terms and conditions of its policy, shall be deemed to be notice to the other undersigned insurance companies. (The Company or its representative hereby undertakes to advise them of such notice.)

SECTION 4 - Servicing carrier Allowances, Expenses and Claims Payment.

4.1 As an allowance for its services as a servicing carrier as specified in this Agreement, the Company shall periodically bill the undersigned insurance companies at the rate of $35 per hour of its professional employee's time in performing such services and they shall pay to the Company the said sums within thirty (30) days of receipt of a bill therefor.

4.2 The Company shall periodically bill the undersigned insurance companies for Allocated Loss Adjustment Expense meaning the types of expenses set forth in 11 N.Y.C. RR, Chap. IV-C Part 105.2 and the Insurers shall pay to the Company the said sums within thirty (30) days of receipt of a bill therefor.

4.3 The servicing carrier allowance set forth in Section 4.1 intended to compensate the Company for non-allocated expenses considered to be normal operating costs for services rendered as a servicing carrier. Examples of such expenses include salaries of personnel, office equipment, space. Other functions and expenses are intended to be performed and paid solely by the undersigned insurance companies.

4.4 It is the express intention of the parties hereto that the Company not sustain a financial loss with respect to its services as a servicing carrier. Therefore, in addition to Section 4.1 above: The undersigned insurance companies shall allow the reimbursement of the Company for normal operating costs and unallocated loss adjustment expenses incurred in connection with their business, which are in excess of the allowances provided in Section 4.1. The undersigned insurance companies shall also allow the Company reimbursement of extraordinary expenses incurred as a servicing carrier, including, but not limited to, any special computer programming required or computer time cost necessary to run such programs.

4.5 The undersigned insurance companies will not question the statements or settlements of the Company, and will accept the statements of losses and expenses billed by the Company as conclusive evidence of their liability to pay for their respective quota share percentages set forth in the policy. With respect to losses and both allocated and non-allocated expenses of the Company to be so billed to the undersigned insurance companies the following guideline shall govern:

a. The Company's allocated and non-allocated expenses, allowances and loss payments hereunder shall be billed to such of the undersigned insurance companies as subscribed to the Special Liability Insurance Policy Form No. N.S.F.1 Ed:8/76 until such time as they shall have paid their respective percentages of $5,000,000 in "Loss" as defined in such policy. Thereafter, the Company's

allocated and non-allocated expenses, allowances and loss payments shall be billed to such of the undersigned insurance companies as subscribed to Special Excess Liability Policy Form No. N.S.P.2 Ed:8/76 until such time as such Insurers shall have paid their respective percentages of $50,000,000 in "Loss" as defined in such policy.

SECTION 5 - Maintenance of Records.

5.1 The Company shall maintain or provide for the maintenance by an independent third party of claims files, records and accounts with respect to all transactions entered into on behalf of the undersigned insurance companies to this Agreement, in accordance with generally accepted insurance accounting principles, as required by law, and as directed by the Administration Committee.

5.2 The undersigned insurance companies and any designated representative thereof shall have the right at all reasonable times to inspect the books, records and files of the Company so far as they pertain to the operations of the Company on behalf of the undersigned insurance companies, and shall have the right to copy or abstract such books, records and files at its own expense. It is agreed that any required or requested examination or audit of the books or other records of the Company with respect to its functions as a servicing carrier of the undersigned insurance companies shall be done at their expense. Such access shall in no way derogate from the exclusivity of the right of the Company to supervise and manage claims for the undersigned insurance companies.

SECTION 6 - Status of Parties.

6.1 Nothing herein shall be deemed to create the relationship of employer and employee between the undersigned insurance companies and the Company, it being understood and agreed that the Company is an independent contractor with all the rights, powers and duties as such.

6.2 Employees of the Company are not employees of the undersigned insurance companies or of the Administration Committee and shall at all times be under the sole control of the Company.

SECTION 7 - Termination.

7.1 The Company may terminate its services immediately with mutual consent of the Administration Committee or its services may be terminated by 60 days prior written notice from the Company to the Administration Committee. Either the Administration Committee or a majority in interest of the undersigned insurance companies may also terminate the services of the Company by 60 days prior written notice to the Company.

7.2 Upon termination of this Agreement as provided in Paragraph 7.1, the Company shall promptly provide for access by any person or organization designated in writing by the Administration Committee to receive the same, all policy records or copies thereof, claim files, reports and other documents relating to claim files and accounting and statistical reports and records completed, or maintained relating to the performance of this Agreement. Provided,

however, that the Company and the Insurers may agree that the Company shall retain and handle all claims reported to it during that time the Company acted as a servicing carrier, in accordance with the terms of this Agreement until the said claims have been terminated or returned to the Insurers under mutually agreed upon terms. The termination of this Agreement shall in no way affect or alter the obligations of the Company or the undersigned insurance companies to account for or to pay over sums due one another pursuant to this Agreement and the provisions of Paragraphs 8.1 and 9.1 shall specifically survive any such termination.

SECTION 8 - Indemnification.

8.1 The undersigned insurance companies shall indemnify and hold harmless the Company and its affiliates and subsidiaries and the directors, officers, agents and employees of the Company or of any such affiliate or subsidiary, against and from all costs, including the amounts of judgments (including interest thereon), settlements. fines or penalties and expenses, incurred in connection with any action, suit or proceeding, civil or criminal, to which the Company or such affiliate or subsidiary or such director, officer, agent, or employee thereof is made a party because of any act, error, or omission by or on behalf of the Company in the conduct of its duties or obligations under this Agreement; provided, however, such indemnification shall not be provided on any matter in which any such person or organization shall be finally adjudged in any such action, suit or proceeding to have committed a breach of duty involving dishonesty, willful misfeasance or reckless disregard of

his/her or its responsibilities. In determining whether the cost of defense is to be paid or in the event of settlement of a matter before final adjudication, indemnification shall be provided only if the undersigned insurance companies are advised by opinion of counsel or adjudication that such person or organization to be indemnified did not commit such a breach of duty.

8.2 Indemnification hereunder shall not be exclusive of any other right to which the Company or any other of the aforementioned indemnitees may be entitled to by law or in equity.

SECTION 9 - Liability.

9.1 Neither the Company nor any of its affiliates or subsidiaries, nor the directors, officers, agents and employees of the Company or any such affiliate or subsidiary shall have any liability to the undersigned insurance companies, or to any other person or entity with respect to its or their performance or failure to perform under this Agreement in the event that any legislation, administrative regulations, or other documents, practice or procedure governing the Swine Flu Program, any Swine Flu Liability Insurance provided with respect thereto, or the operation of the undersigned insurance companies or the Company as their servicing carrier, is found to be unconstitutional, illegal or otherwise unenforceable.

SECTION 10 - Effect of Headings.

10.1 The section headings herein are for convenience only and shall not affect the construction hereof.

SECTION 11 - Notice.

11.1 Whenever written notice is required to be given under any provision of this Agreement, such notice shall be sufficient if sent by certified mail, return receipt requested, to the following adress:

(a) The Undersigned Insurance Companies

The addresses specified in Attachment A.

(b) The Company

Federal Insurance Company
100 William Street
New York, New York 10038
Attention: President

SECTION 12 - Governing Law.

12.1 This Agreement shall be construed in accordance with and shall be governed by the laws and regulations of the State of New York.

SECTION 13 - Amendment.

13.1 This Agreement may be modified, altered, or amended only by a writing signed by an authorized representative of the Company and of the undersigned insurance companies.

13.2 This writing constitutes the entire Agreement of the parties and no agent or employee of either party has authority to change this Agreement or to waive any of its provisions except as otherwise expressly provided herein.

SECTION 14 - Effective Date.

14.1 This Agreement shall become effective on the day and year first above written and shall inure to and bind the parties hereto and their respective successors and assigns.

ATTACHMENT A

	Percentage of $20,000,000 Layer	Percentage of $200,000,000 Layer
Metropolitan Property & Casualty Co. 33 Cardi Drive Warwick, Rhode Island	No	2
General Accident Fire & Life Assur. Corp., Ltd. 414 Walnut Street Philadelphia, Pennsylvania 19105	No	1/2
Truck Ins. Exchange 4680 Wilshire Boulevard Los Angeles, California 90054	No	1/2
American Mutual Liab. Ins. Co. Wakefield, Massachusetts 01880	No	.025
Employers Casualty Co. P. O. Box 2759 Dallas, Texas 75221	No	.10
Employers Mutual of Wausau 2000 Westwood Drive Wausaw, Wisconsin 54401	No	1
Employers Mutual Casualty Co. P. O. Box 712 Des Moines, Iowa	No	.05
Federated Mutual Insurance Co. P. O. Box 328 Owatonna, Minnesota 55060	No	.10
Liberty Mutual Insurance Co. 175 Berkeley Street Boston, Massachusetts 02117	5	No
Kemper Insurance Co. Longrove, Illinois 60049	No	1
Maryland Casualty Co. P. O. Box 1228 Baltimore Maryland 21203	No	1
Michigan Mutual Insurance Co. 28 West Adams Avenue Detroit, Michigan 48226	No	.0625

	$20,000,000	$200,000,000
Penn National Mutual Casualty Co. P. O. Box 2361 Harrisburgh, Pennsylvania 17105	1/2	.25
Sentry Insurance Co. Mutual Co. 1421 Strongs Avenue Stevens Pt., Wisconsin 54481	No	.0875
Shelby Mutual Insurance Co. 19 Mansfield Avenue Shelby, Ohio 44575	No	.05
St. Paul Insurance Co. 385 Washington Street St. Paul Minnesota 55102	5	2-1/2
CNA Insurance 310 South Michigan Avenue Chicago, Illinois 60604	No	2
Selected Risks Insurance Co. Wantage Avenue Branchville, New Jersey 07826	No	.10
Home Insurance Co. 59 Maiden Lane New York, New York	10	5
American Home Insurance Co. 102 Maiden Lane New York, New York 10005	6	1
U.S.F.&G. Calvert & Redwood Streets P. O. Box Baltimore, Maryland 21203	10	5
Nationwide Insurance Companies 246 North High Street Columbus, Ohio 43216	5	2
Continental Insurance Companies 80 Maiden Lane New York, New York 10005	10	1
Fireman's Fund Insurance Company 3333 California Street P. O. Box 3395 San Francisco, California 94119	No	5

	$20,000,000	$200,000,000
Insurance Company of North America 1600 Arch Street Philadelphia, Pennsylvania 19101	5	No
Travelers Insurance Company One Tower Square Hartford, Connecticut 06115	No	6
Aetna Insurance Company 55 Elm Street Hartford, Connecticut 06115	No	2-1/2
Equitable General Insurance Company Ridglea Place P. O. Box 1869 Fort Worth, Texas 76116	No	5
Reliance Insurance Company 4 Penn Centre Plaza Philadelphia, Pennsylvania 19103	1	No
Hanseco Insurance Company c/o John Hancock Insurance Company John Hancock Place P. O. Box 111 Boston, Massachusetts 02117	No	5
Northbrook Insurance Company 80 All State Plaza South Northbrook, Illinois 60062	2-1/2	2
Aetna Casualty & Surety Company 151 Farmington Avenue Hartford, Connecticut 06115	10	10
Federal Insurance Company 100 William Street New York, New York 10038	10	5.025
Hartford Insurance Company Hartford Plaza Hartford, Connecticut 06115	5	5
Crum & Forster P. O. Box 2387 Morristown, New Jersey 07960	No	5

	$20,000,000	$200,000,000
Commercial Union Assurance Co. 1 Beacon Street Boston, Massachusetts 02118	5	No
Royal Insurance Company 150 William Street New York, New York 10038	No	1
Midland Insurance Company One State Plaza New York, New York 10004	No	.05
Prudential Reinsurance Company P. O. Box 908 213 Washington Street Newark, New Jersey 07101	10	5.565
Lloyds of London, English and other Alien Companies	No	17.035
Transamerica Insurance Company 1150 South Olive Street Los Angeles, California 90015	No	.5

ATTACHMENT B

Servicing Carrier	Manufacturer
Aetna Casualty & Surety Co.	Richardson-Merrell
Continental Insurance Company	Warner Lambert - Parke Davis
ESIS Inc. (affiliated with INA)	American Home Products - Wyeth
Federal Insurance Company (Chubb)	Merck, Sharp & Dohme

IN WITNESS WHEREOF, the Company and the undersigned insurance companies have caused this Agreement to be executed by their respective representatives thereunto duly authorized.

COMPANY:

Federal Insurance Company

Attest: _____ By _____

UNDERSIGNED INSURANCE COMPANIES:

Liberty Mutual Insurance Co.

Attest: _____ By _____

Penn National Mutual Casualty Co.

Attest: _____ By _____

St. Paul Insurance Co

Attest: _____ By _____

Home Insurance Company

Attest: _____ By _____

American Home Insurance Co.

Attest: _____ By _____

U.S.F.&G.

Attest: _____ By _____

Nationwide Insurance Companies

Attest: _____ By _____

Continental Insurance Companies

Attest: _____ By _____

Insurance Company of North America

Attest: _____ By _____

Reliance Insurance Company

Attest: _____ By _____

Northbrook Insurance Company

Attest: _____ By _____

Aetna Casualty & Surety Company

Attest: _____ By _____

Federal Insurance Company

Attest: _____ By _____

Hartford Insurance Company

Attest: _____ By _____

Commercial Union Assurance Co.

Attest: _____ By _____

Prudential Reinsurance Company

Attest: _____ By _____

Mr. ROGERS. Are there any other statements?

STATEMENT OF WILLIAM O. BAILEY

Mr. BAILEY. I would like to make a few comments. I am sorry Mr. Waxman and Mr. Maguire are not here because I would like to respond to some questions that they directed to others during the course of the morning. First, I would like to call your attention to the GAO observation, that substantially all of the $8.65 million of premium may prove to be profit to the insurance companies, I fondly hope that is a correct conclusion but it is somewhat premature for GAO or for any of us involved in that program to reach that conclusion.

You recall Mr. Peterson's comment was very, very clear this morning. He said on the basis of the information available to me at this time there is no evidence that the manufacturers did anything wrong which would prompt the Government to bring a claim against them. I submit we have no evidence that the manufacturers did anything wrong either and I think we all fondly hope that that proves to be the ultimate conclusion.

But the Justice Department, by their own testimony, has just begun the process of evaluating those claims that have been submitted. They expect they have seen the tip of the iceberg. They expect four to five times as many claims as they have now received. Their process is one of only trying to determine what the person claims their injuries are with no reference as he stated to what the responsibility that caused those injuries, and so time will tell whether any of that $8.65 million is committed to the defense of our manufacturers or ultimately paid on behalf of those manufacturers for negligence involving their participation in this program.

Second, I would like to remind all of the members of this committee that it was not the manufacturers and not the administration that was unwilling to relieve the manufacturers of their responsibility for negligence. You recall, Chairman Rogers, very clearly I am certain, the very strong statements here that those manufacturers should not be relieved and had not asked to be relieved of their responsibilities for their own mishandling of their part of this program. The insurance protection which the insurance industry afforded at a price of $8.65 million was in response to that retained liability, if you will, by the manufacterers for their own project negligence. I must admit that I found it very difficult to sit here this morning and have Mr. Maguire say he believes the insurance companies held Congress up for ransom. I don't believe the facts would support that in any vein.

I think the insurance industry cooperated with this committee, with Congress, with the administration, with all that were involved to the best of its ability to bring forth a program that was rational for the American public.

The consequences of that program and the claims that have been submitted hardly suggest, as we were accused a year ago be some members of your subcommittee, that we were seeing a ghost. I remind you at that time we said the ability of the American public and their attorneys to allege claims is a rapidly expanding one and we live in a society in which overall good is not sufficient to justify a program.

Those that are injured perhaps properly seek redress for that injury and the claims that have been processed to date and are still piled up in the Justice Department I think indicate that that is so.

So that I really think that the $8.65 million premium which I must admit—and so testified a year ago, I did not know what the proper premium was—this was our very best judgment as to what it would take to get companies to commit their resources to the extent of $220 million. Whether that proves to be too high or too low ultimately is the business we are in and we made our best judgment.

The decision to purchase a guaranteed cost price rather than a variable cost contract was made by others, not by ourselves, and if 2 years from now hopefully—or hopefully not—we are here saying to you we have assumed $100 million of liability for $8.65 million of premium I would not expect any member of this subcommittee or anyone else to shed a tear for us.

We stated our price. We collected it. We assumed our liability and we will stand behind that liability.

Thank you.

Mr. ROGERS. Thank you.

Now, as I recall from earlier testimony you estimated that there would be 20,000 to 40,000 if the whole population were inoculated. I think that was the testimony.

Mr. BAILEY. That was an estimate. Mr. Peterson's estimate today is very consistent with that estimate.

Mr. ROGERS. They had only an estimate of 2,500 claims.

Mr. BAILEY. To 30,000, he said.

Mr. ROGERS. That is considerably under 40,000.

Mr. BAILEY. Forty-eight million people were inoculated and we were asked to make an estimate on the basis of 200 million.

Mr. HARDER. You also have to distinguish between the frequency of claims that would have occurred in an environment where the special public law was not passed and where the plaintiff would proceed against the manufacturers and the suppliers in normal State negligence law versus what is going on today in the much more stringent procedures required under the Federal Tort Claims Act.

Our estimates related to normal environment even though you are seeing from the manufacturers they do not have many claims when vaccines are administered in normal one-on-one kinds of relationships.

Mr. JONES. Mr. Chairman, based on the 815 claims to date, our companies' claim departments, based on their experience in product liability cases, estimate that there will be from four to six times that before the program is over. Mr. Peterson testified to some of the reasons that that will be so. He is aware that there will be more. His estimate may be different.

Mr. ROGERS. He said about 2,500 to 3,000.

Mr. JONES. Ours is that it will be between 3,500 and 4,500. That is our estimate of how many he will get. Taking into consideration that we had to plan on the basis of possibly 200 million shots, and that in fact there were 48 million inoculations, we believe there might have been as many as 30,000 claims were it not for the special features of the legislation.

Mr. ROGERS. 30,000?

Mr. JONES. Yes.

Mr. ROGERS. With 200 million doses of vaccine. This is on 48 million injections.

Mr. JONES. The average of our estimate would be 4,000 claims. We estimate that Mr. Peterson is eventually going to get somewhere between 3,500 and 4,500 claims.

Mr. ROGERS. He says 2,500 and he has had only 800 to date.

Mr. JONES. Let us take his 2,500.

Mr. ROGERS. Four times that?

Mr. JONES. Four times that.

Mr. ROGERS. 10,000?

Mr. JONES. 10,000 claimants with the opportunity to take their cases to a jury; not having to go to the expense of the administrative procedure of the Federal Tort Claim Act makes a significant difference.

Since much of this is hypothetical, let us go back to 20, then, although we really think there would have been a lot more claims under the normal claims procedure. Any estimate has to be hypothetical because we are not operating under that procedure.

Mr. ROGERS. Are you investigating any of the claims presently?

Mr. BAILEY. Yes, sir, we are.

Mr. ROGERS. What areas of investigation are you conducting?

Mr. BAILEY. Limited investigation supplementary to the inquiries that Mr. Peterson described to you this morning designed to determine whose manufactured product was involved and whether there was any evidence of batch error.

Mr. ROGERS. Do you examine the largest claims? Like the billion-dollar case; I presume you will investigate that.

Mr. BAILEY. I do not know first-hand whether that particular case was looked at; the amount of that claim would suggest that it may be less than credible on its face, I would suspect.

Mr. HARDER. In our paper we describe claim procedure. We describe the procedure we are now following.

Mr. ROGERS. So you are following these claims so that if there is a liability judgment you will have those facts.

Mr. JONES. Nineteen companies have formed a committee and Mr. Bailey's company is the chairman of that committee and they retain Hogan and Hartson here in Washington as their counsel.

Mr. ROGERS. It would be helpful to us if you could give us suggestions on how future programs should be handled: Whether there is a reluctance on the part of insurance companies to insure manufacturers; whether we should set up a governmental agency to handle liability; or what. You might give it some thought and let us have something for the record on that.

Mr. JONES. We can speak only for ourselves but I think that Mr. Bailey had an opportunity to give some thought to that. Do you want us to comment now or submit it?

Mr. BAILEY. I was part of the HEW advisory committee that considered this subject. I know HEW is developing proposals. A great deal of importance must be laid on the underlying assumption of responsibility. The reason why this got badly confused, got very difficult for any of the parties to sort out what their options were, was that it was unclear for a long period of time who as-

sumed the responsibility for what part of the program in the first instance and, in the second instance, how each of those parties were going to carry out that responsibility.

And uncertainty produces risk in our business. Excessive risk produces conservatism of pricing, particularly in an untested field, and certainly some of the recommendations of the GAO, some of those that were supported by HEW of getting a program organized and thought through and definitively laid out—"Who is responsible for what?"—will go a long way to alleviating the insurance problems.

Now, the Federal Government has historically—and appropriately, I believe—not been insured by the private sector. They self-insure their risk and the Justice Department administers claims against the Federal Government.

So, to the extent of Federal Government involvement in any substantive way, I think one clearly ought to, by past practice—and, I think, legitimately—carve that portion out of "an insurance concern." Suits against the Government have an established procedure, and that is all we really are talking about in this instance.

The assumption, by the Federal Government of the responsibility of others brought on by this particular program was the unique feature. The dispersion of that liability to the providers—for example, the doctors and the nurses who administered that program—in any kind of a rational government immunization program that does not produce the controversy and the panic, if you will, and emotion that this one did—I think can be handled in the normal insurance fashion. Speaking only for myself, I believe that is also true with respect to the manufacturers' responsibility.

The lesson, I think, we all must learn from this is that somebody has to decide who is responsible for what, determine whether they are going to free others from that otherwise assumed responsibility and let an insurance program develop in the normal fashion.

The manufacturers who were just here said to you they all have liability insurance protection against the whole gamut of products that they manufacture and distribute to the public, and I believe they will continue to.

Mr. ROGERS. They said they were having trouble getting it though. Why is that?

Mr. BAILEY. One describes "trouble getting" in the context of how much they have to pay for it, and the cost of insurance in this area has risen quite rapidly in the last 2 or 3 years. They seem now to be somewhat stabilizing, and I suspect those problems will diminish as the costs stabilize.

Mr. JONES. More than half the pharmaceutical firms that used to manufacture vaccines have withdrawn from the market. There have been problems with pharmaceutical products, not particularly with vaccines, though, but the profitability of vaccines is low, and they have chosen to quit manufacturing them. We have had companies that have withdrawn from the pharmaceutical insurance market because of adverse experience

Each manufacturer is represented by a broker who does the work of going around and getting the coverage they need and getting different insurance companies to take a share of it. I would estimate that in every instance, to cover their higher levels of

liability, they are into the world market. They have had to go outside of the United States to fill out their coverages because the domestic market has shrunk,

Mr. ROGERS. I don't think the suits or claims against the immunization programs other than swine flu are more significant than claims against the other pharmaceutical products. Would they be?

Mr. BAILEY. The record would say they have not been. The record will also now say this particular program, even with the restraints put on the bringing of claims through the requirement of going through the Federal Tort Claims Act, has produced far more claims than the cumulative experience of the drug manufacturers with respect to immunizations over the last 20 years. I hate to say I told you so but we did a year ago.

Mr. ROGERS. You feel there will be less claims filed under the Federal Tort Act than would otherwise be filed?

Mr. HARDER. We are certain of that.

Mr. ROGERS. Why is that?

Mr. BAILEY. I can click off four quick reasons. One, the process is far more difficult to sue or to bring claim against the Federal Government than it is against a private individual, be it a person or a corporation and certainly a high-visibility drug manufacturer.

Second: Because of its complexity, there are a great many lawyers in the United States who do not understand it and who would not undertake to develop the procedures. I suspect that is why you have 3,800 inquiries and only 815 claims. A good many of those will produce claims over time but some of them will go away merely by the process.

Third: You must go through that administrative procedure before you can sue; whereas if they were going directly against a private-sector institution, the claim in this kind of area typically involves a lawsuit. You never get the process of claim and administrative procedure prior to a lawsuit. Your first notice is the filing of the suit and, finally, to whatever extent this may influence the bringing of claims, the reward for the lawyer for successfully bringing a claim against the Government under the Federal Tort Claims Act is more limited than it is with respect to a normal lawsuit. And that has some deterrent effect as well.

Mr. JONES. Mr. Chariman, a Federal Tort Claims Act case is tried before a judge; whereas if you went into the State courts or even into Federal courts, under normal procedure you would have an opportunity to put your case before the jury; and it seems to us juries will believe anything about chemicals.

Mr. ROGERS. What ideas would you have that you might give us for the record regarding the consent or notification of benefit versus risk?

Mr. BAILEY. I would like to make one very brief comment. I agree with Dr. Millar that the objectives of the informed consent—and I noted it down—is primarily for the purpose of informing people of risk and benefits. It is not to build a defense.

I think the point is a valid one. I think it does make sense that people should have the best explanation available of the benefits and risks. I would question, certainly with respect to a suit against a private party, whether the doctrine of informed consent is any restraint with respect to claims for damages. I am not sure.

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Mr. ROGERS. Could you simplify some method of advising people of risk in a national immunization program? I don't know whether you have to have big signs up as they enter the door, but there has to be a simpler way than trying to make sure everybody reads every word on the sheet.

Mr. BAILEY. And that they understand it. The concept of informed consent as a defense against resulting injury has long since passed in the United States, and all Dr. Millar was pointing out is that that does not destroy its validity. Its value is to give people an ability, within their capability and the capability of the state of the art, to describe what those risks and benefits are, to give them, as best one can, an evaluation of what they are getting into.

Mr. ROGERS. How do you do it with an insurance policy? How do you understand all that fine print?

Mr. HARDER. We don't understand it, either.

Mr. ROGERS. You might give us some ideas because this is a problem that has to be looked at.

[The information requested was not available to the subcommittee at the time of printing.]

Mr. JONES. I would like to add a couple of other points as to why we would have more suits if we were in the State courts. First: Under the Federal Tort Claims Act; the contingent fee is regulated, and most personal injury suits are brought on a contingency fee basis. The lawyer would have to invest more time in a contingent fee case under the Federal Tort Claims Act procedure than he would if he were proceeding in the State. Second: The Federal Tort Claims Act, we think very appropriately, eliminates punitive damages, which is, in some cases, a way in which a lawyer recovers a significant fee.

Mr. ROGERS. Thank you very much for your presence here today and, I might add, I ask you to respond to any written questions that might be submitted by the members for the record.

Mr. JONES. We will be happy to and we thank you, Mr. Chairman.

Mr. ROGERS. This concludes the hearing.

[The following statement was received for the record:]

Public Citizen

STATEMENT OF ANITA JOHNSON AND SIDNEY WOLFE, M.D.,
PUBLIC CITIZEN'S HEALTH RESEARCH GROUP, SUBMITTED
TO THE HOUSE OF REPRESENTATIVES HEALTH SUBCOMMITTEE,
SEPTEMBER 16, 1977

Thoughts on the Swine Flu Program

On June 28, 1976, our group testified in opposition to the swine flu program, that, based on vaccine testing and other data, "the major disease in the U.S. this year related to Fort Dix will not be swine flu, but, rather, swine flu vaccine disease."[1] According to the U.S. General Accounting Office, at least 3,888 adverse reactions to the vaccine have been reported,[2] including an estimated 150 to 250 cases of Guillain-Barre syndrome, a serious paralytic disease.

The thousands of formal claims for injury filed against the federal government, together with the unexpectedly low number of people who turned out for vaccination, indicate widespread public belief that the swine flu program lacked merit. While we are at a loss to explain how the swine flu program ever hurdled the usual barriers to foolhardiness, we have the following suggestions for future government involvement in other immunization programs.

(1). Immunization Proposals Should Undergo Early Critical Scrutiny

The swine flu program was promoted by HEW in an atmosphere of fear created by reference to the 1918 flu epidemic, an epidemic which spread like wildfire and killed half a million people. The Fort Dix virus was described as "similar, quite similar,to the agent that probably caused the 1918-19 epidemic."[3] This atmosphere was enhanced by some members of the subcommittee. For example, Rep. Carter said: ". . .swine-type influenza virus killed 540,000 Americans during World War I. The same threat comes before us today. . ."

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[1]Hearings before the House Committee on Interstate and Foreign Commerce, 94th Congress, 2nd session, Swine Flu Immunization Program, p. 137.

[2]"The Swine Flu Program: an Unprecendented Venture in Preventive Medicine," June 27, 1977, p. 85.

[3]Hearings before the House Committee on Interstate and Foreign Commerce, 94th Congress, 2nd session, Proposed National Swine Vaccination Program, p. 4.

The outbreak at Fort Dix was described as 500 cases, one fatal. There was one fatality at Fort Dix, but the fact that he was on a prolonged march at the time indicates that something other than the virulence of the virus was responsible for the death. Only 11 cases of illness from swine flu were detected, and were, with the one exception, mild. The other "cases" referred to by HEW officials, were soldiers who displayed some evidence in the blood of exposure to swine flu, not soldiers who came down with the disease. After the Fort Dix outbreak, no outbreaks of swine flu occurred. A study by Beare and Craig, where volunteers were innoculated with swine flu virus, indicated that the virus produced mild symptoms and was "not specially predisposed to spread among people,"[1] as did another study at Mt. Sinai hospital[2]. The fact that a virus "similar" to the 1918 flu, caused a handful of flu cases, mostly mild, was not a solid basis for promoting nationwide exposure to a new swine flu vaccine.

As with all exposures to drugs, vaccinations should not occur unless there is a strong reason for doing so, since they may cause side effects for no overriding benefit. This is particularly true of mass, nationwide immunizations, where the benefits are not weighed with the known risks or chance of unknown risks for each patient. For mass programs, the standard for proof of benefit should be considerably higher than other drug exposures.

While critical scrutiny of the program was performed by several subcommittee members--most notably Reps. Maguire and Waxman--most comment was overwhelmingly uncritical. HEW employees and advisory committees provided almost unanimous support for every aspect of the program. Even as late as January 1977, when Guillain Barre had appeared and no swine flu had appeared, HEW advisers were in favor of continuing the mass innoculations.

Of all the parties in the swine flu program, the insurance companies were the most critical; they refused altogether to provide insurance to vaccine manufacturers unless the government assumed all their normal liabilities. According to American Insurance Association testimony, ". . .the risks involved in the swine flu program [are] virtually unmeasurable,"[3]

> . . .what the underwriters tell us makes it unmeasurable for them in terms of risk assessment. They have never had to contemplate the risk involved in an immunization program that would involve

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[1] Lancet, July 3, 1976, 4.

[2] Schulman and Palese, Nature, Oct. 1976, as reported in Medical World News (March 7, 1977) p. 34.

[3] The Swine Flu Program, op.cit., p. 86.

> 200 million people in the space of a very few months, involving a vaccine that didn't exist a few weeks ago, being administered by doctors, public health agencies, who have never had to operate on a crash basis, the emergency basis about which one of the doctors here spoke earlier. They think about that and they say, "Too much could go wrong in our view to make that an insurable risk at any price."[1]

Doubtless, their reluctance to sell insurance at any price also reflected fear that without a swine flu actually on the way, the courts could easily determine that even non-serious side effects of the vaccine were not overriden by benefits.

As stated in our testimony, no flu epidemic has occurred without prior spotty outbreaks. Despite an unprecedented degree of surveillance, there has not been a swine flu outbreak anywhere in the world since Fort Dix. With little likelihood that flu was on the way, and a strong possibility that adverse reactions could occur in a mass immunization scheme, small wonder that the insurance companies didn't want the business. (Rather than heed the red flags raised by the insurance companies, the Congress proceeded to adopt the swine flu program en toto and assume the normal legal liabilities of the manufacturers, thereby allowing the insurance companies to profit from selling insurance for essentially non-risks.)

In the future, procedures should be mandated for critical scrutiny of such programs in the early stages, before momentum has been created. The swine flu program was initiated and planned in the Center for Disease Control. Only after CDC was thoroughly committed to the program did outsiders have contact with it. At that time, CDC was promoting the program, not considering it. Lay people, such as consumer representatives and trial lawyers, and state and local officials should be involved at the very beginning.

Congressmen and their staffs should be more willing to examine and criticize administration programs. The swine flu program was difficult to criticize because it was billed as a relatively low cost, disease-prevention program, promoted by the government rather than the manufacturers; all factors that would tend to lull members of the health committees. Nevertheless, extraordinary measures were taken, especially by Congressman Rogers, to get the program passed over growing (though still minority) criticism.

(2). Informed consent procedures should be developed and enforced by a group that is not a proponent of the program.

The National Commission for the Protection of Human Subjects pointed out that the informed consent form overestimated the safety

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[1] The Swine Flu Program, op.cit., p. 93.

of the vaccine as known and that it was designated "Registration Form," thereby obscuring the importance of careful consideration before signing.

The GAO pointed out,

> "The informed consent form used for the swine flu program between October 1 and December 16, 1976, contained (1) no specific warning of possible neurologic disorders, (2) a controversial statement concerning potential vaccine effects on pregnant women, and (3) no specific warning of the probability of getting the flu despite receiving the recommended vaccine. Information available before the swine flu immunizations began (1) identified neurologic disorders as a possible severe reaction associated by time with flu immunization in general, (2) questioned the accuracy and clarity of the statement concerning potential vaccine effects on pregnant women, and (3) estimated the risk of contracting the flu despite vaccination. As a result, the Federal Government's position with regard to claims resulting from any of these reactions may be weakened."[1]

The consent form was also misleading because it failed to convey the extreme improbability of a swine flu epidemic.

Obviously, a forthright informed consent form is important for fairness to patients, but also for legal protection of the government and the manufacturers. The form was developed by the CDC, which was the chief proponent of the swine flu program. In the future, informed consent procedures should be developed by disinterested persons, not enthusiasts who want everyone to consent.

(3). Sunset provisions should be built in to every immunization program.

While there was arguable merit in beginning to manufacture swine flu vaccine in February after the Fort Dix outbreak, the probability of an epidemic became smaller and smaller as the months rolled on. By mid-summer, plans for actual vaccination should have been suspended because there had been no further outbreaks in either the northern or the southern hemisphere (the latter was in winter - flu season). This was increasingly true as the U.S. entered flu season without event. A temporary moratorium on innoculations was called in December after paralytic disease was reported, but as late as January 1977, immunization advisers were recommending to HEW Secretary Califano that mass swine flu innoculation procede.

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[1]GAO, pp. 22-23.

This program should have been automatically ended after several months time, with the burden of proof of necessity on proponents.

(4). It is questionable whether the government should undertake any mass flu immunization.

Unlike other objects of immunization, the structure of flu viruses can change quickly over a short period of time, leaving vaccination ineffective for the prevailing bug. Flu protection is rendered for a relatively short period of time compared to other vaccines, so they cannot be counted on to offer protection for more than one season. (If swine flu does re-appear next winter, everyone will have to be re-vaccinated!). Flu vaccines protect considerably fewer of the people innoculated than other vaccines. If the vaccine protects 30-80% of those exposed, it is foolish to believe, as CDC apparently did, that a flu epidemic could be stopped. Flu vaccines are much less satisfactory in children--the usual vectors of epidemics--whereas children are the group most satisfactorily immunized for other diseases. (Because of bad clinical trial results, children were not included in the swine flu program.) Last, while flu does kill some individuals and is an odious and expensive disease to all, it is not the killer or maimer that polio and smallpox can be. Protection should be concentrated on those most threatened, not on the whole population.[1]

(5). Manufacturers should continue to be liable for their vaccines under both negligence theory and strict liability theory.

The insurance companies and manufacturers have gone to great lengths to convince the Congress that their normal legal liabilities are unfair. A frequent claim made by these parties is that under current tort law the manufacturer has absolute liability for any damage caused by the vaccine.[2] This claim is untrue.

Strict liability lawsuits cannot be won simply be demonstrating that the product caused an injury. The plaintiff must prove that the product was "defective," usually defined as "unreasonably dangerous," judged by the standards at the time of sale.[3] This

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[1]The American Insurance Association testified that the most important factor in the decision not to insure the swine flu program was its "sheer scale," p. 85. Immunization programs targeted at only high risk groups have always been insured through ordinary commercial arrangements.

[2]See for example, testimony of American Insurance Assoc., pp. 90, 92.

[3]The Legal Study commissioned by the Interagency Task Force on Products Liability, U.S. Dept. of Commerce, made this point. "Despite the adoption of 'strict products liability' by most American jurisdictions, the 'fault' concept is, and should continue to be the basis of liability. . .strict liability is not the equivalent of absolute liability." Vol. I, pp. 1, 37.

might be done by showing that the product contained a manufacturing defect which would not have happened in a careful manufacturing process. Strict liability eliminates the need for introducing direct proof of fault in cases based on manufacturing defects, where it is extremely difficult for anyone to obtain evidence which pinpoints the exact conduct of the manufacturer. Plaintiff's proof is shifted from proving that the conduct of the manufacturer was substandard to proving that the product was substandard.

Absolute liability, in our view, would not be desirable, since it would remove the incentive of the manufacturers to design and manufacture carefully. If manufacturers had to pay for injuries which were not within their control to prevent, they would tend to regard lawsuits as unpredictable lightning bolts and abandon all injury-prevention measures. Absolute liability is not a part of current law.

While it is possible that the insurance companies and manufacturers do not understand current product liability law, it is more likely that they are seizing the opportunity, as good "business managers"[1] to limit their legal risks, thereby making manufacturing easier and selling more profitable at the expense of solid, pro-consumer legal doctrines.

The incentive for careful design and production of vaccines must be preserved, and the best, simplest way to do this is to retain the fear on the part of the manufacturers that they may carry the cost of defects if they occur. Vaccine manufacturers sometimes argue that in the swine flu program, they were just carrying out government orders. It is true that the manufacturers did not promote the swine flu program as they have other immunization programs in the past.[2] Nevertheless, to remove their liabilities for good design and manufacture is to beg for a lower quality product, to beg for a manufacturing community that becomes a passive puppet of the federal government with no mind of its own. If the government initiates immunization of dubious benefits and heavy risk, we want worried manufacturers to ponder and object, not just deliver, knowing that no matter what they deliver, their liabilities are nil.

Manufacturers have expressed concern over the obligation propounded in the Reyes case to warn consumers directly (as opposed to doctors only) of the benefits and risks in clinic immunization programs where health professionals do not make benefit/risk assessments for individual patients. We would not object to government assuming this one duty to inform consumers directly by contract or by statute in cases where immunizations are promoted and planned by the government alone. However, we think that the Reyes obligation is a sound one in other cases,

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[1]Hearings, p. 260

[2]See Davis v. Wyeth Laboratories, 399 $F_2$121 (9 cir. 1968).

like the Davis and Griffin situations,[1] where the companies promoted the vaccines, provided materials and were in as good a position as government officials to be sure that consumers were not inoculated like sheep.

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[1] Griffin v. U.S. 500 F_2 1059 (3rd cir., 1974). Pfizer settled this case in part because of a showing that they had promoted the Sabin oral polio vaccination program which led to the plaintiff's injury.

[Whereupon, at 5 p.m. the subcommittee adjourned.]

APPENDIX

REPORT TO THE CONGRESS

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

The Swine Flu Program: An Unprecedented Venture In Preventive Medicine

Department of Health, Education, and Welfare

The swine flu program was, in the Department of Health, Education, and Welfare's view, a decision to practice preventive medicine, which has an inherent element of risk. In a sense, HEW lost its gamble. No swine flu outbreak occurred during the 1976-77 flu season. Nevertheless, much can be learned from the swine flu program that should be useful when planning future immunization programs and related public health efforts.

HRD-77-115

JUNE 27, 1977

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

B-164031(5)

To the President of the Senate and the
Speaker of the House of Representatives

This report describes issues developed during our review of the National Influenza Immunization (Swine Flu) Program. It discusses considerations for future programs with respect to program justification and cost, Federal liability implications, vaccine production and testing, and program planning and implementation.

Although we expanded the scope of the review at the specific request of several House committees, we are issuing the report to the Congress because of the widespread interest in the program. As requested by the committees, we are issuing it now without written comments from the Department of Health, Education, and Welfare because of the need for timely consideration of the issues.

We made our review pursuant to the Budget and Accounting Act, 1921 (31 U.S.C. 53), and the Accounting and Auditing Act of 1950 (31 U.S.C. 67).

We are sending copies of this report to the Director, Office of Management and Budget, and the Secretary of Health, Education, and Welfare.

Elmer B. Staats
Comptroller General
of the United States

COMPTROLLER GENERAL'S
REPORT TO THE CONGRESS

THE SWINE FLU PROGRAM: AN UNPRECEDENTED VENTURE IN PREVENTIVE MEDICINE
Department of Health, Education, and Welfare

D I G E S T

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

The decision to proceed with the program was based primarily on scientific evidence that an epidemic could scourge the Nation and that the health care system could carryout the mass immunizations. However, no known outbreaks of swine flu occurred during the 1976-77 season. (See pp. 11-15.)

SOME QUESTIONS ABOUT FLU NEED TO BE ANSWERED

For any future immunization effort as large or concentrated as the swine flu program, the many preventive health care questions that arose would likely have to be broadly considered again by all parties involved. The solutions devised for the swine flu program were not intended as a pattern for future efforts. (See pp. 15 and 16.)

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

LIABILITY CONTINUES TO BE A PROBLEM

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

--may result in profit to the insurance companies of nearly the entire $8.65 million premium paid by vaccine manufacturers for liability insurance (see pp. 19-21);

--leaves unresolved insurance company concerns about nonmeritorious claim risks (see pp. 21 and 22); and

--may result in indeterminable costs to the Government for litigation, awards, and settlements because of potential weaknesses in the form and procedures used to obtain "informed consent" from persons immunized (see pp. 22-29).

Insurance executives stated that the Government should be responsible for both the liability and the costs of litigation, since the Government will control all key aspects of any public immunization program. HEW's Assistant Secretary for Health stated that a national policy concerning compensation will have to be developed for any future mass immunization program. So that resolution of the liability issue does not delay or adversely affect public acceptance of future programs, GAO recommends that the Congress establish a national liability policy before another mass immunization program is needed. (See p. 29.)

GAO describes two ways the Government can assume liability at less cost than for the swine flu program. First, if experience gained from the swine flu program shows that considerable money can be saved and if HEW intends to continue rigorously testing and approving every vaccine lot, then total Federal assumption of the liability coverage for vaccine production should be considered. Second, the insurance industry could make manufacturers' premiums adjustable retrospectively based on claims experience. (See pp. 29 and 30.)

To evaluate the effect of Federal responsibility and liability for informed consent will take years. HEW should monitor this process as it occurs, for possible future program applications. (See p. 30.)

VACCINE TESTING MORE EXTENSIVE THAN IN 1975

All vaccine released for use in the swine flu program that GAO reviewed ultimately met Food and Drug Administration potency and safety standards. Almost 30 percent of the vaccine was considered subpotent, and the agency did not permit its release to the public until the minimum potency requirement was met. (See pp. 31-34.)

Tests showed that some of the trial vaccine did not meet specified potency levels, and trial participants were not given the same protection as the general public. The potency test does not accurately indicate the protection provided by the vaccine. (See pp. 33-36.)

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

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

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

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

POTENTIAL PROTECTION PROVIDED BY SWINE FLU VACCINE

HEW officials estimated, based on past experience and trials, that the swine flu vaccine would adequately protect 70 to 90 percent of those vaccinated. However, protection is difficult to estimate based solely on previous experience. (See pp. 38-41.)

Further, estimating protection based on trial results was complicated by problems in getting adequate antibody responses in younger people and by the inactivity of one vaccine component. (See pp. 41-45.)

The duration of protection provided by the vaccine is uncertain. (See pp. 46 and 47.)

NOT ENOUGH VACCINE PRODUCED OR PRODUCED IN TIME

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

Vaccine available then could immunize only about 12 percent of the population. Although three of the four manufacturers said they continued to produce at full capacity during the delay and the fourth had met its original estimate, vaccine production fell short of the original estimates by about 43 million doses and required over 2 months longer to produce. (See pp. 49-54.)

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

STATE READINESS AND IMPLEMENTATION

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

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

--less than full commitment by some project directors (see pp. 57 and 58);

--complex, incomplete, and late vaccine recommendations (see pp. 58-60);

--limited quantities and delayed delivery of vaccine (see pp. 60-65);

--less-than-expected participation by private doctors, volunteers, and others (see pp. 65-68);

--weaknesses in project operations (see pp. 68-73); and

--lack of State liability insurance (see pp. 73-75).

Project readiness and implementation were limited by biological and liability problems beyond the projects' control. Consequently, GAO could not determine whether State or local projects could be ready for future mass immunization programs. (See p. 75.)

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

GAO recommends that the Congress consider the effect which inadequate liability protection might have on State participation in future immunization programs. The Government could (1) assume total liability for the program, (2) assume no liability for program participants, or (3) assume limited liability

similar to that provided under the swine flu program. (See pp. 76-77.)

PROGRAM COSTS

Total costs for the swine flu program cannot yet be accurately determined. In some instances, accounting data is too limited to identify precise costs; and, in others, not all costs have been incurred or determined. The total costs may far exceed the $135 million appropriated. (See pp. 78-85.)

AGENCY COMMENTS

Because of the need for timely consideration of the issues, GAO was asked not to obtain written comments. However, HEW, Department of Justice, and State officials were apprised of the matters discussed in this report. Their comments have been considered.

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ABBREVIATIONS

CCA	chicken cell agglutination
CDC	Center for Disease Control
FDA	Food and Drug Administration
GAO	General Accounting Office
HEW	Department of Health, Education, and Welfare

CHAPTER 1

INTRODUCTION

In early February 1976 a New Jersey public health laboratory sent four unusual isolates of influenza (flu) virus obtained from Fort Dix military recruits to the World Health Organization Collaborating Center for Influenza at the Center for Disease Control (CDC) in Atlanta, Georgia. By February 12, 1976, tests had shown that the isolates were a new flu strain closely related to swine flu viruses.

Isolating a new flu strain at the end of one flu season presented a unique opportunity to test the ability of the Nation's health system to organize itself in time to prevent a flu outbreak or an epidemic during the next flu season. By April 12, 1976, the House of Representatives and the Senate had passed a joint resolution (Public Law 94-266) providing over $135 million for a comprehensive, nationwide flu immunization program. The President approved the resolution on April 15, 1976.

Although popularly referred to as the swine flu program, the national flu immunization program was directed at both the swine flu and another flu strain known as Victoria flu. Victoria flu occurred in the United States during January 1976 and reached epidemic proportions during February. It was expected to be a prevalent strain during the coming flu season. Following normal practices, Victoria flu vaccine had already been produced in adequate quantities to immunize all individuals for whom flu was considered a high health risk.

Emphasis was placed on swine flu because it represented a new strain, to which the bulk of the population had no immunity. High-risk individuals would be greatly threatened by either Victoria or swine flu. Therefore, existing Victoria flu vaccine was combined with subsequently produced swine flu vaccine to form a "bivalent" vaccine for these individuals. For the general population, only a "monovalent" swine flu vaccine was provided.

THE OBJECTIVE AND GOALS OF THE SWINE FLU PROGRAM

The objective of the program was to establish an integrated, comprehensive immunization system capable of making swine flu vaccine (or bivalent vaccine, as appropriate) available to every person for whom it was not

contraindicated. Goals called for using both the public and the private health care delivery systems to immunize the entire population by the end of November 1976. This deadline was considered critical because, if an outbreak occurred, the disease could spread so rapidly that further immunization would have little controlling effect.

The season of intense flu transmission in the United States is generally considered to be September through March. The national strategy, therefore, called for vaccinating high-risk groups during July and August and the general population during September through November 1976.

The swine flu program represented a departure from the normal flu prevention and control policy in the United States. In previous years immunization of those groups particularly susceptible to the effects of flu infection was emphasized. During the pandemics of 1957 and 1968, limited mass immunization was attempted. (See pp. 39 and 40.)

Widespread vaccination of the general population had generally not been an objective because:

--Normally, foreknowledge of a coming flu virus is insufficient to permit development of an entirely appropriate vaccine.

--The attack rate of flu nationally between pandemics is usually low.

--Healthy individuals normally have a low frequency of serious complications from flu.

CHARACTERISTICS OF THE FLU VIRUS

Every flu virus has two surface antigens (proteins)--hemagglutinin and neuraminidase--that allow the virus to penetrate body cells and to spread throughout the respiratory tract. Hemagglutinin allows the virus to attach itself to a cell where it can penetrate and reproduce. Neuraminidase is believed to facilitate virus spread by helping release it from an infected cell so it can attach itself to other cells.

One unique characteristic of the flu virus is that hemagglutinin and neuraminidase change. Minor changes occur frequently and are referred to as antigenic drifts. At longer intervals, major changes, referred to as antigenic shifts, occur in hemagglutinin and neuraminidase.

Flu pandemics have been associated with major antigenic shifts. Pandemics are major epidemics due to a single virus strain which sweep around the world in a short time and cause marked increases in morbidity and mortality. Populations with no previous exposure to newly appearing antigens have no immunity against these new strains.

The rapidity with which flu may spread is unique among infectious diseases. In the well-studied Asian and Hong Kong flu pandemics of 1957 and 1968, the time from the initial isolation of a new flu strain to the spread of the disease to all major areas of the world was less than 6 months.

The reasons for the rapid spread of flu are only partly understood. The short incubation period (24 to 48 hours), the large populations susceptible to infection, and the ease with which the disease is transmitted (fluids in the nose and mouth are expelled into the air when a person sneezes, coughs, or talks) play important roles. Because epidemics and pandemics occur most often in the winter, meterological conditions may also be important. Widespread simultaneous outbreaks often occur after a period of sporadic cases. This indicates that the virus is seeded throughout susceptible populations even by mildly ill individuals.

EFFECT OF FLU PANDEMICS

The effect of flu pandemics has been measured since the early 1800s by the number of deaths occurring in excess of the number of deaths expected. Excess deaths due to flu and resultant complications, such as pneumonia, are especially evident. Mortality is usually highest in the aged and in persons with chronic illnesses, such as pulmonary and cardiovascular diseases.

The worst flu pandemic on record occurred in 1918 and caused an estimated 20 million deaths worldwide and approximately half a million deaths in the United States. A unique feature of this pandemic was the unusually high mortality in persons 20 to 40 years old. The 1918 virus was similar in structure to the swine-flu-like virus isolated at Fort Dix in February 1976. Excess mortality in the United States during the Asian flu pandemic of 1957-58 was estimated at 69,800 deaths. During the Hong Kong flu pandemic of 1968-69, an estimated 27,500 excess deaths occurred.

According to CDC, the total costs of flu pandemics cannot be accurately determined. But for the 1968-69 pandemic, the cost of physicians' visits, hospitalizations, prescriptions, and losses of earnings in the United States was estimated at $3.9 billion.

FLU VIRUS VACCINES

If a human population has hemagglutinin and neuraminidase antibodies of a flu virus strain, the antigens of that strain can be neutralized and infection prevented or modified. Current flu vaccines, which contain antigens of killed viruses, stimulate the production of protective antibodies in a person without causing infection. Also, recently improved purification processes have allowed for increasing the vaccine antigenic content or potency without accompanying increases in serious adverse reactions.

Because of the ability of flu virus surface antigens to change, the appropriate antigenic composition of a vaccine is of major importance. Continuous surveillance of current flu viruses for evidence of antigenic change and the incorporation of the new antigens into the vaccine are essential.

In past epidemics, the time between a new virus isolation and peak disease incidence did not allow for appropriate vaccine preparation and mass distribution. The swine flu virus was detected at the end of a flu season. Consequently, the necessary leadtime was available to prepare and distribute a new vaccine before the next flu season.

Vaccine production

In the United States six manufacturers are licensed to produce flu vaccine, and four are producing vaccine. Each manufacturer produces killed virus vaccine that has an expiration date permitting use within 18 months. The date may be extended, however, based on certain laboratory tests. The 18-month period is used because of antigenic drifts in flu viruses. Past vaccine production volume has usually been about 20 million doses annually.

Two manufacturers produce a "whole" virus vaccine from the entire killed virus, while the other two produce a "split" virus vaccine by chemically disintegrating the virus. In the swine flu program, both whole and split virus vaccines were produced in bivalent and monovalent formulations.

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RESPONSIBILITIES OF PROGRAM PARTICIPANTS

For the swine flu program, the Department of Health, Education, and Welfare (HEW) planned to purchase 200 million doses of vaccine, which were to be made available at no cost to State and local health agencies. The agencies were to distribute the vaccine through public health, volunteer, and private sector channels, so that every person for whom the vaccine was not contraindicated could be immunized. Responsibilities for the HEW agencies involved and State and local health agencies follow.

The Center for Disease Control

CDC was the focal point for the mass immunization program. CDC was primarily responsible for:

--Purchasing and distributing about 200 million doses of vaccine.

--Instituting intensive epidemiologic and laboratory surveillance of the population to

1. Measure the extent and severity of flu on a national basis.

2. Evaluate the effectiveness of the vaccine and the vaccine delivery systems.

3. Investigate and control outbreaks.

--Providing financial and technical assistance and guidance to State and local health agencies in organizing and carrying out intensive mass immunization programs; capitalizing on organized settings, such as schools, governmental offices, and large private employers; as well as sponsoring special clinics and community programs.

--Organizing national interest groups and organizations to carry out public awareness campaigns at the national level and, through their local chapters or affiliates, to support State and local immunization programs.

--Serving as the focal point for diagnostic activities in support of State and local public health laboratory facilities.

The Food and Drug Administration

The Bureau of Biologics in the Food and Drug Administration (FDA) was responsible for testing vaccine before its release. These tests included laboratory analysis and clinical trials to ascertain the appropriate dose of vaccine and to document vaccine potency, safety, purity, and effectiveness.

The National Institute of Allergy and Infectious Diseases

The Institute was to greatly expand the scope and extent of existing intramural and extramural activities to carry out research, beginning in the summer of 1976 and continuing until another antigenic shift in the flu virus occurs. The following were to be included in such research:

--Intensive study of flu viruses circulating in the swine population and of changes in these viruses as related to increased transmissibility to man.

--The determinants of swine-to-man transmission and of later dissemination in man.

--Studies of the production of antibodies and of adverse reactions to the vaccines that were to be produced, to provide the data needed for determining dosage and usage.

--Determination of the efficacy of amantadine, the only drug licensed in the United States for treating viral respiratory disease, in preventing the spread of swine-flu-type viruses.

--Determination of the protection provided by swine flu vaccine in population groups, if outbreaks occur.

--Studies to test the technology for producing and using live flu vaccine during pandemics and to obtain data for comparing the efficacy of live virus vaccines and of killed virus vaccines made of whole viruses, split viruses, or surface antigens of the virus.

State and local health agencies

These agencies were relied upon to organize and coordinate immunization activities. HEW provided 63 project grants to 50 States and 13 cities and territories to help

pay additional expenses of mass immunization. The funds supported limited temporary employment and permitted the purchase of supplies (other than vaccine) and equipment.

The projects were to try to obtain commitments from major health care providers or potential providers, such as industries, schools, hospitals, nursing homes, and governmental agencies to immunize their employees, students, and patients. In addition, special clinics and community programs were to be provided to reach persons not vaccinated in other organized settings.

Special programs were to be directed toward providing the elderly with bivalent vaccine. Public awareness campaigns were to be carried out to maximize public acceptance of the need for flu vaccination. Heavy reliance was to be placed on voluntary assistance.

CHAPTER 2

PROGRAM JUSTIFICATION: PREVENTIVE MEDICINE

The decision to vaccinate the entire U.S. population against swine flu was, in HEW's view, a decision to practice preventive medicine, which has an inherent element of gamble. Faced with the possibility of an epidemic that could cost many lives and billions of dollars--and offered a chance to prevent it--HEW planned, and the Congress approved, a $135 million mass immunization program.

This decision was the result of scientific judgments about the possibility of a swine flu epidemic and assumptions about the capabilities of vaccine manufacturers and the Nation's health delivery system to counter it. Even though the decision was a gamble, the officials said that gambling with money would be better than doing nothing and gambling with lives.

In a sense, HEW lost its gamble with money. No swine flu outbreaks or epidemics had occurred by March 31, 1977--the end of the normal flu season. In addition, some persons suffered serious adverse reactions to immunization, although they represent a very small percent of the total immunized. On the other hand, much has been or can be learned from the program that should foster more informed decisionmaking by the Federal Government and by other participants in future immunization programs and related public health efforts.

EVENTS LEADING TO MASS IMMUNIZATION

In early February 1976, a New Jersey public health laboratory sent four unusual isolates of flu virus obtained from Fort Dix, New Jersey, to CDC. By February 12, 1976, CDC had shown that the virus was of a flu strain closely related to swine flu viruses. A special meeting of representatives from the Army, the State of New Jersey, and several health agencies of HEW was held at CDC on February 14. At this meeting plans were discussed to confirm the authenticity of the isolates and to evaluate the extent of the outbreak at Fort Dix.

By February 19, CDC had confirmed the outbreak and had distributed reports of the Fort Dix findings to all State epidemiologists; laboratory directors; and the World Health Organization in Geneva, Switzerland. Isolates from the outbreak were sent also to London's World Health Organization

Collaborating Centre for Influenza and National Institute for Biological Standards and Control. On February 20, isolates from Fort Dix were provided to all vaccine manufacturers and investigators for further study and for development of material suitable for vaccine production.

On March 10, 1976, HEW's Advisory Committee on Immunization Practices--a panel of Government and private experts in immunology which normally makes recommendations for using flu vaccines--met at CDC with representatives of HEW, the Army, and others. The Army advised the Committee of the following results of its studies at Fort Dix:

--Five swine-flu-like viruses had been isolated, including one from a recruit who died.

--Eight persons (later revised to six) hospitalized with flu had shown an increase in swine flu antibody levels through blood tests, a strong indication of swine flu.

--Several hundred recruits had been identified through blood tests as having swine flu antibodies.

--The outbreak had been observed during the first week in January, and the last case had appeared during early February.

Also CDC advised the Committee that other investigations around the country had revealed no significant evidence of swine-flu-like virus activity outside Fort Dix.

On the basis of this information, the Committee concluded that:

--Human-to-human transmission of swine-flu-like virus had occurred at Fort Dix.

--Other outbreaks might be in process or might be in the future.

--Vaccine must be produced and a plan for vaccine administration should be developed.

The Committee did not state whether persons should actually be immunized.

A March 13, 1976, memorandum from the Director of CDC to the Assistant Secretary for Health analyzed the

advantages and disadvantages of (1) no Federal action, (2) a limited Federal role with primary reliance on existing delivery systems and on spontaneous, nongovernmental action, (3) a national immunization program under virtually total Government responsibility, and (4) a combined public and private sector program. The memorandum recommended the last approach, as offering the best chance of immunizing the entire population.

Under the recommended plan, the Federal Government would advise manufacturers to produce, and would contract through HEW for, 200 million doses of vaccine. This vaccine would be made available at no cost to State health agencies which would plan for its distribution through public health, volunteer, and private sector channels. Federal cost for this program was estimated at $134 million.

After the CDC memorandum had been forwarded to HEW's Assistant Secretary for Health, the CDC Director conducted a telephone poll of Advisory Committee members concerning the recommendation. He reported that most of the members favored the mass immunization program.

The recommendation was approved virtually intact through HEW, the Office of Management and Budget, and the President's Domestic Council. On March 24, 1976, before endorsing the program, the President met with HEW officials, flu experts, and other scientific advisors. Immediately afterwards he announced the national swine flu program to the press. By April 12, the House and Senate had passed the joint resolution which provided about $135 million for a comprehensive, nationwide immunization program. The President approved the resolution on April 15.

Between April and July 1976, HEW initiated and completed initial clinical trials of the vaccine and awarded project grants to help States and territories implement the program. Meanwhile, no additional swine flu outbreaks had been detected anywhere in the world, despite increased surveillance.

As HEW began negotiations with vaccine manufacturers, however, a serious problem jeopardized initial program implementation--the question of liability insurance for vaccine manufacturers and other participants. In July the manufacturers threatened to halt production and to withhold existing supplies of vaccine unless the problem could be solved. At this time, HEW and the manufacturers generally concluded that legislation would be required

to solve the problem. (See ch. 3.) On August 10, 1976, the Congress, spurred by HEW and an urgent Presidential request and possibly reacting to mysterious deaths in Pennsylvania (although attributed to a cause other than swine flu--Legionnaires' Disease) approved the stalled swine flu program by authorizing the National Swine Flu Immunization Program of 1976 (Public Law 94-380, 42 U.S.C. 247b). Projects began immunizations on October 1.

JUSTIFICATION BASED ON SCIENTIFIC JUDGMENTS AND ASSUMPTIONS ABOUT HEALTH CARE NEEDS AND SYSTEM CAPABILITIES

Many of the limited facts available were used to both support and condemn the program. The validity of either position could be tested only over time. The decision to vaccinate everyone in the United States was based primarily on scientific judgments that a swine flu pandemic could occur at any time, regardless of whether additional outbreaks were detected in the interim. Underlying this decision were several assumptions, including (1) vaccine manufacturers could produce enough acceptable vaccine and (2) the public and private health care system could deliver the vaccine promptly to the entire population. Criticism of this decision was also based on judgments and assumptions.

Because less than one-fourth of the total U.S. population has been vaccinated, assumptions of health system delivery capabilities were never fully tested. (See ch. 7.) The manufacturers did not produce the quantities of vaccine needed to immunize the entire population. (See ch. 6.)

Conflicting opinions about the need to vaccinate

In April 1976 consultants from 15 countries attended a World Health Organization meeting to discuss the implications of the Fort Dix outbreak. One recommendation from the meeting urged countries producing flu vaccines to continue producing Victoria flu and Hong Kong flu 1/ vaccines and to initiate production of a killed virus vaccine made from the new swine-flu-like virus. Three possible strategies proposed for using the swine flu vaccine were (1)

1/This flu strain is of a different type and is much milder than the one which caused the 1968-69 Hong Kong flu pandemic.

stockpiling it as an emergency measure, (2) combining it with the currently recommended vaccines, or (3) administering it as an individual vaccine. Each country was to decide which course was most appropriate for its resources and needs.

A CDC official stated that several countries in addition to the United States planned swine flu programs. Only the United States decided to administer the vaccine in a mass immunization program.

Between the announcement of the national program in March and the first vaccinations in October, no other swine flu outbreaks were detected. While HEW officials and Federal Government advisory groups supported the program during this time, criticism came from other scientists and physicians, public health officials, and public interest groups.

Canada, the only country to originally endorse the U.S. position, subsequently recommended selective rather than mass immunization. A CDC official reported that world opinion, though not openly critical of the U.S. decision, was to some degree, skeptical. However, an HEW official discounted most of the skepticism from other countries as mere rationalization. He stated that few, if any, other countries could readily produce enough vaccine for a mass program even if they wanted one. We did not evaluate other countries' vaccine production capabilities.

Critics' positions

As time passed without any detected cases of human-to-human spread of swine flu, critics argued that there was little probability of a pandemic. Further, because any immunization program carries a risk of adverse vaccine reactions, some critics urged that the vaccine be stockpiled until further evidence of virus spread became available. The critics' major contentions follow:

--A worldwide surveillance network had failed to detect any outbreak of swine flu since the outbreak at Fort Dix. Because previous pandemics have always been preceded by at least several outbreaks, the likelihood of a swine flu pandemic during the 1976-77 flu season became so remote that mass immunization was not justified.

--The evidence collected at Fort Dix and in a subsequent British study suggested that the new strain of swine flu was milder than other human flu viruses and that the single death attributed to the new strain could be disputed. The evidence suggested also that the new strain lacked the ability to compete successfully against other flu strains, especially Victoria, which was more likely to be the predominant strain during the 1976-77 flu season.

--The severity of the 1918-19 pandemic was due to conditions peculiar to the time. Overcrowding in military camps and widespread troop movements provided ideal conditions for propagating the disease around the world, and no antibiotics were available to combat secondary infections, such as pneumonia.

--The effectiveness of vaccines in protecting against flu is questionable.

--A mass immunization program would drain public health resources and result in lost opportunity costs to other programs.

HEW's position

HEW officials recognized that the swine flu virus might not result in a pandemic. However, they stated that major antigenic shifts in flu viruses had always led to pandemics. They pointed out that killed-virus flu vaccines had rarely been associated with severe adverse reactions or permanent disability. Such vaccines were considered medically safe and quite suitable for widescale community use.

HEW officials opposed stockpiling. They estimated that, even under ideal conditions, 3 to 3-1/2 months would would be required to distribute and administer the vaccine and allow it time to attain maximum effect. In previous epidemics, the average time from isolation of a new virus to major outbreaks in the United States was less than 6 months. They said that stockpiling could result in planning and organizing a mass immunization program, only to have an epidemic occur because they failed to stay ahead of the virus. They considered such action generally contrary to the concept of preventive medicine.

HEW positions on other criticisms follow:

--Although the Fort Dix outbreak was short lived, it was extensive. Similar small outbreaks elsewhere may have occurred, but gone undetected. These outbreaks may be "seeding" the population with the swine flu virus before exploding into a pandemic.

--The swine flu virus at Fort Dix was similar in structure to the 1918-19 virus. However, there was no data to justify an assumption that the Fort Dix virus would be as strong as the earlier virus. The strength of a flu virus cannot be determined before its epidemic occurrence in large numbers of people. The decision to vaccinate had to rest solely on the recognition that most of the population was susceptible to the new virus.

--The Hong Kong pandemic of 1968-69 resulted in over 27,000 excess deaths and cost an estimated $3.9 billion in medical care, industrial and school absenteeism, and future earnings of those who died. It is better to gamble with unnecessary health expenditures than with unnecessary death and illness.

--Although past immunization efforts against the Asian flu in 1957 and the Hong Kong flu of 1968-69 had failed to have any perceptible effect, it was because too little vaccine was administered too late. Isolating a new flu strain at the end of one flu season, as was done with the new swine flu virus, presented a unique opportunity for the Nation's health system to organize itself in time to prevent a flu outbreak or an epidemic during the next flu season.

--Lost opportunity costs to other programs were unpredictable and were not considered significant enough to halt the program.

Questionable assumptions about health system capability

HEW officials assumed that (1) manufacturers would be willing and able to produce enough acceptable vaccine in a short time and (2) State and local public health officials and private physicians would be willing and able to plan, organize, and execute the mass immunization program. The testing of these assumptions surfaced substantial problems regarding:

--The issues of professional and product liability, heightened by the prospect of a mass immunization program. (See ch. 3.)

--The combined ability of manufacturers and the Federal Government to produce, test, and make available sufficient quantities of acceptable vaccines for the entire population. (See chs. 4, 5, and 6.)

--The capability and willingness of State and local governments and private health care providers to effectively participate. (See ch. 7.)

--The direct and indirect costs of the program. (See ch. 8.)

HEW confronted these significant problems as they arose and at the same time recognized that, as time passed without an outbreak of swine flu, the probability of an epidemic decreased.

HEW never considered the continued absence of a reported outbreak of swine flu as sufficient evidence that a swine flu epidemic would not occur. Therefore, HEW never formally re-evaluated the decision to continue the program. Consequently, the program, although delayed and hampered by the problems which plagued it, was continued until December 1976. It was stopped at this time because of several reported instances of Guillain-Barre syndrome potentially related to the vaccine. A limited program using bivalent vaccine was restarted in February 1977, so that high-risk individuals would be immunized against Victoria flu.

CONSIDERATIONS AND RECOMMENDATION FOR FUTURE IMMUNIZATION PROGRAMS

Although detecting and preparing for swine flu was unique, the planned mass immunization program encountered some problems that will likely recur with any future mass immunization. At least some of the problems may--or already do--affect other public or private health care efforts.

Some questions that will have to be answered are:

--Was the Fort Dix outbreak an isolated incident that might have gone undetected in previous years?

--Must there be more than one outbreak, such as the one at Fort Dix, before an epidemic can be reasonably predicted?

--Must an epidemic be scientifically predictable--rather than just possible--before mass immunization is justified?

--When more than one flu virus is present, how can determinations best be made as to what vaccine or combination of vaccines is needed most by different segments of the population?

--How can the disease surveillance system be improved to better identify and trace virus spread?

--How can the availability of sufficient quantities of safe and effective vaccines best be assured?

--What will be the Federal role in covering professional and product liability claims?

--How can effective participation of State and local government and private health care providers be assured?

--How will the costs and benefits of any mass immunization program be determined or be related to potential alternate uses of public health resources?

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

In any event, where program decisions must be made based on very limited scientific data, we recommend that the Secretary, HEW, establish key points in the program process for formal program reevaluation.

CHAPTER 3

SWINE FLU PROGRAM LIABILITY

IMPLICATIONS FOR THE FEDERAL GOVERNMENT

Liability problems threatened to end the national swine flu program before vaccinations could begin. Therefore, the Congress passed Public Law 94-380 providing for an exclusive remedy against the United States for personal injury or death arising out of the program. Although effective at getting the program started, this solution

--may result in a profit to the insurance companies of nearly the entire $8.65 million premium for vaccine manufacturer swine flu liability insurance;

--leaves unresolved insurance company concerns about nonmeritorious claim risks; and

--may result in indeterminable additional costs to the Government for litigation, awards, and settlements because of potential weaknesses in both the informed consent form and procedures.

As of March 31, 1977, claims and suits against the Federal Government for damages from the swine flu program totaled over $300 million. The total amount of claims and suits ultimately filed against the Federal Government may exceed $1 billion. (See p. 83.)

Liability will continue to be a problem for future federally run or sponsored mass immunization programs. Therefore, permanent solutions to the problems surfaced by the swine flu program should be sought.

LEGISLATIVE SOLUTION TO LIABILITY CONCERNS

Liability became an issue in the swine flu program because several participants, including 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. (See pp. 73-75.)

Insurance company concerns

Insurance officials pointed out that, in the proposed immunization program, public exposure and visibility of manufacturers would be magnified many times. They said that this exposure, coupled with the current legal climate, which rewards rather than reimburses claimants, could subject the manufacturers to an incalculable number of claims, and particularly to nonmeritorious claims alleging injury from immunization. One insurance official estimated that even if none of the swine flu claims were meritorious, potential defense costs alone could range from $9.5 billion to $25 billion. The result would be substantial losses for both insurance companies and the manufacturers, regardless of negligence in producing or distributing vaccine. Consequently, because of what the insurance companies' considered unmeasureable, and thus uninsurable, financial risks, they excluded the swine flu vaccine from the manufacturers' normal product liability coverage.

Manufacturers' concerns

Because of their experience with flu vaccine, the manufacturers did not expect the Government to indemnify them for their own negligence in producing or handling the vaccine. Their standard product liability policies normally include a substantial deductible portion. Between 1970 and 1975, over 70 million doses of flu vaccine were produced and distributed with fewer than 20 claims for damages. At least five of these claims were found to be nonmeritorious, and the maximum settlement for the others was $26,000. All costs to litigate, defend, and settle these claims were paid by the manufacturers under their deductibles.

The manufacturers' liability concerns stemmed from recent court decisions holding the manufacturers liable for injury or adverse reactions where no negligence in producing or handling vaccine was shown. The courts held the manufacturers strictly liable unless they communicated warnings of any hazards to the users of their products. In two cases, Reyes v. Wyeth Laboratories, Inc., 498 F. 2d 1264 (5th Cir. 1974), and Davis v. Wyeth Laboratories, Inc., 399 F. 2d 121 (9th Cir. 1968), the manufacturers of Sabin live polio vaccine were held liable to plaintiffs vaccinated in public clinics who were not properly warned of the hazards.

The manufacturers believed that the courts might apply the same strict liability standards in any litigation arising out of the swine flu immunization program. The vaccine would frequently be administered on a mass basis in public clinics

without the physician-patient relationship that generally accompanies the administration of prescription drugs. Consequently, the manufacturers sought protection against claims attributable to the swine flu immunization program other than those claims attributed to their own negligence.

The solution: legislation

HEW attempted to meet the concerns of the manufacturers by offering to include provisions in the vaccine contracts which would make it clear that the Government would assume the usual responsibilities of the manufacturers for (1) investigating and determining the risks of vaccination, (2) developing a statement of the benefits and risks of vaccination, and (3) taking reasonable steps to assure that all persons vaccinated would be notified of those risks and benefits. The Anti-Deficiency Act (31 U.S.C. 665 (a)) precluded HEW from including indemnification provisions in the contracts because such provisions might create obligations in excess of HEW's appropriation. Consequently, HEW could not assure the manufacturers that they would be protected from liability by a Government-developed information statement on the benefits and risks of vaccination.

In enacting the National Swine Flu Immunization Program of 1976, the Congress provided for an exclusive remedy against the Federal Government for personal injury or death arising out of the manufacture, distribution, or administration of the swine flu vaccine. It also made the Federal Government responsible for developing and implementing a written informed consent form and procedures for assuring that the risks and benefits of the vaccine were fully explained to each individual immunized.

Under the act, all claims for injury or death resulting from the program must be filed against the Federal Government and decided through procedures of the Federal Tort Claims Act (28 U.S.C. 2671 et seq.), as amended for purposes of the swine flu program. The Government has the right to recover costs to defend and settle these claims if negligent conduct or failure to carry out any contractual obligation or responsibility by participants is found. As a result of the act, the manufacturers agreed to continue producing and to distribute vaccine.

LIABILITY INSURERS' PROFITS FROM MANUFACTURERS' SWINE FLU INSURANCE MAY NEARLY EQUAL PREMIUMS

To insure against the Federal Government's right to recover, the four vaccine manufacturers obtained a total of

$230 million of liability insurance. The first $10 million of the $230 million is self-insured by the manufacturers. The remaining $220 million was purchased from more than 60 foreign and domestic insurance companies for an $8.65 million premium. Because this cost is considered a vaccine production cost, the Federal Government will fund both the $10 million self-insurance and the $8.65 million premium, or a total of $18.65 million.

Potential insurance company costs for manufacturer negligence are limited under the program. Under swine flu legislation, the Federal Government assumed the financial risks of nonmeritorious claims. Also the manufacturers' liability policies expand the definition of loss to include costs of litigation and payments for expenses incurred in investigating, negotiating, settling, or defending any right-to-recover suit by the Federal Government. According to an insurance industry representative, general liability policy limits normally apply only to costs incurred for claims and suits that result in a settlement or an award.

In addition, the premiums will not be retrospectively adjusted to reflect actual claims experience. Therefore, no portion of the premium will be refundable to the manufacturers, and hence the Government, even if a less-than-expected amount of claims are experienced.

Because of these insurance policy limitations, the liability legislation, and Federal funding of both the self-insurance and liability insurance premium, all recoveries by the Federal Government from manufacturers for litigation and settlement costs, up to $18.65 million, will be a recovery of Federal funds, the first $10 million of which will come from the manufacturers' self-insurance fund.

The insurance companies will defend the manufacturers in suits initiated by the Government. All costs to defend the manufacturers will be charged against the $10 million self-insurance fund. If the manufacturers are found negligent, litigation costs and settlements originally incurred by the Government will also be charged against the $10 million self-insurance until it is exhausted. Only then will costs be assumed by the insurance companies. The unexhausted balance of the manufacturers' self-insurance fund, plus interest, is returnable to the Federal Government. If the self-insurance fund is never exhausted, no expenses for litigation and settlement of claims will be charged against insurance company funds. Consequently, according to an insurance industry representative, the $8.65 million premium, less brokers commission and anticipated administrative expenses, could be total profit.

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It is too soon to determine how much of the $8.65 million premium the insurance companies will realize as profit. But, if the Congressional Budget Office estimate is accurate, nearly the entire premium will be profit.

Before the program began, the Congressional Budget Office projected that only $2.58 million in liability payments and litigation costs will be recovered from all third party program participants. Besides the vaccine manufacturers, this projection included all participating public or private agencies and medical or other health personnel providing vaccination without charge in accordance with informed consent procedures. Even if all recoveries are from the vaccine manufacturers, the $2.58 million would be paid out of the $10 million self-insurance funds. The insurance companies would, therefore, still make about an $8.65 million profit.

The accuracy of the Congressional Budget Office's projections will be proved only by experience. However, (1) between 1970 and 1975, the insurance companies paid no claims for negligence in the manufacture of flu vaccine and (2) FDA officials reported that, in addition to reviewing manufacturer test results, FDA had performed tests for safety, potency, and sterility on every lot of vaccine before release to the public. (See ch. 4.) Although the drug manufacturers are not relieved of their production liability, HEW's approval of every lot may significantly reduce the likelihood that the Government could recover for damages awarded or paid based on manufacturers' negligence.

UNRESOLVED INSURANCE INDUSTRY CONCERNS

The swine flu program legislation removed the insurance companies' concern about the financial risks of nonmeritorious claims by providing an exclusive remedy against the Federal Government under procedures of the Federal Tort Claims Act. This act, with certain exceptions, eliminates trial by jury, restricts liability for punitive damages, and limits attorney fees to a maximum of 25 percent of any judgment or settlement. Also a Department of Justice official said the Department's costs to litigate a claim or suit are substantially less than the costs of a private law firm. As a result, the number of nonmeritorious and frivolous claims and the costs to defend against them may be reduced. Additionally, the number of claims initially anticipated could be reduced because less than 25 percent of the population was vaccinated. As a result, the swine flu program will provide little experience for the insurance companies to predict nonmeritorious claim risks for future programs, especially ones that provide for remedy under any procedure other than the Tort

Claims Act. Consequently, the insurance companies' concern which caused them to withdraw coverage of the manufacturers for the swine flu program will continue to exist.

LIABILITY IMPLICATIONS OF FEDERAL RESPONSIBILITY FOR INFORMED CONSENT

Potential weaknesses in the consent forms used in the swine flu program and in the Federal Government's procedures to assure that every person immunized was informed of the vaccine's benefits and risks may result in excessive costs to the Government for litigation, defense, and settlement of claims.

If through Federal tort claims procedures and subsequent litigation, either (1) the informed consent form is judged insufficient to warn of the risks or (2) consent was not given or is judged inadequate because procedures used to communicate a warning in a particular case were deficient, the Federal Government may be held liable for damages caused by both severe and mild adverse reactions.

Although the Davis court case (see p. 18) defined the parameters of informed consent and provided a standard to determine when a warning is necessary, it did not specify how this duty was to be satisfied. A study performed for CDC indicates that there is wide divergence of opinion among the courts concerning the standard to be applied in determining whether the consent given is actually informed.

It will take several years to evaluate the effects of (1) decisions through Federal tort claims procedures about liability for the swine flu informed consent form and for the procedures used to communicate the warning in each case and (2) whether the Federal Government can or will recover costs of litigation and settlement from program participants negligent in informed consent procedures. In the interim, the Government can take additional steps to promote informed participation by prospective vaccinees in future immunization programs.

Potential weaknesses in consent form

There are no specific criteria for drafting informed consent forms. The adequacy of the language is defined only after being tested through legal procedures. However, the Davis court case set forth as one parameter that potential vaccinees must receive full disclosure of the existence and extent of the risk.

The informed consent form used for the swine flu program between October 1 and December 16, 1976, contained (1) no

specific warning of possible neurologic disorders, (2) a controversial statement concerning potential vaccine effects on pregnant women, and (3) no specific warning of the probability of getting the flu despite receiving the recommended vaccine. Information available before the swine flu immunizations began (1) identified neurologic disorders as a possible severe reaction associated by time with flu immunization in general, (2) questioned the accuracy and clarity of the statement concerning potential vaccine effects on pregnant women, and (3) estimated the risk of contracting the flu despite vaccination. As a result, the Federal Government's position with regard to claims resulting from any of these reactions may be weakened.

Informal procedures used to develop consent forms

Without criteria or formal procedures for developing informed consent forms, HEW's chances of making potentially expensive errors of omission were increased.

Before the passage of Public Law 94-380, in August 1976, HEW had drafted, printed, and distributed to the projects a one-page informed consent form. (See apps. I and II.) The form was entitled, "Important Information About Swine Influenza (Flu) Vaccine" and was produced in two nearly identical versions, one for persons who would receive monovalent vaccine and one for persons who would receive bivalent vaccine. At the bottom of the two versions was a section to sign and tear off, entitled "Registration Form."

The form was drafted primarily by CDC with the advice of an HEW attorney. CDC officials said that the risk and benefit statements on the form had been drafted based on flu and vaccine information provided by CDC personnel and on consideration of recent court decisions on manufacturers' informed consent liability. The form was then reviewed by personnel in each of the 63 grant projects, the Advisory Committee on Immunization Practices, and other CDC personnel. Their feedback was incorporated where appropriate.

Public Law 94-380 required HEW to consult with the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission) on the content of the consent form. Formal approval was not required. The form was reviewed by the National Commission at a meeting with CDC officials on August 17, 1976. During the meeting, Commission members expressed concern over several issues. At least two members thought a new form should be drafted. The National Commission did not prepare a formal list of mutually agreeable recommendations at this meeting.

CDC officials at the meeting drafted a second page "Introduction" to the form (see app. III) in response to the National Commission's concerns. In addition, the "Introduction" included a statement to assure that individuals are advised with respect to their rights and remedies relating to any adverse effects of vaccine administration. A CDC official said that the Director of CDC had obtained oral approval of this "Introduction" from the National Commission Chairman. By August 31, 1976, over 83 million "Registration" forms and 39 million "Introductions" had been printed and shipped to CDC; the States; and to other Federal agencies, such as the Veterans Administration and the Bureau of Prisons. Also several States had printed both forms.

On September 20, 1976, the Chairman of the National Commission sent a letter to the Director of CDC recognizing CDC's "good faith" effort to incorporate the Commission's concerns, but expressing continuing concern about (1) contradictory statements on the two pages concerning vaccine safety during pregnancy, (2) possible confusion concerning the purpose of the "Introduction," and (3) incomplete information on whom individuals were to contact in cases of adverse reactions. No changes in the form were made with regard to these comments until after the program had been halted in December 1976. A new consent form was subsequently developed.

CDC drafted the new form during January because of concerns expressed by the Assistant Secretary for Health, the Advisory Committee on Immunization Practices, and others that a warning should be included about the risks of Guillain-Barre syndrome. The new one-page form, entitled "Voluntary Consent Form" (see app. IV), had a tear-off section entitled "Consent." It also incorporated new language to resolve the continuing concerns of the National Commission and others about the adequacy of the first two-page form. The Assistant Secretary requested a new form for the potential restart of the immunization program.

CDC's draft was to be reviewed by the National Commission at its next meeting scheduled for February 15, 1977. However, on February 7, 1977, the Secretary of HEW convened an open meeting of distinguished medical, scientific, and other experts to consider restarting the program. After the meeting, the Secretary announced a partial resumption of the immunization program for high-risk individuals to begin on February 8, 1977. CDC's draft of the new consent form was revised by the Secretary, with verbal input from the National Commission and congressional committee staff. However, the National Commission did not make official comments or give formal approval.

CDC officials said that the new form is not a balanced risk/benefit statement, only a risk statement. They believe the form will discourage some people from being vaccinated because it disproportionately portrays the risks. Although the new form states that 3 of every 4 persons vaccinated will probably not get the flu, in reality the probability is closer to 9 of 10, according to some CDC officials. Without a widespread epidemic of flu, the extent to which the consent form influences individuals to be or not to be vaccinated is indeterminable.

No specific warning on neurologic disorders

Vaccine recommendations made by the Advisory Committee on Immunization Practices in July 1976 warned of three possible types of adverse reactions to flu vaccinations:

--Fever, malaise (discomfort), myalgia (muscle pain), and so forth.

--Allergic reactions.

--Neurologic disorders.

Each of these warnings was specified in CDC's Morbidity and Mortality Weekly Report on July 23, 1976, and on circulars packaged with the vaccine for distribution. The first two were specified on the original "Registration" form. No specific warning on neurologic disorders was included.

The Advisory Committee's recommendation stated that a survey of medical literature since the early 1950s had revealed only about a dozen reports of neurologic disorders, including three fatalities, involving persons receiving flu vaccine. Two of the fatalities displayed clinical characteristics or had antecedents which strongly suggested causes other than flu vaccine. Evidence suggested that the third could have been caused by another viral disease. However, the association in time may be significant enough to warrant a warning.

CDC officials stated that reactions such as neurologic disorders were satisfactorily covered on the "Registration" form by the statement under "Special Precautions," which combined severe and allergic reactions stating that

"As with any vaccine or drug, the possibility of severe or potentially fatal reactions exists. However, flu vaccine has rarely been associated

> with severe or fatal reactions. In some instances people receiving the vaccine have had allergic reactions."

In reviewing this form and the Advisory Committee's supplemental recommendation, the National Commission had no comments on the lack of a specific neurologic disorders warning.

Because of the incidences of encephalitis and Guillain-Barre syndrome and resultant claims for damages the adequacy of this statement is important in terms of protecting the Government. A study of liability in preventive medicine performed for CDC concludes that it is likely the courts will hold that there is a duty to warn even when the risk is statistically insignificant. Consequently, by generalizing the Advisory Committee's specific statement on neurologic disorders, HEW increased its risks of adverse decisions through the Federal tort claims process, which could significantly increase Federal costs of litigation and settlement. Because the Federal Government is solely responsible for the content of the informed consent form, it is unlikely that any of these increased costs would be recoverable because of other program participants' negligence.

The new consent form, issued in February 1977, has a specific statement on the risks of Guillain-Barre syndrome, but does not contain the neurologic disorders warning included in the Advisory Committee's July 1976 recommendations.

Controversial informed consent statements for pregnant women

The initial "Registration" form stated simply that "flu vaccine can be taken safely during pregnancy." The Advisory Committee on Immunization Practices' July 1976 supplemental recommendations concluded that

> "* * * there are no data specifically to contraindicate vaccination with the available killed virus vaccine in pregnancy. Women who are pregnant should be considered as having essentially the same balance of benefits and risks regarding influenza vaccination and influenza as the general population."

During its review of the "Registration" form, the National Commission discussed these two statements with HEW officials. Some Commission members concluded that the positive statement on the "Registration" form read like a warranty and should be replaced by a statement similar to the conclusion made by the Advisory Committee. The Commission did not endorse the

wording of the Advisory Committee's conclusion, however, because it could not be easily understood by the public.

The second page "Introduction" form prepared in response to the National Commission's concerns included the exact wording of the Advisory Committee's statement on pregnancy. In a September 20, 1976, letter to the Director of CDC, the National Commission Chairman expressed additional concern over the issuance of another pregnancy statement on the second page "Introduction" rather than issuance of a single page revised form. The Commission was concerned that the statement on the "Introduction" was not necessarily consistent with the statement on the "Registration" form and may complicate understanding with respect to the advisability of vaccination during pregnancy. Also neither statement resolved the Commission's earlier concerns that (1) the clinical trials had not determined either the safety or efficacy of the vaccine with regard to pregnant women and (2) the Advisory Committee's conclusion had been based on experience rather than on conclusive studies showing benefits and risks.

Others also expressed concern about the statements on pregnancy. In congressional testimony on September 13, 1976, an attorney from a public interest law firm stated that "* * * the lack of data specifically contraindicating vaccination during pregnancy is due to the lack of any studies which show either the indications or contraindications during pregnancy." The attorneys also noted that (1) the Advisory Committee's conclusion was not written in lay terms and could not be easily understood by the public, (2) the conclusion gave no information concerning the risks to the fetus, (3) the assertion that the swine flu vaccine can be taken safely during pregnancy had not been deleted from the "Registration" form, and (4) the two statements appearing on two separate pages might be difficult to follow or synthesize. The attorney suggested that the two-page informed consent form be rewritten to be clear, straightforward, and correct.

The attorney also indicated that because of the problems with both the "Introduction" and "Registration" forms, the Federal Government could be subjected to large monetary settlements or awards for injuries to pregnant women or their offspring regardless of defects in the vaccine or negligence in its administration.

The new consent form uses neither statement on pregnancy from the original forms. Instead, it states simply for pregnant women:

> "There is not now any specific data on whether the risks are the same or different from what they are for the general population. For this reason a pregnant woman should be advised by a doctor on the benefits and risks for her or her offspring."

A CDC official said that this change had been made in response to the concern of the National Commission and others.

No statement of probability of contracting swine flu after being vaccinated

The "Introduction" form states that a special swine flu vaccine was prepared and tested which should protect most people who receive it. The Director of CDC's Virology Division, Bureau of Laboratories, stated that the results of the clinical trials for swine flu vaccine show that (1) at least 70 percent of persons over 25 years of age who receive the vaccine will be fully protected and (2) up to 90 percent of the vaccinees will be protected from any serious infection which would cause confinement to bed or hospitalization. (See ch. 5.) Therefore, 3 of every 10 persons vaccinated could still contract swine flu.

An analysis of recent court decisions, performed for CDC before swine flu immunizations began, indicated that for the consent to be truly informed, the warning must specify the risks of contracting the disease from both the vaccine and the natural virus. Though there was no recognized risk of contracting flu from the swine flu vaccine, there was a quantifiable risk of contracting the flu after vaccination.

The lack of such a specific warning would become important only if persons who were vaccinated contracted swine flu and as a result made claims for damages. Then, through Federal tort claims procedures, a determination would have to be made as to whether the word "most" adequately conveyed the risk involved. The new consent form, although possibly oversimplified in its statement, does specify that "a single shot will protect approximately three out of four persons age 25 and over * * *."

Informed consent procedures: meeting HEW guidelines could not always be assured

Even if HEW's prescribed informed consent procedures are determined adequate, neither HEW officials nor project coordinators could visit every clinic to assure that the procedures were followed and that every person immunized was informed of

vaccine benefits and risks. This further adds to the prospect that, regardless of defects in the vaccine or negligence in its administration, the Federal Government can be held liable for damages caused by both severe and mild vaccine reactions. The extent of resultant litigation and settlement costs depends on the number of claims filed, extent of injury, and decisions on the adequacy of procedures used in each case. The methods used by HEW and the States to assure compliance with informed consent guidelines are discussed in more detail in chapter 7. (See pp. 69-71.)

CONSIDERATIONS AND RECOMMENDATIONS FOR FUTURE IMMUNIZATION PROGRAMS

Insurance executives stated that because the Federal Government will control all key aspects of any immunization program conducted as a matter of public policy, the Government should be responsible for both the liability and the costs of litigation. HEW's Assistant Secretary for Health stated that a national policy concerning compensation will have to be developed for any future mass immunization program.

So that resolution of the liability issue does not delay or adversely affect public acceptance of future programs, we recommend that the Congress establish a national liability policy before another mass immunization program is needed.

The Secretary of HEW is required by the liability legislation to study the scope and extent of liability for personal injury or death arising out of immunization programs and alternative approaches to providing protection against such liability. We recommend that this study focus on the most cost-effective approach to compensate vaccine injury victims which at the same time will promote the continual production of vaccines by the manufacturers.

Two alternatives to consider for manufacturer liability insurance

The liability legislation for the swine flu program makes participants responsible for their own negligence. As shown, this approach may result in profits for the insurance industry at Federal expense with respect to the vaccine manufacturers. However, because of the potential expense related to defending nonmeritorious claims, the insurers believe that the manufacturers will be uninsurable for future mass immunization programs at an acceptable premium, without some Federal assumption of liability. We recommend that the Secretary, HEW, consider

two alternatives for Federal assumption of liability at less cost than for the swine flu program as discussed below.

First, if experience gained from the swine flu program shows that considerable savings can be realized and if HEW intends to continue rigorous testing and approval of every vaccine lot, then the Secretary, HEW should consider total Federal assumption of the liability coverage for vaccine production. In effect, by giving the manufacturers $10 million for self-insurance and $8.65 million for the liability insurance premium, the Federal Government may already have relieved the manufacturers of their financial responsibility for negligence and may have assumed financial liability for vaccine production.

A second alternative would be for the insurance industry to make premiums for the manufacturers' liability insurance adjustable retrospectively based on claims experience. Consequently, if claims do not exceed the premium, the manufacturers, and hence the Government, could recover the unused premium minus insurance company costs. However, if costs to litigate and settle claims exceed the face value of the insurance coverage, the manufacturers, and hence the the Government, will incur costs in addition to the initial premium. Because of the limited profit potential of this approach, its success would depend on insurance company willingness to insure the manufacturers on such a basis.

Informed consent recommendation and considerations

To evaluate the effect of Federal responsibility and liability for informed consent will take years. We recommend that the Secretary, HEW, monitor this process as it occurs for possible future program implications. In the interim, steps such as the following should be considered:

--Develop criteria and standard procedures for drafting and reviewing informed consent forms. Such criteria and procedures should allow for the timely development of the form without time-pressured consideration of appropriate comments and opinions. Full disclosure of the benefits and risks of vaccination should be clearly stated.

--Develop a plan to systematically monitor and document that HEW's informed consent procedures and requirements are implemented at the projects and clinics. (See pp. 75 and 76.)

CHAPTER 4

REGULATION AND TESTING OF VACCINE USED FOR THE SWINE FLU PROGRAM

All vaccine released for public use in the swine flu program that we reviewed met FDA potency and safety standards. The vaccine underwent testing procedures more extensive than those used for flu vaccine released in 1975.

To insure that potency requirements were met and to verify potency test data submitted by manufacturers, FDA performed its own tests before releasing swine flu vaccine for public use. FDA potency test data for about 55.5 million doses indicated that about 15.5 million doses were subpotent. FDA did not permit this vaccine to be released to the public until it met the minimum potency requirements. FDA tests also showed that some vaccine used in the clinical trials did not meet specified potency levels. Further, the potency test has deficiencies as an indicator of protection provided by the vaccine.

Manufacturers and FDA routinely conducted safety and other tests on vaccine before it was released to the public. Similar tests were not always conducted on clinical trial vaccine lots by FDA until after the lots were made available for use in the trials. Consequently, the added protection provided to the general public by FDA verification testing of manufacturer test data was not afforded to all clinical trial participants.

FDA REGULATORY ROLE

Although flu vaccine has been licensed since the 1940s, the vaccine's composition is periodically changed to conform to the prevailing flu virus causing illness. When the composition is changed or other changes are made, such as those involving the manufacturing process, a license amendment is submitted. FDA officials stated that, based on the information submitted in the amendment, they determine whether the changes require clinical testing under investigational new drug regulations.

Because swine flu vaccine was to be made from a new flu virus strain, FDA had to approve a flu vaccine license amendment for each manufacturer to permit release of vaccine. FDA also establishes potency levels and certifies vaccine labels and package circulars proposed by the manufacturers.

Investigational new drug applications

When FDA determines that clinical studies are necessary, the sponsor of a new drug must test the drug under closely controlled circumstances. The evidence obtained from such studies is included in a license application submitted by persons seeking to market a biological product.

Under FDA procedures, the sponsor, after submitting an investigational new drug application, must wait 30 days before beginning clinical trials unless notified by FDA that trials may begin sooner. This delay enables FDA to review the application to make certain it contains necessary information and to insure that patients are not exposed to unwarranted risks. The sponsor may initiate clinical testing 30 days after FDA has received its application, unless in the meantime FDA has raised objections. FDA may waive the 30-day requirement if it believes such action is justified. The 30-day period was waived for the swine flu clinical trials because FDA decided that very little time was available before the trials had to begin. Also, according to HEW officials, the 30-day period was waived, in part, because of the extensive experience with flu vaccines.

FDA usually requires the sponsor to submit, as part of the application, a report on the results of preclinical animal tests from which the sponsor has concluded that clinical trials can be conducted with reasonable safety. FDA did not require preclinical animal investigations because, according to FDA officials, the swine flu vaccine was not a completely new product. FDA determined that existing data and experience on flu vaccine was applicable and adequate to satisfy preclinical requirements.

Requirements after approval of vaccine license amendment

After approval of all licensing requirements and before vaccine is released to the public, FDA may require manufacturers to submit samples of production lots and related test results. FDA reviews these and sometimes conducts tests within its own laboratories to verify the results obtained by the manufacturers. FDA may either release a lot or reject it when necessary to insure conformance with standards.

FDA is required to insure that manufacturers continue to meet standards for safety, purity, and potency after issuance of a license. FDA officials said that this legislative mandate is met when they review manufacturer test records and

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inspect manufacturing facilities. According to FDA officials, FDA is not required by law to perform its own tests on flu vaccine for clinical use or for release to the public.

Manufacturers must show through the required tests that their product conforms to standards of safety, purity, and potency. Other tests are performed to verify amounts of ingredients specified on vaccine labels.

TESTING PROCEDURES FOR SWINE FLU PROGRAM VACCINE MORE EXTENSIVE THAN THOSE USED IN 1975

During 1975 FDA reviewed manufacturer test results and performed its own tests for potency, sterility, safety, and endotoxin (an undesirable flu vaccine contaminant) levels on every lot of flu vaccine before its release to the public. FDA performed the same tests on swine flu program vaccine lots covered by our review. FDA reported that these tests had been conducted on every lot of vaccine released. In addition, FDA's assays of various vaccine ingredients were expanded over 1975 levels because of increases in personnel and funding provided by the swine flu program.

WEAKNESSES OF POTENCY TEST

Since 1968 manufacturers have been required to determine the potency of flu vaccine by use of the chicken cell agglutination (CCA) test. The test assesses virus concentration by measuring the ability of the virus to clump chicken red blood cells. It expresses vaccine potency in terms of "CCA" units; the higher the CCA value, the greater the vaccine's potency.

FDA officials and others involved in vaccine regulation have stated that the CCA test is seriously limited as a method of determining the potency of flu vaccine. A potency test is designed to measure the ability of a product to produce a given result by laboratory tests or clinical trials. Preferably, the result measured relates directly to the product's protective value. However, swine flu clinical trials showed that increasing the vaccine's potency did not necessarily result in an increase in antibody response among volunteers.

FDA officials believe that the CCA test has certain deficiencies, which include variations in red blood cells due to different sources of supply and the opportunity for subjective test interpretations. FDA has been unable to correct these problems through workshops with manufacturers.

FDA has researched alternative potency tests since 1968 and obtained data on several experimental potency tests during the swine flu program vaccine clinical trials. FDA officials said that they anticipate having a more reliable and relevant potency indicator in the near future.

FDA AND MANUFACTURERS DIFFER IN POTENCY TEST RESULTS

Three of the four swine flu vaccine manufacturers consistently reported potency test results which were higher than FDA test results for the same lots of vaccine submitted to FDA under the swine flu program. For example, 1 manufacturer's test results on 49 vaccine lots submitted during 1976 showed that 47 had a higher potency value than that shown by FDA's tests, 1 had the same test results, and the remaining lot scored lower.

According to FDA officials, in assessing potency for flu vaccine released to the public, FDA tests every vaccine lot to insure that the manufacturer's vaccine is at least equal to a specified CCA value. In establishing the swine flu vaccine potency level, FDA officials consulted with CDC and National Institute of Allergy and Infectious Diseases officials. These groups agreed that based on clinical trial evidence, the potency requirement for swine flu vaccine should be 200 CCA units. The officials concluded that the clinical trials indicated that adequate antibody responses with acceptable levels of adverse reactions were generally obtained at this potency level.

We reviewed test results for about 55.5 million doses of vaccine that the manufacturers had tested and submitted to FDA for release to the public. Based on the results of its own potency tests, FDA advised the manufacturers that about 15.5 million of these doses were subpotent. In these cases the vaccine was not permitted to be released to the public. Every lot released to the public that we reviewed met FDA potency test requirements.

Potency testing on clinical trial vaccine

Potency problems encountered with vaccine lots submitted for release to the public also existed with lots used in clinical trials. One purpose of testing the vaccine in clinical trials was to establish an effective yet safe dosage level by determining antibody responses and adverse reactions to various potency values. HEW officials tested responses and adverse reactions to each manufacturer's vaccine generally

at potency levels of 200, 400, and 800 CCAs. Clinical trial instructions called for the manufacturers to supply vaccine at these levels. FDA also evaluated several vaccines with lower dosage levels for use in children, as well as another type of flu vaccine that was eventually recommended for high-risk groups.

Three of the 4 manufacturers' test results for 34 vaccine lots submitted for use in the trials showed that in every case manufacturers' potency values exceeded those determined through FDA tests. FDA tests also showed that 29 of the 34 lots were below the desired clinical trial values. For example, 1 manufacturer reported a potency value of 1,224 CCAs for a vaccine lot which, according to FDA tests, had a CCA value of 720; the lot was supposed to have a CCA value of 800. A vaccine lot designated in the clinical trials as a 220-CCA vaccine submitted by another manufacturer contained 228 CCAs based on the manufacturer's tests and only 132 CCAs based on FDA's test.

Appendix V compares manufacturer and FDA clinical trial potency test results for swine flu vaccines. None of the vaccine designated as 400 or 800 CCAs met these levels when FDA tested them. For the 400- or 800-CCA vaccines, the highest FDA potency test results were still lower than the lowest determination made by the manufacturers.

Although FDA tests on clinical trial vaccine indicated that the potency was generally lower than desired, FDA did not require manufacturers to increase the potency to the specified levels before using the vaccine in clinical trials. According to FDA officials, this would have delayed the clinical trials for almost 1 month.

FDA officials said that they had considered that the differences in potency values were to be expected as a result of test variations occurring under the conditions of testing experimental vaccines in a short time. They stated that three of the four manufacturers, based on preliminary CCA testing by the FDA, had in fact added additional antigen to these experimental vaccines. FDA officials said that a long time would be required to obtain vaccine material very close to the 200, 400, 800 estimates and this interval would have seriously delayed the clinical trials. The results of the first clinical trial with these vaccines indicated that they performed comparably over a very broad range of CCA values. They felt that the time required to obtain precise potency values with reformulated vaccines would have greatly delayed, but not changed, vaccine recommendations.

FDA SAFETY TESTS NOT PERFORMED ON ALL VACCINE BEFORE THE CLINICAL TRIALS

Safety tests performed on the swine flu vaccines included (1) a general safety test of the vaccine in animals, (2) tests for sterility and endotoxin levels, and (3) random tests to assay various vaccine ingredients or additives. Our review of selected lots of vaccine showed that FDA had routinely verified manufacturer safety test results before vaccine lots were released to the public. However, according to FDA officials, FDA did not routinely verify manufacturer test data on clinical trial vaccine before it was made available for use in trials. Our review of manufacturer test data for clinical trial vaccine lots and of lots for which FDA safety test results were available disclosed no indication of safety hazards. Still, the added protection provided to the general public by FDA verification testing of manufacturer test data was not afforded to all clinical trial participants.

General safety test

The general safety test in animals is designed to identify extraneous toxic contaminants that may have been introduced into the vaccine through the manufacturing process. The test is time-consuming, requiring a minimum of 7 days. During the test, vaccine is administered to two guinea pigs and two mice. For the vaccine to meet safety requirements, all test animals must survive, show no unexpected or irregular symptoms, and weigh no less at the end of the test period than at the beginning. If these requirements are not met in the initial test, up to two retests are allowed on the species which failed. FDA officials said that retests are allowed because failures may be caused by factors peculiar to the test animal rather than to the product.

We reviewed FDA and manufacturer general safety test results for 52 lots of swine flu vaccine intended for release to the public. Although some retesting was done, all lots ultimately passed both tests.

Other tests

FDA and manufacturer data showed that test results for sterility and endotoxin on every vaccine lot that we reviewed were satisfactory. Also random tests of some ingredients and additives did not indicate any problems.

RECOMMENDATION FOR FUTURE IMMUNIZATION PROGRAMS

Because of the weaknesses in the CCA test for potency and the continual differences in manufacturer and FDA test results, FDA should continue to perform potency tests on all lots of flu vaccine until manufacturer test results can be relied on. In addition, the Secretary, HEW, should require the Administrator, FDA, to accelerate efforts to

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

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

Also, to enhance both the accuracy of clinical trial data and the protection afforded to clinical trial participants, we recommend that the Secretary require that flu vaccine intended for clinical trial use be tested on a basis consistent with tests of vaccine intended for public use.

CHAPTER 5

POTENTIAL PROTECTION PROVIDED BY SWINE FLU VACCINE

HEW officials estimated that the swine flu vaccine would adequately protect 70 to 90 percent of those vaccinated. Potential protection was estimated based on HEW observations of the effectiveness of past vaccines and on the results of swine flu clinical trials.

The changing nature of flu viruses and problems of achieving optimal composition and timely distribution of the vaccine have made it difficult to effectively immunize against flu in the past. Previous efforts to combat pandemic flu have not been successful. The swine flu program differed from past vaccination efforts because the swine virus was isolated earlier and because the high-priority Federal mass vaccine delivery program was the first of its kind. Consequently, the potential protection provided by the swine flu vaccine is difficult to estimate based solely on previous experience.

The swine flu clinical trials measured antibody responses in individuals vaccinated. The trials did not demonstrate how well an antibody level protects against a flu attack. They did measure what percentage of individuals vaccinated would achieve an antibody level which HEW officials said would provide adequate protection. Estimating the protection provided by swine flu vaccine based on the results of these trials was complicated by problems in achieving adequate antibody responses in younger age groups and uncertainty regarding the role of one vaccine component which was inactive in the vaccine. In addition, the length of protection provided by the vaccine is uncertain.

QUESTIONABLE PROTECTION PROVIDED BY PREVIOUS FLU VACCINES

HEW officials reported that estimates of potential protection provided by swine flu vaccine were based on previous experience with flu vaccines in the United States and other countries. They stated that the effectiveness of flu vaccines against the most virulent flu virus types over the past 25 years had ranged between 67 and 90 percent protection. They added that there was no reason to assume that the swine flu vaccine would be any less effective.

Scientific literature shows considerable disagreement as to the specific degree of effectiveness of past flu virus vaccines. Although experts believe that prior flu vaccines provided some protection, estimates of effectiveness ranged from 20 to 90 percent. The degree of effectiveness of the swine flu vaccine has been questioned by some immunization program critics because of the failure of past flu vaccines to appreciably affect the course of epidemics.

Flu viruses usually undergo minor but continuous changes from year to year. The virus is unique among agents which infect man in that it can change its identity to such an extent that the specific immunity established in response to a previous infection may give little protection against a new flu virus. This change is a significant consideration because the protective value of a flu vaccine is probably related to its similarity with the invading virus. Occasionally, perhaps every 10 to 15 years, a flu virus changes significantly, rendering existing vaccine, as well as the body's defense mechanisms, virtually worthless. Flu differs from polio, smallpox, measles, and other viral diseases because the infecting virus agents for these diseases do not change.

Because of the leadtime needed for the flu vaccine manufacturing process, decisions as to vaccine composition have usually been made months before the flu season began. When the virus characteristics change after the vaccine has been manufactured, the vaccine's protective value is less than optimal by the time it is used. Even during previous pandemics, when major virus changes were detected in other parts of the world before the virus spread to the United States, vaccine production and use could not keep pace with the spread of the virus.

The Asian flu pandemic of 1957 and the Hong Kong flu pandemic of 1968-69 demonstrate the effect of major virus changes and of problems in administering vaccine in time to impede spread of the disease. Outbreaks of Asian flu were reported in China in April 1957. The pandemic circled the globe in less than a year. It peaked in the United States in November 1957. In a 1969 article 1/ addressing both the Asian flu and Hong Kong flu pandemics, the Director of the Division of

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1/R. Murray, "Production and Testing in the USA of Influenza Virus Vaccine Made from the Hong Kong Variant in 1968-69," Bulletin of the World Health Organization, vol. 41, 1969, 495 and 496.

Biologics Standards 1/ stated that, in November 1957, 49 million doses of Asian flu vaccine had been released, but because of distribution and other delays, the amount used before the peak of the Asian flu pandemic had been much less. He noted that, considering the time required to build up protection against the disease, the number of people effectively immunized was small. In the United States an estimated 69,800 deaths resulted from this pandemic.

Similarly, the Hong Kong flu pandemic was first recognized in August 1968. The pandemic peaked in the United States during the first week of January 1969, less than 4 months after the virus material necessary to produce vaccine was made available to manufacturers. At this time only 15 million doses had been released. An estimated 27,500 deaths in the United States were attributed to this virus.

The Director of the Division of Biologics Standards questioned whether the use of flu vaccine had any detectable effect on the 1957 or 1968 pandemics. He stressed that priority be given to research into the problem of making sufficient vaccine available in time to counter a threatened flu epidemic.

A group of Government virologists who reviewed experience with flu between 1957 and 1972 concluded:

> "It is generally agreed that inactivated vaccines containing the appropriate antigenic concentration in suitable potency will provide a reasonable degree of immunity for a limited period of time. This statement simply means that on some occasions the vaccine has worked and on others it has not. * * * There is no doubt that properly constituted aqueous inactivated vaccines can provide some measure of protection. How much protection they afford is open to question. Protection rates are clearly influenced by many features peculiar to the vaccine, the virus, and the host--and by methods used by the investigators."

1/FDA's Bureau of Biologics was established on July 1, 1972, at which time the Secretary, HEW, transferred the Division of Biologics Standards from the National Institutes of Health to FDA. Before July 1972 the Division of Biologics Standards was responsible for biologics regulation.

The swine flu program was the first Federal attempt to immunize the entire population before a potential flu epidemic. HEW officials believed that the resultant opportunity for optimal vaccine composition and timely mass immunization would enhance the swine flu vaccine effectiveness. HEW officials reported that, because no further outbreaks of swine flu occurred, a direct observation of effectiveness in humans has not been possible.

DIFFICULTIES IN ESTIMATING PROTECTION PROVIDED BY SWINE FLU VACCINE

The potential effectiveness of any vaccine could best be determined by challenging (deliberately exposing) vaccinees to the disease and comparing the results to those in a control group of deliberately exposed nonvaccinated persons. However, HEW officials said scientists decided that tests involving a live virus challenge with a new viral strain such as the swine flu virus are very difficult to perform and could pose a potentially serious health hazard in the United States. According to HEW officials, "Over the past decade or so there has been a general scientific consensus that antibody studies * * * not challenge experiments would be sufficient as the indicator of vaccine efficacy."

The 1976 swine vaccine clinical trials, conducted by Government-sponsored investigators, measured participants' antibody levels before and after receiving the vaccine. Though the trials did not demonstrate how well an antibody level protects against a flu attack, they did measure what level of antibody a vaccine recipient should expect to attain. According to HEW officials, an antibody level of 40 or greater should provide sufficient protection. HEW officials estimated that, based on the clinical trials, approximately 70 to 90 percent of swine flu vaccine recipients would develop antibody levels of at least 40.

Adequate protective antibody levels were not achieved in persons age 24 and under in the first phase of clinical trials. A second phase was necessary. As a result, vaccine recommendations were made late in the program for some age groups of persons age 24 and under. Also the dosage recommended to provide protection for high-risk children under age 3 was based on very limited data.

Compounding the difficulty in determining the protection provided by swine flu vaccine is that one antigenic component,

neuraminidase, which is normally active in flu vaccines, is inactive in the swine flu vaccine. The importance of this component is uncertain. In addition, because no swine flu outbreak occurred during this flu season and because swine flu may still have pandemic potential, the length of protection provided by the vaccine may be important. However, the length of protection is also uncertain.

Recommendations made late in the program for some younger age groups

The results of the initial clinical trials were reported on June 21, 1976. While both vaccine types, split and whole product, performed acceptably in groups over 24 years of age, whole product vaccines produced better, but less than the desired, antibody responses in the 18-to-24 age group. Neither vaccine was acceptable for those under 18. For this latter group, improved antibody responses were obtained with more potent concentrations of whole virus vaccine; however, the incidence and severity of adverse reactions were considered unacceptable at these levels.

The initial trials included about 1,250 children, ages 3 to 18, and over 500 young adults ages 18 through 24. Children under 3 years of age were not studied in the initial trials because of their greater susceptibility to vaccine reactions and the resultant desire of investigators to test the vaccine in older children before proceeding with this group.

The Advisory Committee on Immunization Practices did not establish vaccine recommendations for persons under age 18 based on the results of the initial trials. The Committee recommended a single dose of whole virus vaccine for persons 18 through 24, but noted a possible need for a second dose if additional trials so indicated. Consequently, HEW officials began additional clinical trials with 3,300 participants age 24 and under to determine if a second dose would create a "booster" effect resulting in an adequate protective response, yet keeping reactions to a minimum. Children under 3 were included in these tests.

Based on preliminary data from the ongoing trials, on September 17, 1976, the Advisory Committee 1/ recommended

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1/These recommendations were developed for the Advisory Committee by the Committee on Infectious Diseases of the American Academy of Pediatrics.

that high-risk children 3 to 18 years of age receive 2 doses of 200-CCA, split virus bivalent vaccine, administered at least 4 weeks apart.

Additional recommendations for those under age 24 were not made until November 19, 1976. At that time the Advisory Committee recommended

--2 half-strength (100-CCA) doses of split virus bivalent vaccine for high-risk children 6 months to 3 years of age,

--2 full-strength (200-CCA) doses of split virus monovalent vaccine for normal children ages 3 to 18, and

--a second dose of monovalent vaccine for young adults ages 18 through 24.

If the first two groups received initial vaccination during the remaining days of November, they would not have had adequate antibody protection until early to mid-January, about 2 weeks after their second vaccination. Thus, they would not have the full recommended protection until the peak of the flu season. In addition, the supply of split virus vaccine available in November was inadequate to immunize all the normal children ages 3 to 18 years.

For the young adult group the recommendation for two vaccine doses was not made until 4 months after the first vaccine recommendation. Project officials told us that some of this group may not have been made aware that they needed a second dose.

Recommended dosage for high-risk children under 3 years of age based on limited trial data

Besides the problem of timeliness, bivalent vaccine was recommended for high-risk children 6 months to 3 years of age even though no children under 3 were tested with bivalent vaccine and very limited trial data was available for children 6 months to 3 years of age especially for antibody responses. Because of the limited data in this age group and the traditional difficulty of developing vaccine for very young children, one official of the National Institute of Allergy and Infectious Diseases believed that vaccine would not be recommended for children under 3 unless an outbreak of swine flu occurred.

A total of 88 children 6 months to 3 years of age were tested using 2 doses of monovalent swine flu vaccine. Vaccines from the four manufacturers were used--two manufacturers make split virus vaccines and the other two make whole virus vaccines. Vaccine recommendations for high-risk children 6 months to 3 years of age were based on results of ongoing trials as reported on October 22, 1976. At that time, results were available for only 21 children for antibody response and 43 for adverse reactions.

The data indicated that antibody levels were adequate for children 6 months to 3 years of age with only one manufacturer's split virus vaccine. However, antibody response data for this vaccine was available with respect to only five children. Vaccine of the other split virus vaccine manufacturer provided an acceptable antibody response in only two of the five children for which antibody responses were available. Adverse reactions were unacceptable for the whole virus vaccines.

The vaccine recommendations for high-risk children 6 months to 3 years of age were made by the Advisory Committee although the advice of the Committee on Infectious Diseases of the American Academy of Pediatrics was obtained. With regard to the recommendations for this age group, the Chairperson of the Committee on Infectious Diseases stated that:

--The extreme risk to this age group if a flu outbreak occurred outweighed the potential adverse reactions from the vaccine.

--Even though children under 3 had not been tested with bivalent vaccines, the Committee believed that if the children could tolerate monovalent vaccine, they could also tolerate bivalent.

--The Committee believed most children would receive the split virus bivalent vaccine which produced the best antibody response. 1/

The importance of neuraminidase is uncertain

In an effective vaccine, antigens stimulate the production of antibodies which can neutralize or inhibit the spread

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1/The manufacturer of this vaccine produced about 27 million doses as opposed to about 6.8 million for the other split virus vaccine manufacturer.

of a virus. Many experts believe that an ideal flu vaccine should contain both hemagglutinin and neuraminidase antigens so that the body might build antibodies against both. Although the role of neuraminidase is not well defined, hemagglutinin is considered more important.

Hemagglutinin works to help prevent the contraction of flu infection. Experts believe that neuraminidase probably helps prevent the spread of infection and reduce the severity of any infection that occurs.

Unlike previous flu vaccines, the swine flu vaccine has a relatively inactive neuraminidase component. A CDC official said that the seed virus, which cultivates the primary ingredient of flu vaccine, used by each of the manufacturers had readily detectable levels of neuraminidase before production. However, he did not believe that a manufacturing deficiency caused the inactivity of the neuraminidase component. He believed that the neuraminidase antigen of the swine virus is unstable and loses its activity during the vaccine production process.

Flu vaccine experts would prefer to have a vaccine with an active neuraminidase component; however, an HEW official pointed out that the hemagglutinin component is more important and might provide adequate protection by itself.

Several laboratory and animal studies support this observation. These studies show that hemagglutinin antibodies directly neutralize the flu virus. Vaccine containing only hemagglutinin was given to animals and produced almost 100-percent protection. When vaccine containing only neuraminidase was given to animals, protection was significant but less than that with hemagglutinin.

We could not identify any studies isolating the hemagglutinin effect in man. One study that attempted to isolate the effect of neuraminidase in man disclosed that it produced about 50-percent protection.

FDA and CDC officials said that they have no plans to increase the neuraminidase activity in the swine flu vaccine. Consequently, the role of neuraminidase and the question of whether it will be added to the swine flu vaccine should the vaccine be used again next year are uncertain.

Uncertain duration of protection provided by swine flu vaccine

Opinions vary on how long the flu vaccine might provide protection. A manual of diagnosis and therapy, published by one of the flu vaccine manufacturers, states that immunity provided by vaccination lasts only 1 year.

An official of the National Institute of Allergy and Infectious Diseases said that the usual figure given for length of protection is 1 year. However, he referred to studies which showed results ranging from little protection after the first year to good protection after 2 or 3 years. The official noted that although antibody levels of 20 or 40 are generally associated with resistance based on past experience, it is very difficult to define a protective antibody level.

A CDC official stated that the length of time an antibody response of 40 would provide protection depends on the previous priming or exposure of those vaccinated. He said that children would not have continued protection; whereas, older population groups that had previous exposure should have longer protection--at least through the next year. However, this official noted that certain studies indicate that a substantial number of persons would have some protection after as many as 3 years.

In February 1977 CDC reported that:

"Some decline in antibody titers [measures of antibody response] resulting from swine flu vaccination is expected, but is not expected to be large.

"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 $\geq$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 $\geq$40 declined from 97 percent to 73 percent. Titers of $\geq$20 were virtually unchanged.

> "While many infections are thought to be prevented by a titer of at least 20, a titer of $\geq$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."

Other past pronouncements and scientific literature offer little support for expecting the vaccine to provide adequate protection beyond 1 year.

The length of protection 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.

CHAPTER 6

VACCINE PRODUCTION

HEW estimated in late March 1976 that vaccine manufacturers could produce and deliver 200 million doses by the end of November. However, between June and August after production had begun, there were serious concerns as to whether vaccine would be available to start the program at all. Manufacturers had been unable to satisfy needs for liability insurance and had threatened to stop production and withhold existing supplies of vaccine.

The liability issue was resolved for the swine flu program with the passage of legislation on August 12, 1976. (See p. 18.) Only one manufacturer had stopped production, and then only for a short time. However, total production, about 157 million doses, fell short of the original estimates by about 43 million doses. The one manufacturer that had stopped production was the only one that produced more vaccine than originally estimated.

The total period of vaccine production required about 2 months longer than estimated. Delivery of the initial supplies of vaccine to immunization projects was delayed from July to October.

Only about 25 million doses were available for distribution by October 1. By December 1 fewer than 112 million doses had been shipped to the States and other projects. Thus, if swine flu outbreaks followed by an epidemic had occurred, vaccine was available to immunize about 12 percent of the population by October 1 and only about 53 percent by December 1. As in the case of previous pandemics, too little vaccine would have been available too late, but for different reasons. (See pp. 39 and 40.)

ESTIMATED QUANTITIES OF VACCINE NEEDED

HEW's initial cumulative vaccine production and distribution target dates called for:

--8 million doses by July 9.

--120 million doses by September 3.

--200 million doses by October 29.

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The schedules were revised slightly when HEW issued a request for vaccine production proposals on May 27. The request asked for proposals to supply vaccine at a maximum of 160 million doses of monovalent swine flu vaccine and a maximum of 40 million doses of bivalent swine and Victoria flu vaccine. The request included schedules providing for delivering vaccine in 100,000-dose increments beginning in July, with both monovalent and bivalent to be produced and shipped concurrently. Thereafter, bivalent was to be delivered as soon as possible but no later than September 1. Seventy-five percent of the minimum guaranteed amount of monovalent vaccine was to be delivered by September 1; complete deliveries were to be made on or before November 15.

QUANTITIES OF VACCINE PRODUCED DID NOT MEET PROGRAM GOALS

The first indication that manufacturers would not be able to produce the desired quantities occurred in June. At that time the manufacturers submitted their first formal proposals for vaccine production and delivery. The proposals included estimates showing that only about 80 million doses could be produced by October 1, with delivery starting in July, and that 146.7 million doses could be available by December 1.

Revised proposals were submitted in August and September, but estimated quantities of vaccine to be available decreased rather than increased.

The August proposals showed that only 20 million doses could be available by October 1 and that only about 113 million doses could be available by December 1. These estimates reduced the June estimates by almost 75 percent for the amount of vaccine expected by October 1 and by almost 25 percent for the amount expected to be produced for the entire program. The estimates were also about 43 percent lower than the estimated 200 million doses needed to immunize the entire population.

HEW officials noted that the supply proposed in August was clearly insufficient to meet the target date for immunizing the entire population by mid-November. Therefore the Secretary of HEW urged manufacturers to increase the supply as soon as possible. HEW agreed to support any level of effort by the manufacturers necessary to increase the supply. HEW also agreed to extend the production period and to accept deliveries through January 15, 1977.

Vaccine availability estimates included in letter contracts signed as of September 22, 1976, showed a further decrease in the supply by mid-November. The estimates were lowered to 108.9 million doses by December 1; deliveries were to begin in October 1976. Even with production time extended to January 15, manufacturers again estimated that they could produce only 146.7 million doses, as estimated in the June proposal.

In September HEW lowered its estimate of need for vaccine from 200 million doses to 160 million. The reduction was largely based on public attitude surveys taken in August, which showed that only about 53 percent of the population over 18 years of age planned to be immunized.

During congressional testimony on September 13, three of the four vaccine manufacturers stated that their total production capabilities had been committed to producing swine flu vaccine. The fourth manufacturer had stopped production for a short time because its June production estimates had been met. As previously stated, however, this manufacturer subsequently produced additional vaccine and was the only company that exceeded its original June estimate.

The inability of manufacturers to produce the desired quantities was attributed principally to these intervening and unforeseen circumstances:

--A less-then-expected yield per egg.

--A mistake resulting in one manufacturer producing about 6 million doses of an incorrect vaccine.

Vaccine yield per egg was less than expected

Simply stated, production involves innoculating fertile eggs with seed virus. After several days, the virus-rich embryonic fluids are harvested. The virus is purified, concentrated, and inactivated. Finally, the inactivated virus concentrate is diluted so that the end product will be of a specified strength or will contain a specific amount of viral antigen per dose. Thus, the dose yield per egg depends not only on the biological process of virus developing in the embryo, but also on the strength specified. The production cycle of a particular batch of vaccine takes about 2 months.

The proper strength for a new type of flu virus vaccine is determined through clinical trials. These trials involve testing a range of strengths in volunteers to determine which strength gives the best antibody response with the least rate of adverse reactions. Although the initial clinical trials for the swine flu program were not completed until June 1976, in April HEW estimated a yield of about two doses per egg. This estimate was based largely on experience with production of flu vaccines and preliminary information about the swine flu vaccine.

At least one manufacturer attributed the vaccine production problem to a less-than-expected yield per egg. This manufacturer noted that the actual yield had averaged a maximum of only 1.3 doses per egg and that this had adversely affected the total amount of vaccine the company could produce within the HEW time frame. HEW's contracting officer said the other three manufacturers had also reported a lower yield per egg than the estimated two doses.

During congressional testimony in September 1976, the Assistant Secretary for Health stated that though HEW was aware of problems with yield per egg, which some manufactureres were experiencing from time to time, most of these had been reported as resolved satisfactorily.

Because of the biological nature of dosage yield per egg, we determined neither the validity of the factors which influenced dosage yield per egg nor its actual effect on the quantities of vaccine produced. (See ch. 4.)

<u>One manufacturer produced about 6 million doses of an incorrect vaccine</u>

One manufacturer mistakenly produced about 6 million doses of a different swine flu vaccine. The vaccine produced (called Shope strain) was developed from a 1931 swine flu virus strain which is related to, but different from, the swine flu virus isolated during the Fort Dix outbreak.

HEW concluded that the Shope virus vaccine could not be recommended for use in the swine flu program because it did not produce the same level of antibodies as did the swine flu vaccine. The Shope vaccine was not to be offered to the public except under extreme emergency conditions--in the event of an epidemic in which all the swine flu vaccine had been exhausted. If needed, this vaccine would have been used for persons over 35 years

of age. The production of 6 million doses of Shope vaccine by mistake delayed the availability and reduced the expected quantity of the manufacturer's swine flu vaccine.

AVAILABLE VACCINE WAS NOT RELEASED

To make immunization available to all Americans, swine flu program strategies and timetables called for vaccine to be delivered between July 9 and November 15, 1976. Although some vaccine had been produced, none was made available for use in July. As previously discussed, manufacturers were unwilling to furnish vaccine for the swine flu program without adequate liability protection. Also HEW did not provide manufacturers specific information pertaining to vaccine formulas, packaging inserts, and delivery specifications before the planned July starting date. Manufacturers claimed this had inhibited their ability to provide vaccine as planned.

Liability protection was provided by the Congress through Public Law 94-380 on August 12, 1976, and HEW provided contract and cost specifications to the manufacturers by early September. Vaccine was finally released by the manufacturers for use on October 1--about 3 months after the planned starting date for immunization phase of the swine flu program. The October 1 release date was used because Public Law 94-380 provided that liability claims could not be filed against the United States until after September 30, 1976.

Untimely decisions on vaccine formulas, packaging inserts, and delivery specifications

Three of the four manufacturers testified before the Subcommittee on Health and the Environment, House Committee on Interstate and Foreign Commerce, on September 13, 1976, that to meet vaccine quantity and delivery schedules proposed in June, HEW's decisions on vaccine formulas and packaging inserts should have been made available by mid-July 1976. The manufacturers pointed out that these decisions were essential before they could prepare, label, or deliver finished vaccine.

Because of the need to have the vaccine tested, manufactured, and delivered within a short time, HEW assumed many responsibilities for which manufacturers are normally responsible. These responsibilities included, but were not limited to:

--The investigation and determination of the safe and effective dosage and adequate directions for using vaccine.

--The investigation and determination of the risk and benefits of innoculation with the vacine and the development of an adequate statement on the risk and benefits.

--The content of the labeling of the vaccine, including its compliance with laws and regulations.

Accordingly, HEW was responsible for furnishing manufacturers specific requirements for vaccine formulas, labeling, packaging, and logistics of delivery. The CDC contracting officer said that normally this information would be provided in the request for vaccine production proposals. However, the request was issued on May 27, 1976, without some of the final specifications, and several amendments to the request were made after it was issued. For instance:

--The request did not contain specific vaccine formulas (i.e., CCA strength per dose), and this information was not available until late July, after the initial clinical trials had been completed and evaluated. Since the formulas were not available, the requests for proposals asked the manufacturers to submit proposals showing estimated vaccine volume and deliveries based on each of the three vaccine formulas (200, 400, and 800 CCAs) used in the clinical trials. (See pp. 34 and 35.) However, manufacturers could not prepare vaccine of appropriate strength for release without the formulas.

--Package inserts were not finalized and furnished to the manufacturers until September 1976. These inserts showed risk and benefits associated with the vaccine and could not be prepared until the clinical trials had been completed. Package inserts were required for each shipment of vaccine.

Some manufacturers also claimed that HEW's delay in providing final contract terms--including quantities--adversely affected vaccine availability. Though the technical terms of the contract--pertaining to packaging, labeling, and shipping--might have caused delays in release of vaccine, there is no indication that the absence of a contract adversely affected production of vaccine.

The manufacturers initiated production by late March 1976. Although they had no formal commitments from the Government on standards, quantities to be produced, or final terms of purchase contracts, they knew there would be no competitive bids for vaccine. They also knew that CDC planned to purchase all swine flu vaccine the manufacturers could produce and that vaccine would have to be procured within a very short time for it to reach the population before the coming flu season.

HEW initially planned to award contracts to the four manufacturers by May 28, 1976. However, because of liability problems, letter contracts providing for deliveries of vaccine and for payment on a provisional basis were finally signed in September 1976. Final contracts had not been signed as of June 16, 1977.

INSUFFICIENT QUANTITY OF VACCINE TO PROTECT ALL CHILDREN UNDER 18 YEARS OF AGE

Because of the limited quantity of vaccine suitable for immunizing normal (not high-risk) children 3 to 18 years of age, less than 10 percent could have been immunized. Consequently, no mass immunization of this age group was attempted.

Two full-strength (200-CCA units) doses of split virus monovalent vaccine were recommended for this group on November 19, 1976. The 2 manufacturers of split virus vaccine produced about 44.7 million doses, of which about 9.8 million doses were in monovalent form. Thus, the necessity for a 2-dose regimen to achieve the desired antibody response dictated that fewer than 5 million of the estimated 58 million normally healthy children ages 3 to 18 could be immunized.

RECOMMENDATION FOR FUTURE IMMUNIZATION PROGRAMS

HEW must determine vaccine formulation and packaging and delivery specifications in a timely fashion if vaccine delivery is to meet necessary schedules. If manufacturers still cannot produce enough vaccine in time to meet the delivery schedules, we recommend that the Secretary, HEW, seek alternative procurement methods. Such methods might include plans for (1) standby facilities at other drug-manufacturing plants and (2) standby Federal production facilities.

CHAPTER 7

PROJECT READINESS AND IMPLEMENTATION

Each swine flu grant project offered immunization to anyone for whom the vaccine was not contraindicated. However, due to the lack of swine flu activity and a less-than-expected demand for vaccine, the Nation's system for mass immunization was not fully tested. Some problems surfaced in planning and implementing swine flu immunizations at the project level which should be considered for any future mass immunization programs.

Immunization projects were not ready to begin in July as planned and were unable to fully implement program strategies. State and local public health structures demonstrated varying degrees of willingness to respond to the potential national health threat from swine flu. Project readiness and implementation were limited by:

--Less than full commitment by some project directors.

--Complex, incomplete, and late vaccine recommendations.

--Limited initial quantities and delayed delivery of vaccine.

--Less-than-expected participation by private medicine, other health care providers, and volunteers.

--Weaknesses in project operations.

--Lack of State liability insurance.

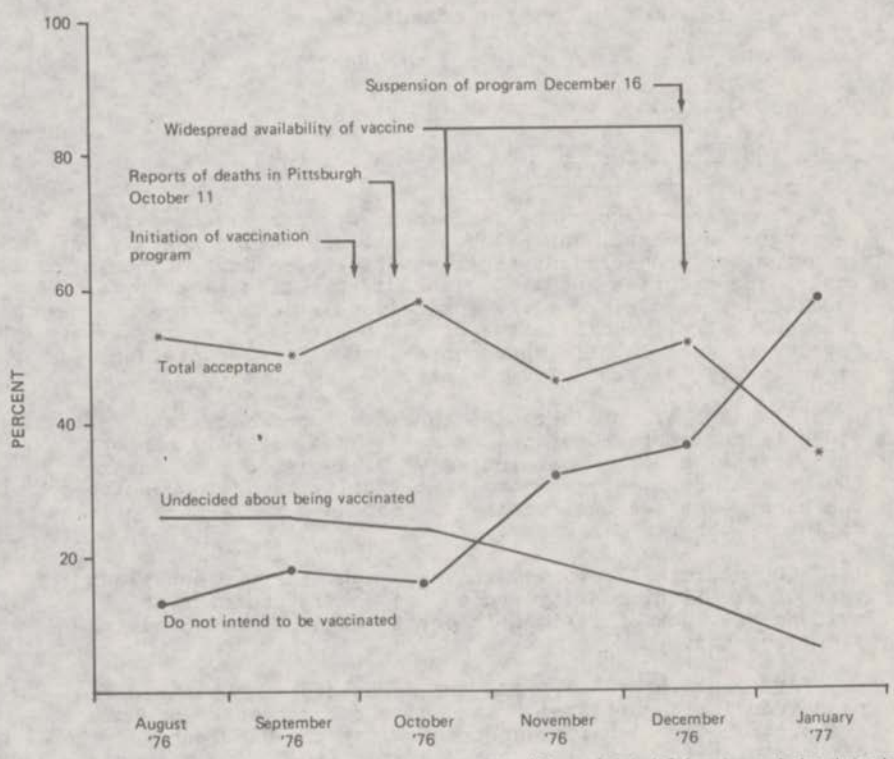
DEMAND FOR VACCINE WAS LESS THAN EXPECTED

The original intent of the swine flu program was to immunize every person in the United States for whom the vaccine was not contraindicated. However, when the program was suspended on December 16, 1976, only about 22 percent of the total population had been immunized. Even so, an HEW official noted that the 45 million immunizations was the greatest number ever given in a 2-1/2-month period.

Public opinion surveys taken monthly during the swine flu program showed that almost everyone was aware of the program. However, the surveys showed also that the number of people who did not intend to be vaccinated increased continuously and overall acceptance of the program declined after immunization began in October. The following chart developed for CDC summarizes the survey results.

Figure 1

PUBLIC ATTITUDES TOWARD VACCINATION AGAINST SWINE FLU
AUGUST 1976–JANUARY 1977
UNITED STATES



Source: Opinion Research Corporation national sample of adult population (18+ years) in the U.S. Interviews took place during the first 10-14 days of the months indicated.

Reasons frequently given during the surveys for non-acceptance of the program were that

--the vaccination was not necessary,

--there could be adverse effects,

--the vaccination would not prevent flu, or

--the vaccine could cause flu.

LESS THAN FULL COMMITMENT
BY SOME PROJECT DIRECTORS

Commitment of project leadership was perceived essential to program success. The national strategy relied heavily on immunization projects for their experience in conducting immunization programs and as logical distribution centers for vaccine. Vaccination of the entire population by mid-November depended on full mobilization of all health delivery systems--both private and public--under the general leadership and direction of the project directors.

Although all project directors developed acceptable plans and obtained approved grants, some did not actively support the national program--particularly the decision to immunize the general population. Some openly criticized or questioned the need for a national program to the news media and to local community program directors.

CDC officials reported that, though many project plans were of excellent quality, some project directors clearly evidenced a lack of serious intent to conduct mass immunization programs.

At least three State project directors deemphasized the mass immunization program. Each director seemed to support the program for high-risk groups because the bivalent vaccine offered protection against the Victoria flu. Each director believed Victoria flu would be the prevalent strain in the 1976-77 flu season.

One of the three State projects received a grant for about $700,000 in June 1976. The grant was awarded based on plans to immunize about 1.5 million high-risk persons and 4.2 million other susceptibles. On July 7, 1976, the project director issued a news release stating that high-risk individuals should be immunized and that vaccine would be available for others who wanted it. Although the director

did not rule out the possibility of a swine flu epidemic, he said the evidence indicated that seeding for the swine flu virus had not occurred. The news release added that, based on present information, the likelihood of a swine flu epidemic during the 1976-77 flu season was low and that immunization would probably have to be repeated next year if the threat of swine flu still existed.

Another State project, after receiving an immunization grant of about $400,000, issued a statement that emphasis would be placed on immunizing only high-risk individuals. Remaining susceptibles would be immunized in regular clinics, at their request, with minimum effort to encourage them to do so. CDC officials who reviewed the flu program in this State reported that counties were not carrying out community-wide immunization programs. The Director of CDC, in a letter to the project director, expressed concerns about the project director's commitment to the national immunization effort and the appropriate use of Federal funds.

A third State project submitted plans for immunizing 75 to 90 percent of the State's population and received an immunization grant for about $500,000. Shortly after requesting the grant, the project director issued the following instructions to local health officers and district flu coordinators responsible for carrying out community programs.

> "* * * Let's not encourage people to get shots, [we] can't really say [the shots are] * * * absolutely necessary, and you don't need more work than CDC will generate for you. But, must push to inform [the] public that they will have reactions and may even get the flu in spite of [the] campaign (different kind of flu). * * *"

In a letter to the State nurses association--a prime source for volunteers--the project director said that the possibility of swine flu becoming epidemic during 1976 was not overwhelming.

COMPLEX, INCOMPLETE, AND
LATE VACCINE RECOMMENDATIONS

Project directors were limited in their ability to develop strategies for immunizing population groups under 25 years of age. Throughout the planning stages of the program--April through September--there were no firm dosage recommendations for these groups. Dosage recommendations made in September and November were complex and difficult to

manage and were received too late to effectively protect these groups before the season of intense flu activity. (See pp. 42 and 43.)

The complicated and incomplete vaccine recommendations which existed throughout the program caused project directors difficulties in administering vaccine and in informing the public on proper dosage requirements. Contrary to experience in most years when vaccine recommendations were the same for everyone, the swine flu program had two formulations of vaccine (bivalent and monovalent), two types of each formulation (whole and split virus), and different dosage recommendations involving both formulations and types for specific age groups and doses for some age groups had to be administered over an extended period.

To further complicate matters, the Committee on Infectious Disease of the American Academy of Pediatrics had issued a precaution against using whole virus vaccine for high-risk children ages 3 to 18. The Committee stated in September 1976 that if whole virus vaccine were used, side effects would be greatly accentuated. However, the labeling on individual vials of vaccine shipped to immunization projects did not indicate whether the vaccine was whole or split.

The first of two clinical trials to determine vaccine dosage recommendations was completed in June 1976. The first trials did not produce dosage recommendations for the under-18 age groups and produced only partial recommendations for the 18-through-24 age groups. The second trials resulted in vaccine recommendations for virtually all age groups, but not until mid-November 1976--or almost 2 months after immunizations began. (See pp. 41 and 42.)

Although dosage recommendations were incomplete, CDC encouraged planning for immunizing all age groups. Thus, some project directors developed strategies for coordinating the swine flu program with back-to-school immunization and assessment programs. These plans were changed because a safe and effective dosage had not been determined for normal (not high-risk) children when immunizations began on October 1.

Further, based on the July recommendation, project directors had to develop procedures for informing and educating the 18-through-24 age groups about the need for one dose and a possible need for a second dose at a later unspecified time. The under-18 age groups had to be informed that no dosage recommendations had been made for them but that one might be made later. When recommendations were received for essentially

all age groups in September and November, project directors had to develop procedures for informing and educating the under-25 age groups about the recommendations and for administering vaccine doses at least 4 weeks apart.

Because the recommendation for normal children ages 3 to 18 was not made until November 19, 1976, insufficient time was available to protect them before the predicted flu season. Because of the lack of sufficient quantities of vaccine, inherent problems in administering a two-dose regimen, and the fact that normal children generally do not suffer severe complications from flu, HEW did not encourage community-wide programs for this age group.

Fewer than 4 million of the approximately 27 million young adults (both high-risk and normal) in the 18-through-24 age group had been vaccinated by November 19 when the recommendation for a 2-dose regimen 4 weeks apart was made. Assuming that immunization project directors could adjust or develop strategies and schedules to reach this age group in such settings as schools, colleges, and industry, the group still would not have received full protection until late December, or well into the predicted flu season.

LIMITED INITIAL QUANTITIES AND DELAYED DELIVERY OF VACCINE

Project directors could not implement approved plans for achieving a complete readiness status because of the uncertainties concerning vaccine availability. A basic assumption in developing program strategies for immunizing the population before the next flu season was that adequate vaccine supplies would be available to start programs in July 1976. Vaccine was not made available to immunization projects until October 1. From June through late September, delivery dates and quantities of vaccine were uncertain. Both vaccine production estimates and delivery dates were changed several times during this period.

The uncertainties surrounding vaccine availability inhibited the ability of immunization project coordinators to make firm commitments for (1) program strategies, (2) staffing, (3) clinic locations and dates, and (4) promotional publicity.

Project strategies required repeated modification

Delays in delivery dates and subsequent decreases in vaccine quantities (see ch. 6) invalidated many project strategies and timetables. Immunization schedules were shortened, and gradually accelerating programs, planned for July through November 1976, were changed to shorter, high-intensity programs beginning in October 1976. Two-phased strategies planned in many projects were merged into single-phased operations, and some project strategies that called for organized State teams to carry out immunization on a county-by-county basis were changed to county-operated programs.

To immunize the entire population by the end of November, most State and local health agencies planned large-scale, communitywide mass immunization programs. To reach all the population, private medical resources and other health care delivery systems were also considered essential. By June 17, 1976, the projects had developed acceptable plans and received grants totaling about $24.2 million to carry out their immunization programs.

Most project plans called for a two-phased program. The first phase was designed to begin immunizing high-risk groups in mid-July, and the second phase, directed at the remaining population, was scheduled to start in September. Project plans provided for delivering vaccine to high-risk groups through private physicians, nursing homes, retirement homes, special clinics for the aged, and health departments. The second phase included using organized settings, such as clinics, schools, industries, nursing and medical facilities, private physicians' offices, and health departments plus shopping centers and other places where large groups of people could be reached.

Immunization strategies varied significantly among projects. Some projects chose to form central or regional immunization teams to travel from community to community conducting immunization clincs. Other projects either relied on existing health care delivery systems and completely delegated planning, organization, and implementation to local health jurisdications or used a combination or variation of the above strategies.

Officials at some projects reviewed had adopted a "wait and see" attitude in August and September 1976 even though vaccine had been promised for October 1, 1976. The general

feeling among project directors was that the type of program eventually run would depend on when and how much vaccine would become available and who would be recommended for immunization. Some directors pointed out that continually changing the program was counterproductive to the immunization goals.

Of the 63 projects, 48 requested $1.6 million in supplemental grants. Many offered justifications based on program modifications caused by vaccine delivery delays and related uncertainties.

Staffing delayed because of nonavailability of vaccine

Although swine flu vaccine use was scheduled to begin in July 1976, some projects had not recruited and trained staffs as late as August or September because of uncertainties surrounding vaccine availability.

All projects reviewed planned to use existing State and local health department employees for key positions and to supplement them with temporary employees. However, in four of the five projects reviewed, temporary staffing had not been completed.

Each of the four project directors told us that staffing had been delayed pending firm data on vaccine availability. The directors said that if their programs had been staffed early based on initial plans for vaccine deliveries, they would have exhausted existing grant funds before--or shortly after--program implementation. Another director, who had recruited and formed staff in August 1976, stated that staffing funds would be spent by December 1976.

At least 12 project directors ultimately requested supplemental grant funds totaling about $184,000 for local staffing. Also one other project obtained direct personnel assistance from CDC valued at about $2,800. Justification for many of these supplemental assistance requests was based on vaccine delays, decreases in vaccine quantity, and extension of the program.

Clinic locations and dates could not be finalized

County coordinators were primarily responsible for scheduling and publicizing clinic sites and dates. Although some tentative site schedules were established in August and September 1976, coordinators told us that firm schedules could not be made until vaccine quantity and flow had been firmly established.

Some coordinators who scheduled clinics without specific advance information on vaccine availability had to cancel and reschedule them when quantities were found to be less than expected. For example:

--Many counties which planned clinics beginning from mid-September through early October had to cancel and reschedule them as vaccine became available.

--Some projects had to change original plans to use schools as organized settings for mass immunizations because of uncertain vaccine recommendations for the younger age groups.

--A massive "Flu Sunday" scheduled for a metropolitan area in October 1976 had to be delayed until November.

Public awareness activities restricted

Uncertainties and delays in receiving vaccine and vaccine dosage recommendations severely limited promotional activities within most projects. Also, because of concerns about the liability issue, supplemental national publicity was untimely. HEW and the projects published very little positive, timely promotional information to offset negative or conflicting publicity in the news media about the need for the program, adverse reactions, and deaths associated with vaccination.

Project publicity activities restricted

Many project directors did not initiate multimedia publicity campaigns until early October 1976 or later, when vaccine was available to begin mass immunization. Some directors pointed out that it would be counterproductive to promote the program and then have to cancel clinics or be unable to meet demand for vaccine. They chose instead to begin their public awareness efforts slowly so that demand would not outstrip the limited supply. One project, which planned to begin its multimedia campaign in August 1976, spent about $2,600 for advertising clinic locations and dates which later had to be rescheduled.

Recognizing the promotional problems, CDC made additional grant funds available to the projects in November to launch promotional campaigns. Although some States obtained supplemental grants for publicity in November and December 1976, the program was suspended on December 16 because of adverse reactions to the vaccine.

Untimely supplemental national publicity

To achieve public awareness and promote demand for the vaccine, CDC planned to work with the Advertising Council, Incorporated, to develop a motivational theme and informational and promotional material to be used in national, State, and local publicity campaigns. CDC intended to give State and local health agencies this material before immunization began. However, material prepared by the council was not disseminated to the States and media until late November 1976.

The council is a nonprofit advertising organization representing some of the largest advertising agencies across the country. The council assists in publicity campaigns which meet its criteria of public service, including programs of nonprofit and nonpolitical intent.

In March 1976 the council offered to help develop the promotional and informational material required. However, the advertising agency assigned to develop the material was also providing promotional services to one of the vaccine manufacturers. In addition, the council was concerned that it too could be held liable in suits alleging failure of a program participant to provide adequate informed consent.

On July 22, 1976, CDC and the council agreed to terminate their contract because the manufacturers' liability issue had not been resolved. The council had not developed any publicity material when the contract was terminated.

When the liability issue was resolved in August 1976, the council again offered its services to CDC. However, a contract for these services was not finalized until October 4, after States had begun immunization programs. During October the council's publicity effort had to be redirected from promoting the program to responding to adverse and conflicting publicity. Thus, material prepared by the council was not disseminated to the States and media until late November 1976--almost 2 months after immunizations began.

Untimely response to negative publicity associated with adverse reactions

CDC's national publicity objectives were to (1) inform the public of the potential for a swine flu epidemic and (2) motivate the public to be immunized. These objectives would be met through organized generation and release of

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information to program participants and the media and through responses to media inquiries. However, between beginning immunizations on October 1, 1976, and late November 1976, when the council's material became available, CDC's publicity was often limited to responding to media inquiries concerning crises that arose, such as publicity associating deaths with the immunization program.

When the council's initial contract was terminated on July 22, 1976, no publicity material had been developed. CDC, with some assistance from two consultants, assumed the added responsibility of developing the material, including television and radio advertisements, posters, newspaper layouts, and slide presentations. This material was disseminated to the States before the immunization phase of the program began on October 1, 1976.

CDC officials stated that publicity efforts were adequate up to the occurrence of deaths during October 1976, which were initially attributed to the program. An HEW official said that CDC knew that some individuals who had been vaccinated would die within a short time due to other causes. However, CDC had not developed the quantity, variety, and quality of material needed to immediately counter the adverse publicity that resulted. Therefore, CDC could not provide the projects facts to respond to initial media inquiries.

Many States did not have the facts to counter the adverse publicity. Some projects responded by closing their clinics, which further fostered suspicions concerning the safety of the vaccine.

LESS-THAN-EXPECTED PARTICIPATION BY PRIVATE MEDICINE, OTHER HEALTH CARE PROVIDERS, AND VOLUNTEERS

In developing the national strategy, HEW noted that involvement by private medicine, other health care providers, and volunteers was essential for reaching all groups of people. Most projects planned for extensive participation by these groups. In general, however, participation by these groups was less than expected.

Limited participation by private medicine

To stimulate interest, support, and participation of private physicians, representatives of medical societies were appointed to project advisory committees, flu facts and other

educational materials were published in physicians' bulletins, and State and county flu coordinators contacted physicians directly. Also CDC contacted national medical associations to obtain their support and participation. However, CDC's medical professional liaison stated that no national medical organization had ever formally endorsed the program. In only two of the five projects reviewed did a State medical society generally endorse the flu program and encourage its members to participate.

CDC coordinators and some immunization project directors reported that cooperation and participation from private medicine was generally less than expected. They said physicians were reluctant to participate because of the many uncertainties and controversies over issues such as liability coverage; rationale for the program; complex dosage recommendations; safety and efficacy of the vaccine; complicated informed consent requirements; and confusing labeling, which did not distinguish between the types of vaccine.

In many projects, active participation in mass immunization clinics was minimal and some physicians even discouraged their patients from being vaccinated. For example:

--One county originally intended to have private physicians conduct the entire program, including the mass immunization clinics. However, private physicians withdrew their support because of their concern over liability coverage. The program was ultimately conducted by county health personnel.

--Only about 400 of the 1,900 physicians expected to participate in 1 city requested vaccine, and 106 of them requested 50 doses or less. In another city about 380 of the estimated 1,000 physicians requested vaccine.

--In 3 counties of 1 State, fewer than 200 of about 1,500 physicians requested vaccine.

Participation by other health care providers was less than expected

HEW anticipated using nursing homes, hospitals, retirement homes, and industries to immunize their patients and employees. These organizations offered a setting in which large groups of people could be reached. Most immunization projects planned to make full use of these organizations.

In some projects participation by these organizations was less than expected. For example, less than 55 percent of one project's industries, nursing homes, and senior citizen centers responded to the initial request to provide vaccinations. Because of the low response, project health department personnel provided vaccinations at many nursing homes and senior citizen centers. CDC officials reported that concern over liability coverage, informed consent, and deaths associated with the vaccine diminished initial commitments. They noted that many industries which were originally willing to vaccinate their own employees decided instead to send them to public clinics.

Vaccine availability lessened the extent of involvement by health care providers. Some projects could not or did not make vaccine available to industries in the quantities requested until mid-October or later. These projects discovered that earlier demands of some industries had waned. For example, as of November 1976, one county had allocated about 98 percent of all the vaccine it had received. The county could not meet requests from private industries for 80,000 doses. One industry originally requested 20,000 doses, but rejected the 6,000 doses offered because this limited amount could not meet anticipated demand. When excess vaccine became available, demand had decreased and the request was retracted.

Volunteer support was less than expected

Most projects developed plans for establishing a corps of volunteers to assist in all phases of the program. CDC coordinators for immunization projects stated that uncertainties concerning vaccine delivery and recommendations had led to a loss of trained volunteers and disenchantment of large volunteer organizations, such as the Red Cross.

Two counties visited did not plan weekend and holiday clinics due to a lack of volunteers. Clinics in these counties were limited to weekdays when enough volunteers were willing to participate. Other clinics had fewer volunteers than originally planned, but enough for the small number of persons desiring immunization. Some clinics visited did not have enough trained volunteers to assist in all phases of operations as planned. Some counties originally planned for 24 to 30 registered nurses and other volunteers at each clinic. Due to the reduced demand for vaccine, original estimates were reduced to 5 to 8 registered nurses and 15 other volunteers. In one county, only three registered nurses and two other volunteers showed up at one clinic

visited. Another two volunteers were pulled from the line of persons waiting to be vaccinated. Because of the reduced number of volunteers, the three jet injectors at the clinic site were not in constant use and vaccinees were required to stand in line for up to 1 hour.

OTHER WEAKNESSES IN PROJECT OPERATIONS

Our review of 5 projects and 26 clinics together with monitoring data available from CDC also identified the following weaknesses:

--Some projects and counties limited clinic operations to local health departments and neighborhood clinics, with disappointing results.

--Some projects, counties, and clinics did not comply with informed consent procedures and could not account for all vaccine used or wasted.

Inaccessible clinic sites reduced public participation

CDC reported that clinic accessibility is a key factor in delivering services. Accessibility is largely a product of clinic location and the hours of operation. Clinics held on weekdays in health departments and neighborhood centers were generally less productive than clinics held on weekends and at night in shopping centers and other natural gathering places.

Clinics conducted on weekends seemed most successful for reaching large numbers of vaccinees in many urban areas. CDC reported that many areas conducted followup weekend clinics which were usually as productive as the initial ones.

In four metropolitan counties in one State project reviewed, almost half as many persons were vaccinated on one Saturday in November as had been vaccinated during the entire first 6 weeks of the program. However, CDC reported that this metropolitan area had not established consecutive weekend clinics and had lost the momentum generated, which had limited participation. In another major city, over 16,500 persons were vaccinated during 1 weekend. A followup clinic accounted for over 18,200 vaccinations. Combined, the vaccinations given on these two weekends accounted for over 10 percent of all vaccinations given during the city's program.

A suburban county visited held weekend clinics at neighborhood schools with varying degrees of success by geographic area. On a given weekend some school clinics vaccinated 3,000 or more persons while others vaccinated fewer than 200. The only clinic this county held in a shopping center was on a Friday and Saturday in November, when over 4,600 persons were immunized. Also 2 weekday clinics held at a neighborhood center and a school in a metropolitan city averaged fewer than 50 vaccinations a day. Each clinic was staffed with at least eight health department employees who spent most of their time in relative inactivity.

In addition, a CDC official said other factors, such as economic and racial background, had affected vaccine acceptance. However, CDC felt that clinic accessibility could be readily identified and dealt with. CDC reported that some States had adjusted their operational strategies for the swine flu program with great success by establishing more night and weekend clinics in shopping centers and other high traffic areas.

Informed consent procedures not adhered to

HEW developed guidelines for the projects aimed at assuring that persons immunized by other than their private physicians were informed of the swine flu vaccine's benefits and risks. The guidelines set forth eight minimum requirements for informed consent. Every grant application included procedures for securing informed consent before vaccination that were acceptable to HEW. The requirements and procedures then filtered down from the projects through various health jurisdictions to clinics where the vaccinations were given.

Most of the 26 clinics visited met many of the HEW requirements; however, most clinics did not meet all of the requirements. (See next page.) A few clinics visited were so poorly organized that even minimum informed consent requirements could not be assured. For example:

--A clinic run by HEW employees for HEW employees (1) did not have the introduction to the two-page consent form available, (2) permitted some persons to be vaccinated who had not signed a consent form or registered in any way, and (3) did not collect all consent forms that had been signed.

--A county clinic did not maintain adequate crowd control. Thirty to 40 persons were crowded around the vaccination area, and nurses were vaccinating anyone with a consent form. No one verified that the forms had been signed. One operator admitted that he had no idea whom he was vaccinating and subsequently stopped using the jet injector.

Minimum informed consent requirements	Compliance by clinics visited: Yes	No
Gave every person a written statement (registration and introduction forms)	23	3
Documented that the statement had been provided	22	4
Screened to determine if person could read statement provided	8	a/18
Screened to identify high-risk individuals	24	2
Answered questions about vaccine, contra-indications, risks, and benefits	25	1
Maintained translations of written statement	20	6
Displayed posters showing recommendations for age groups under 25	13	13
Directly advised persons under 25 years of age regarding the recommendations	17	9

a/Clinic screeners told us that persons had not been specifically asked if they could read the form, but they assumed those who could not read would so indicate.

HEW's methods to assure compliance with the requirements included (1) periodic site visits to clinics by swine flu officials, (2) additional visits by HEW regional personnel in conjunction with monitoring visits for other health programs, and (3) distribution of a supplemental questionnaire to all grantees concerning their planned policies and procedures to comply with HEW guidelines. A CDC official told us that results of HEW clinic visits had been discussed but not documented. Also the results of the questionnaire were collected but not summarized. Consequently, although changes at some clinics may have resulted from these reviews, the overall effectiveness of HEW's monitoring efforts could not be determined.

State health department officials also made periodic visits to vaccination clinics. Some State officials reported changes in clinic operations as a result of these visits. In addition, State health officials, using HEW guidelines, trained clinic managers and other key program personnel. However, in the absence of monitoring each clinic, States could not assure that consent forms were being handed out, read, understood, signed, and turned in. CDC officials said that the small number of individuals attending clinics and the quality of clinic organization made failures in the consent process unlikely.

As part of a national opinion survey conducted monthly on the swine flu program, CDC questioned a sample of persons vaccinated to measure their awareness of informed consent. According to CDC, the results 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 limitations of national sampling procedures.

The January 1977 survey showed that 90 percent of people vaccinated recalled having been shown or given a form which told about the benefits and risks of swine flu vaccination. This includes persons vaccinated by private physicians and hospitals, which were not required to use the informed consent form.

As CDC has reported, the informed consent system was obviously not perfect.

Vaccine inventory and accountability requirements not adhered to

On September 1, 1976, HEW issued a flu assessment manual which provided a prototype vaccine inventory and accountability system. Though HEW noted no significant problems in project compliance with the manual, final vaccine accountability and project assessment may not be possible.

The most common problem was obtaining accurate usage information from private physicians. Most projects initially gave physicians a limited amount of vaccine. When reordering, physicians were to report usage by age group and type of vaccine. However, when physicians did not reorder and when the program was halted in December 1976, project staff were faced with the task of contacting each physician that had been provided vaccine to ascertain the necessary data. Examples of resulting problems follow.

--One county asked about 380 physicians who had received vaccine to account for it. Only about half of the physicians responded. According to the county coordinator, physicians who did not respond were not subsequently contacted because (1) there were too many for the project staff to telephone individually and (2) it would be an insult to the physicians' professional status.

--Private physicians who participated in another project's mass immunization clinics occasionally took vaccine from the sites for their own use. At the end of the program, several physicians mailed vaccine back to the State. One physician mailed back 300 doses of bivalent vaccine which, after being unrefrigerated for days, had to be discarded.

Another problem was the failure of some projects to comply with HEW inventory and accountability requirements. Although all the projects could account for vaccine received and shipped out, the system occasionally deteriorated as the vaccine was distributed to health districts, regions, counties, and other jurisdictions.

Neither of two health districts in one State visited could determine the exact quantities of vaccine used or wasted. For example:

--Neither district recorded distributed vaccine when it was returned. When the vaccine was redistributed it was counted again, resulting in an understatement of vaccine inventory. Therefore, the district could not accurately determine either the amount of vaccine distributed or on hand.

--Clinics in both districts could not account for vaccine used or wasted. Neither district required each clinic to submit a daily tally sheet of vaccine administered or to determine the amount of vaccine wasted.

Military participation in the projects was voluntary

In May 1976 a project visited requested the assistance of military personnel and equipment. The project director was informed that all Army bases had been instructed not to commit personnel and equipment to civilian projects. The project actively solicited military participation through June and July 1976. The director felt that the medical expertise

of military personnel, especially those in reserve units who are trained in delivering health services and in using military jet injectors, could have been effectively used.

On July 31, 1976, the project was informed that the Department of Defense was developing a national policy regarding using military personnel and equipment to support civilian immunization programs. Until this policy was issued, commitment of military personnel and equipment, even for planning purposes, was precluded.

The Department of Defense issued its policy on September 22, 1976. Since neither the funds nor the authority had been provided to use military personnel in support of civilian projects, the policy limited military participation to training activities by National Guard and Reserve medical units. Any service performed by these units had to be a byproduct of this training. Medical equipment could be loaned, upon request, but military personnel could participate in civilian programs as volunteers only.

By the time the Department of Defense policy was issued, the projects knew that vaccine would not be available in the quantity needed to begin simultaneous mass immunizations on October 1, 1976. When the projects had sufficient vaccine, demand had decreased to a point where planned clinics were being canceled. As a result, military participation in civilian projects was not pursued.

LACK OF STATE LIABILITY INSURANCE

The inability of some States to secure adequate liability protection for some or all participants nearly prevented their participation in the immunization program. However, the legislative solution arrived at may provide an effective precedent for future immunization programs.

A statement prepared by HEW's General Counsel noted that since States are sovereigns, most State and local governments are immune from tort liability under the doctrine of sovereign immunity. In addition, most local governments are not liable for employee negligence in the administration of vaccine in programs regarded as "government" functions. However, when a State or local government purchases liability insurance, immunity from tort liability is generally waived to the extent of the insurance coverage.

The HEW statement continued that, though most State and local governments are immune from tort liability, State and

local government employees may be liable for negligence in performing routine functions, such as administering vaccine in public clinics. Private physicians and other health professionals who serve either as employees of, or volunteers for, State and local governments are also probably liable for their own negligence.

Private physicians, health professionals, and State and local government employees who administered the swine flu vaccine in publicly run clinics could be sued by the Federal Government for damages and litigation costs resulting from (1) negligent administration of the vaccine, (2) failure to give adequate warning of the benefits and risks of vaccination, or (3) negligence in storing or handling the vaccine before its administration.

Some States required or authorized one or more types of protection for State and local government employees against whom suits are brought for acts of omission within the scope of their official duties. The three most common types of protection required or authorized were (1) the purchase of liability insurance, (2) indemnification of employees for damages and litigation costs, and (3) legal representation for employees sued for acts within the scope of their official duties.

In June 1976 CDC conducted a State-by-State analysis of the liability protection provided for program participants in publicly run immunization clinics. The analysis showed that only 10 States provided adequate liability protection for all participants. Fourteen States provided no liability protection for any participant. The remaining 26 States provided either liability insurance; indemnification; immunity under a tort claims act or other State law; or sovereign immunity to some, but not all, participants.

The solution--an effective method of assuring State participation

The swine flu program legislation was designed to achieve participation by public and private agencies and organizations and by medical and other health personnel by protecting them against liability claims for other than their own negligence. Like the vaccine manufacturers, State and local government employees and professional and nonprofessional volunteers, who administered the vaccine without charge and in compliance with CDC's informed consent procedures, were protected by the Federal Government against the costs associated with nonmeritorious claims. However, the Federal Government has,

notwithstanding any provision of State law, the right to recover damages awarded or paid as well as litigation costs resulting from negligent conduct on the part of any participant.

A CDC official said that only one State had purchased liability protection against the Government's right to recover. This insurance protection cost $90,000 and was limited only to the swine flu program.

CONCLUSIONS AND RECOMMENDATIONS FOR FUTURE IMMUNIZATION PROGRAMS

Project readiness and implementation were limited by biological and liability problems beyond the projects' control. For example:

--The lack of vaccine dosage recommendations for the entire population limited the projects' ability to develop strategies for immunizing persons under 25 years of age.

--Uncertainties surrounding vaccine availability inhibited the ability of the projects to make firm commitments for (1) program strategies, (2) staffing, (3) clinic locations and dates, and (4) promotional publicity which normally require specific advance scheduling.

Consequently, we could not determine whether State or local projects could be ready for future mass immunization programs.

Project operations

State and local agencies will have to make consistent firm commitments if any future mass immunization program is to succeed. In addition, they will need better program guidance and assistance from HEW in managing local projects. We recommend that the Secretary, HEW, revise and refine existing guidelines to provide:

--Criteria for establishing clinic locations and hours of operation to assure that sites selected are the most accessible for mass immunization.

--An informed consent procedure checklist, setting forth the minimum requirements established by HEW, to be completed at every clinic and returned through the project to HEW.

--Standardized vaccine inventory and accountability requirements relating to (1) obtaining accurate usage information from private physicians and health districts, regions, counties, and other jurisdictions and (2) obtaining accurate vaccination coverage rates by geographic area so that if vaccine is limited, it can be allocated accordingly.

--Procedures for obtaining the use of military jet injectors and personnel if the current national policy is revised.

Future mass immunization programs may be conducted under more stringent time constraints due to the timing of any detected flu activity and resulting increased demand for vaccine. If a flu outbreak or an epidemic is to be prevented, every component of the Nation's health system must be fully used. However, current national policy does not assure maximum use of military medical expertise in State and local programs. Therefore, the Secretary, HEW, should request the Department of Defense to revise its policy.

State liability insurance

We recommend that the Congress consider the potential impact of inadequate liability protection on State participation in future immunization programs. For future programs, the Federal Government can (1) assume total program liability, (2) assume no liability for participants, or (3) assume limited liability similar to that provided under the swine flu program.

If the Federal Government assumes total program liability, it will be assuming responsibility for functions over which it has no control. HEW cannot assure that the vaccine will be effectively administered, that adequate warning will be given, or that the vaccine will be adequately stored and handled. Although this alternative will effectively relieve the States of the need for liability protection, it could result in a significant increase in program costs to the Federal Government.

If the Federal Government assumes no liability for participants, some States will have to purchase additional liability protection for participants or limit program involvement to individuals already protected. The cost of insuring all participants may be prohibitive, or insurance may be unattainable; therefore, States may have to indemnify against damages and litigation costs, provide State exemptions from liability, or perhaps not participate in the program.

If the Federal Government assumes limited liability similar to that provided under the swine flu program, the cost of liability protection will be more equitably distributed. While the Government will assume the costs associated with nonmeritorious claims, it will retain the option of recovering damages and litigation costs resulting from negligent conduct on the part of participants. The States may then select the type of liability protection they can most effectively provide participants against potential Federal Government suits.

CHAPTER 8

PROGRAM COSTS

Total costs for the swine flu program cannot yet be accurately determined. In some instances, accounting data is too limited to identify precise costs, and in others, not all costs have been incurred or determined. Some costs--such as lost opportunity costs to other health programs--can be estimated only over time. However, total cost attributable to the swine flu program may far exceed the $135 million appropriated.

Total program costs include:

--Expenditures from funds appropriated for the program.

--Expenditures from other Federal funding sources.

--Expenditures from State and local funds to supplement the Federal grants.

--Lost opportunity costs to other health programs.

--Costs incurred for health care and lost earnings by individuals who have adverse reactions to the vaccine.

Expenditures from the $135 million appropriated for the swine flu program are projected to be about $100.2 million through June 1977. The total charges to the appropriation and other funding sources will not be known until after the program ends on August 1, 1977. Costs yet to be determined include:

--The final cost of the vaccine. Contracts for purchasing vaccine had not been finalized as of June 16, 1977.

--Department of Justice costs of litigation and Federal funds for settlements and awards for claims over $2,500 which are not recoverable from third parties. (HEW will pay settlements of $2,500 or less from the $135 million appropriated.) The total dollar amount of claims and suits filed as of March 31, 1977, exceeded $300 million.

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

--State and local program costs in addition to those funded by the Federal grants, such as

-direct appropriations (one State, for example, appropriated $1.4 million for the program),

-personnel costs of full-time employees detailed from other programs, and

-additional costs for swine flu liability insurance.

--Lost opportunity costs to other programs.

--Costs incurred for health care and lost earnings by individuals because of immunization reactions.

BUDGETED COSTS

The $135,064,000 appropriated for the swine flu program was to underwrite the development, production, and distribution of necessary vaccines and to provide financial aid to help States carry out the immunization program. The budget follows.

Activity by agency		Budget amount
CDC:		
Disease control		$127,851,000
Vaccine	$100,000,000	
Project grants	26,000,000	
Direct operations	1,851,000	
FDA:		
Vaccine licensing and monitoring		3,213,000
NIAID (note a):		
Research		4,000,000
Direct operations	$ 3,500,000	
Grants	500,000	
Total appropriation		$135,064,000

a/National Institute of Allergy and Infectious Diseases.

Funds spent by CDC

CDC's final costs had not been determined as of June 16, 1977. Some direct operation costs were still being incurred, and final vaccine costs had not been determined. CDC had

spent or expected to spend all the funds budgeted for project grants and direct operations.

Vaccine costs

As of March 31, 1977, $66 million of the $100 million had been paid to manufacturers for vaccine production on a provisional payment rate (rate per dose shipped). The $100 million set aside for vaccine was based on an estimated 200 million doses to be purchased at an average cost of $0.50 a dose. However, only about 157 million doses were manufactured, and the unit cost per dose will be less than $0.50.

The exact costs of vaccine had not been determined. As of June 16, 1977, none of the manufacturers had signed final contracts. Interim letter contracts had been signed by all four manufacturers by September 22, 1976. Three of the four manufacturers and CDC have agreed to all cost elements of the final contracts. No elements may be added. Contract signing has been delayed since November 1976 pending (1) an Internal Revenue Service ruling on whether to tax as income $2.5 million included in each contract for self-insurance retention funds and (2) a decision by the Secretary of HEW on whether to waive application of the Government's cost accounting standards because of abnormal pricing provisions in the contracts. The Internal Revenue Service ruling was made on April 27, 1977. The decision regarding waiver of the cost accounting standards was still pending as of June 16, 1977.

In addition, one manufacturer and CDC are still in dispute concerning a $1.2 million production cost for Shope vaccine (a vaccine developed for another strain of swine flu) which could not be used in the program. The CDC contracting officer told us that CDC can make a unilateral determination of the price it will pay for this manufacturer's swine flu vaccine. The manufacturer 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.

Total expenditures for vaccine production are to be determined within 90 days after final vaccine deliveries are made, when final costs will be negotiated. According to Public Law 94-380, the monovalent swine flu vaccine will be provided at actual cost and a "reasonable" profit will be permitted for the manufacture of the Victoria component of the bivalent doses. Final vaccine costs will be determined only after the HEW Audit Agency has completed a postcontract award audit of all cost elements included in the contracts.

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In addition to the costs of vaccine, claims for vaccine-associated injuries which do not exceed $2,500 will be paid from funds budgeted for vaccine purchases. As of March 31, 1977, CDC reported that such claims totaled over $33,000. Since additional claims may be filed and some claims might not be found meritorious, the total cost of claims paid from CDC's budget will become known at some future time.

Immunization project grants

As of March 31, 1977, HEW had awarded $25.8 of the $26 million grant funds to help State and local health departments carry out the swine flu program. CDC officials told us that the remaining $200,000 would be awarded.

Program modification and delays resulting from liability problems, delays in vaccine deliveries, decreased quantities of vaccine, adverse reactions, and other problems have increased the total program cost. Initially, 63 grants were awarded for about $24.2 million to carry out the program during July through November. Forty-eight of the 63 projects subsequently requested supplemental grants totaling about $1.6 million ($1.3 million financial assistance and $300,000 direct manpower assistance). Supplemental grants generally were for additional personnel, publicity, and materials costs associated with (1) the delays in vaccine availability, (2) adverse publicity, and (3) adverse reactions. The delays ultimately led to the extension of the program through January 1977.

Immunization projects are not required to account for expenditures from the Federal grants until 60 days after the end of the flu program. Since the program does not end until August 1, 1977, actual expenditures from the Federal grant funds are not known.

Direct operations

As of March 31, 1977, CDC had spent almost the $1.9 million budgeted. Projected CDC costs through June 30, 1977, for direct operations will exceed the $1.9 million budget by about $100,000.

Funds spent by FDA

FDA was allocated $3,213,000 to test vaccine and to conduct clinical trials. As of March 31, 1977, FDA had spent only $1,334,000 and had projected expenditures of an additional $239,000 through the end of fiscal year 1977.

Of the estimated $1,640,000 remaining, about $1 million will be transferred to the National Institute of Allergy and Infectious Diseases, as explained below.

Funds spent by the National Institute of Allergy and Infectious Diseases

The Institute was allocated $4 million for research. As of March 31, 1977, the Institute had expended about $1.3 million and projected to expend $3.4 million more during the next 3 years. Thus, the Institute's costs will probably exceed the $4 million allocated by about $700,000. To pay these additional costs, about $1 million will be transferred to the Institute from the $1,640,000 not spent by FDA.

PROGRAM COSTS PAID BY OTHER FEDERAL SOURCES

Some costs of the swine flu program have been or will be charged to other Federal sources. Principally, these include (1) salaries of full-time CDC employees diverted to the swine flu program from other health programs, (2) Department of Justice costs for litigating claims for vaccine-associated injuries and deaths, and (3) payments for meritorious claims or suits exceeding $2,500. The total amount of these costs will not be known until after the program has ended and all claims have been adjudicated.

Although CDC had primary responsibility for organizing and coordinating the swine flu program, the swine flu budget did not include funding for recruiting and forming a permanent staff within CDC specifically for the swine flu program. Funds were available for 44 temporary employees to assist with clerical and administrative duties. However, from the beginning, existing full-time CDC employees were expected to be diverted to the swine flu program from other health programs. As of March 31, 1977, the costs of CDC personnel and other resources diverted to the flu program totaled almost $1 million. This amount will increase before the flu program ends.

A Department of Justice official said that on January 28, 1977, the Office of Management and Budget approved a Department of Justice supplemental budget of $1,228,000 for swine flu litigation in fiscal year 1977. The budget included 28 new positions (19 additional attorneys and 9 support staff). The Department estimates that at least 28 positions will be needed through fiscal year 1980. Thereafter, the staff will be reduced based on the number of suits still in litigation.

As of March 31, 1977, the budget request had not been approved by the Congress and the Department had only five attorneys and one support staff detailed to the swine flu program.

All claims and suits for injury or death associated with the swine flu program will be litigated in accordance with the Federal Tort Claims Act, as amended. The number and amount of claims and suits which will be found meritorious and the awards or settlements which will be made cannot be predicted. As of March 31, 1977, 282 claims and 14 suits had been filed totaling over $300 million. 1/ In addition, over 3,000 inquiries requesting procedures for filing claims had been received. A Department of Justice official estimated that between 4,000 and 4,500 claims and suits will ultimately be filed, totaling over $1 billion.

PROGRAM COSTS PAID BY STATE AND LOCAL AGENCIES

In addition to the Federal grant funds, State and local resources were used to develop, organize, and carry out the flu program. Total expenditures by State and local agencies were not available as of March 31, 1977. Though projects may estimate total program costs, they will be able to specifically account for only the Federal grant expenditures.

Public Law 94-380 requires HEW to determine the costs incurred by State and local agencies. HEW expanded an existing contract with the Association of State and Territorial Health Officers to estimate State and local agency costs by surveying State and local agencies. The survey began in March 1977, and HEW intended to give the Congress the costs estimates on April 1, 1977. However, because of administrative routing and approval requirements for the survey and difficulties in obtaining cost estimates from some projects, the report has been delayed.

Commitment of resources has varied from project to project, depending on individual strategies for using volunteers and other health care providers. One project estimated that an amount equal to its approximately $500,000 grant would be expended from State revenues. Another project appropriated $1.4 million in State funds to supplement its $900,000 Federal

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1/This includes one suit for $200 million, which a Department of Justice official stated will probably not result in an award or settlement.

grant. Some projects, while not specifying a cost, indicated that State and county employees had been redirected to the flu program.

Because the program was extended, State and local health employees were diverted from their normal duties for longer periods, thereby increasing costs to State and local projects.

LOST OPPORTUNITY COSTS

A formal determination of lost opportunities to other health programs has not been made. HEW and other swine flu program participants knew from the beginning, however, that some penalty costs to other health programs might be incurred because existing health department personnel would be diverted to the swine flu program.

We did not measure the adverse effects of these diversions. A statistical analysis showing either decreases in the number of people receiving other health services or the number of people diverted from other health programs does not necessarily mean an adverse impact. Determining the impact would require identification and analysis over time of the effects on outcomes, such as disease incidence trends.

The diversions of health department employees had in some cases caused delays, modification, or cancellations to other health programs in projects reviewed. For example:

--A major city had to delay its annual school immunization program until the second semester.

--A county discontinued its diabetes screening until the end of the flu program.

--Throughout the swine flu program, one urban county discontinued a Medicaid program designed to provide early and periodic health care screening and treatment for eligible children.

In addition, CDC delayed plans for expanding an experimental strategy for immunizing against measles because of the priority on the swine flu program. The new strategy--referred to as an outbreak containment strategy--was similar to the smallpox vaccination campaign in Africa in which only persons in areas where a disease outbreak had been detected were vaccinated. At the onset of the flu program, CDC had applied this strategy in five States and planned to expand it in another four States. However, expansion of the experimental strategy was limited to two States because of the priority on the swine flu program.

HEALTH CARE COSTS AND LOST EARNINGS OF INDIVIDUALS WHO HAVE ADVERSE REACTIONS TO THE VACCINE

HEW developed guidelines for reporting and investigating adverse reactions related to swine flu immunization. Any illness occurring after flu vaccination in which the patient required (1) hospitalization or (2) bedcare and an outpatient visit to a public or private health facility was to be reported to HEW. Less serious reactions were not to be reported.

Although HEW provided guidance on when and how adverse reactions were to be reported, it did not provide recommendations on how adverse reactions were to be identified. While some projects planned active surveillance systems, most projects relied on individuals vaccinated, private physicians, hospitals, and health departments to take the initiative for reporting adverse reactions.

The total number of adverse reactions and corresponding health care costs and lost earnings cannot be determined because illnesses which did not require either hospitalization or an outpatient visit were not required to be reported and surveillance systems employed by some projects could not assure that all reportable reactions were identified. One project director indicated that an optimistic goal would be to identify 40 percent of the total adverse reactions in the State. He noted that intensified surveillance by the State after the first Guillain-Barre case was reported, identified 25 other severe reactions that had not been reported.

At least 3,888 adverse reactions to the vaccine had been reported to CDC by April 10, 1977. Although HEW plans to determine certain economic losses associated with these reactions, the final estimate will not reflect all costs incurred.

CONSIDERATIONS FOR FUTURE IMMUNIZATION PROGRAMS

The swine flu program has shown that the total cost of such an effort is difficult to predict and may include much more than funds appropriated. Further, the total direct cost may be difficult to identify and certain indirect costs may be incalculable.

CHAPTER 9

SCOPE OF REVIEW

We made our review at CDC in Atlanta; the Bureau of Biologics, Food and Drug Administration; and the National Institute of Allergy and Infectious Diseases, National Institutes of Health in Bethesda, Maryland. We reviewed legislation, examined records and files, interviewed agency officials, and monitored events as they occurred between August 1976 and March 1977.

We also monitored program implementation at five immunization projects--the States of Florida, Georgia, Maryland, and Pennsylvania and the city of Philadelphia. These projects received over $3.2 million in grants for the program. We examined records and files; interviewed State, county, city, regional, and district health officials; and visited 26 mass immunization clinics within these project areas.

These five projects were not selected as a representative sample of program results in other areas. We supplemented information obtained from these projects with (1) a limited number of project self-evaluation reports and (2) information developed by CDC concerning the other projects. We did not contact the drug manufacturers.

We contacted officials of the Department of Justice in Washington, D.C., to determine the status of claims for damages against the Federal Government resulting from the program. We also contacted HEW Region IV Audit Agency officials concerning their reviews of vaccine cost.

IMPORTANT INFORMATION ABOUT SWINE INFLUENZA (FLU) VACCINE (MONOVALENT)

July 15, 1976

The Disease

Influenza (flu) is caused by viruses. When people get flu they may have fever, chills, headache, dry cough or muscle aches. Illness may last several days or a week or more, and complete recovery is usual. However, complications may lead to pneumonia or death in some people. For the elderly and people with diabetes or heart, lung, or kidney diseases, flu may be especially serious.

It is unlikely that you have adequate natural protection against swine flu, since it has not caused widespread human outbreaks in 45 years.

The Vaccine

The vaccine will not give you flu because it is made from killed viruses. Today's flu vaccines cause fewer side effects than those used in the past. In contrast with some other vaccines, flu vaccine can be taken safely during pregnancy.

One shot will protect most people from swine flu during the next flu season; however, either a second shot or a different dosage may be required for persons under age 25. If you are under 25 and a notice regarding such information is not attached, this information will be provided to you wherever you receive the vaccine.

Possible Vaccine Side Effects

Most people will have no side effects from the vaccine. However, tenderness at the site of the shot may occur and last for several days. Some people will also have fever, chills, headache, or muscle aches within the first 48 hours.

Special Precautions

As with any vaccine or drug, the possibility of severe or potentially fatal reactions exists. However, flu vaccine has rarely been associated with severe or fatal reactions. In some instances people receiving vaccine have had allergic reactions. You should note very carefully the following precautions:

- **Children under a certain age should not routinely receive flu vaccine. Please ask about age limitations if this information is not attached.**
- **People with known allergy to eggs should receive the vaccine only under special medical supervision.**
- **People with fever should delay getting vaccinated until the fever is gone.**
- **People who have received another type of vaccine in the past 14 days should consult a physician before taking the flu vaccine.**

If you have any questions about flu or flu vaccine, please ask.

REGISTRATION FORM

I have read the above statement about swine flu, the vaccine, and the special precautions. I have had an opportunity to ask questions, including questions regarding vaccination recommendations for persons under age 25, and understand the benefits and risks of flu vaccination. I request that it be given to me or to the person named below of whom I am the parent or guardian.

INFORMATION ON PERSON TO RECEIVE VACCINE

Name (Please Print) _____ Birthdate _____ Age _____

Address _____ County of Residence _____

_____

Signature of person to receive vaccine or Parent or Guardian _____ Date _____

FOR CLINIC USE

Clinic Ident. _____

Date Vaccinated _____

Manufacturer and Lot No. _____

CDC 7.31
7-76

U.S. Department of Health, Education, and Welfare / Public Health Service / Center for Disease Control / Atlanta, Georgia 30333

APPENDIX II

IMPORTANT INFORMATION ABOUT SWINE AND VICTORIA INFLUENZA (FLU) VACCINE (BIVALENT)

July 15, 1976

The Disease

Influenza (flu) is caused by viruses. When people get flu they may have fever, chills, headache, dry cough or muscle aches. Illness may last several days or a week or more, and complete recovery is usual. However, complications may lead to pneumonia or death in some people. For the elderly and people with diabetes or heart, lung, or kidney diseases, flu may be especially serious.

It is unlikely that you have adequate protection against swine flu, since it has not caused widespread human outbreaks in the past 45 years. You may or may not have adequate protection against Victoria flu, although many Americans had this flu last winter. It was responsible for over 12,000 deaths.

The Vaccine

The vaccine will not give you flu because it is made from killed viruses. Today's flu vaccines cause fewer side effects than those used in the past. In contrast with some other vaccines, flu vaccine can be taken safely during pregnancy.

One shot will protect most people from swine and Victoria flu during the next flu season; however, either a second shot or a different dosage may be required for persons under age 25. If you are under 25 and a notice regarding such information is not attached, this information will be provided to you wherever you receive the vaccine.

Possible Vaccine Side Effects

Most people will have no side effects from the vaccine. However, tenderness at the site of the shot may occur and last for several days. Some people will also have fever, chills, headache, or muscle aches within the first 48 hours.

Special Precautions

As with any vaccine or drug, the possibility of severe or potentially fatal reactions exists. However, flu vaccine has rarely been associated with severe or fatal reactions. In some instances people receiving vaccine have had allergic reactions. You should note very carefully the following precautions:

- **Children under a certain age should not routinely receive flu vaccine. Please ask about age limitations if this information is not attached.**
- **People with known allergy to eggs should receive the vaccine only under special medical supervision.**
- **People with fever should delay getting vaccinated until the fever is gone.**
- **People who have received another type of vaccine in the past 14 days should consult a physician before taking the flu vaccine.**

If you have any questions about flu or flu vaccine, please ask.

*USGPO: 1976 — 214-225

REGISTRATION FORM

I have read the above statement about swine and Victoria flu, the vaccine, and the special precautions. I have had an opportunity to ask questions, including questions regarding vaccination recommendations for persons under age 25, and understand the benefits and risks of flu vaccination. I request that it be given to me or to the person named below of whom I am the parent or guardian.

INFORMATION ON PERSON TO RECEIVE VACCINE		
Name (Please Print)	Birthdate	Age
Address	County of Residence	

FOR CLINIC USE
Clinic Ident.
Date Vaccinated
Manufacturer and Lot No.

Signature of person to receive vaccine or Parent or Guardian — Date

CDC 7.32
7-76
U.S. Department of Health, Education, and Welfare / Public Health Service / Center for Disease Control / Atlanta, Georgia 30333

Important Information from the U.S. Public Health Service about Swine Flu and Victoria Flu Vaccines

INTRODUCTION

You probably have heard a good deal about swine flu and swine flu vaccine. You may know, for example, that swine flu caused an outbreak of several hundred cases at Ft. Dix, New Jersey, early in 1976- and that before then swine flu had not caused outbreaks among people since the 1920's.

With the vast majority of Americans being susceptible to swine flu, it is possible that there could be an epidemic this winter. No one can say for sure. However, if an epidemic were to break out, millions of people could get sick. Therefore, a special swine flu vaccine has been prepared and tested which should protect most people who receive it.

Certain people, such as those with chronic medical problems and the elderly, need annual protection against flu. Therefore, besides protection against swine flu, they also need protection against another type of flu (Victoria flu) that was around last winter and could occur again this winter. A separate vaccine has been prepared to give them protection against both types of flu.

These vaccines have been field tested and shown to produce very few side effects. Some people who receive the vaccine had fever and soreness during the first day or two after vaccination. These tests and past experience with other flu vaccines indicate that anything more severe than this would be highly unlikely.

Many people ask questions about flu vaccination during pregnancy. An advisory committee of the Public Health Service examined this question and reported that "there are no data specifically to contraindicate vaccination with the available killed virus vaccine in pregnancy. Women who are pregnant should be considered as having essentially the same balance of benefits and risks regarding influenza vaccination and influenza as the general population."

As indicated, some individuals will develop fever and soreness after vaccination. If you have more severe symptoms or if you have fever which lasts longer than a couple of days after vaccination, please consult your doctor or a health worker wherever you receive medical care.

While there is no reason to expect more serious reactions to this flu vaccination, persons who believe that they have been injured by this vaccination may have a claim. The Congress recently passed a law providing that such claims, with certain exceptions, may be filed only against the United States Government. Information regarding the filing of claims may be obtained by writing to the U.S. Public Health Service Claims Office, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20852.

Attached is more information about flu and flu vaccine. Please take the time to read it carefully. You will be asked to sign a form indicating that you understand this information and that you consent to vaccination.

CDC 7.21A 8-76 U.S. Department of Health, Education, and Welfare / Public Health Service / Center for Disease Control / Atlanta, Georgia 30333

VOLUNTARY CONSENT FORM

IMPORTANT INFORMATION ABOUT SWINE AND VICTORIA INFLUENZA (FLU) VACCINE (BIVALENT)

February 1977

A program for voluntary immunization of individuals against both swine and Victoria flu was begun in the fall of 1976 under a special act of Congress. Over 42 million people were vaccinated under the program. In December the Public Health Service received reports that some who had been vaccinated had suffered an illness called Guillain-Barré which is described later in this document. As a result, the program was suspended December 16 to determine whether and to what extent Guillain-Barré was caused by the flu shots.

After review of additional and more detailed information and after further consultation with medical and other experts concerning both the occurrence of a limited number of cases of Victoria flu and the causes of Guillain-Barré, the immunization program has been resumed on a limited basis. The reason for this partial resumption is to give certain American people, particularly the elderly and persons with chronic illnesses who have a high risk of suffering serious adverse consequences from influenza, an opportunity to be vaccinated against Victoria influenza.

THE FLU

Flu is caused by viruses. When people get flu they may have fever, chills, headache, dry cough or muscle aches. Illness may last several days or a week or more, and complete recovery is usual. However, complications may lead to pneumonia or death in some people. For the elderly and people with diabetes or heart, lung, or kidney diseases, flu may be especially serious.

If you are less than fifty years old, you are unlikely to have developed natural immunity to swine flu because no significant number of people have been sick with it for some 45 years. You may or may not have some natural immunity to Victoria flu.

While there was a substantial number of cases of Victoria flu last year, there has been no significant number of reported cases of swine flu since a brief and limited outbreak of the disease at Fort Dix, New Jersey in early 1976.

It is not possible to estimate the risk to an individual of getting the flu this year.

THE VACCINE

This vaccine contains the only available immunization against Victoria flu. It also contains the swine flu vaccine. It will not give you flu because it is made from killed viruses. A single shot will protect approximately three out of four persons age 25 and over from these two types of flu for the rest of the current flu season; the vaccination may not be effective in approximately one out of four persons age 25 and over. For persons under 25 a second shot must be taken at least one month after the first shot to provide the same likelihood of protection.

RISKS AND SIDE EFFECTS

Most people will have no harmful side effects from the vaccine. Some will have tenderness in the area of the shot for a day or so. A few will have fever, chills, headaches, or muscular aches within the first 48 hours. However, as with the administration of any vaccine or drug, there is always the possibility of more severe effects and in rare instances even of death.

GUILLAIN-BARRÉ

As mentioned, there is recent evidence that Guillain-Barré appears in some people after vaccination. When it appears, it generally does so within a few weeks of vaccination. Information collected for the purposes of the flu immunization program to date shows that among persons who have not taken flu vaccine, slightly more than one in a million get Guillain-Barré during any eight week period. However, during the period of eight weeks after vaccination, about ten out of every million persons vaccinated have suffered Guillain-Barré. Thus, while the risk is not high, evidence suggests that persons who are vaccinated are approximately ten times more likely to get Guillain-Barré than those who are not vaccinated.

Guillain-Barré can be relatively mild to very severe. It causes a paralysis, usually of the legs and arms. In most cases the paralysis disappears and the recovery is complete. Recent statistics indicate, however, that in about five percent of the cases the patient dies, and in about ten percent of the cases some muscles will be weak for a long time or permanently. Thus, the risk of death from Guillain-Barré for persons of all age groups who are vaccinated is approximately one out of two million. For elderly and chronically ill persons the risk of death from Guillain-Barré is approximately one out of every one million persons vaccinated.

PREGNANCY

Many people ask about the risks of flu vaccination during pregnancy. There is not now any specific data on whether the risks are the same or different from what they are for the general population. For this reason a pregnant woman should be advised by a doctor on the benefits and risks for her or her offspring.

SPECIAL PRECAUTIONS

Some people should not take flu vaccine. You should note very carefully the following precautions:

- A child under 3 years of age in good health should not ordinarily receive flu vaccine. If the child has a serious chronic illness, the vaccine may be recommended but you should see a doctor first.
- People allergic to eggs should be vaccinated only on the advice and under the supervision of a doctor.
- People with fever should not be vaccinated until the fever is gone.
- People who have received another type of vaccine in the past 14 days should see a doctor before taking the vaccine.

If after vaccination you have any symptoms more severe than a moderate fever, chill, headache or mild muscular ache within the first 48 hours or any symptoms continue longer than 48 hours, you should see a doctor.

INJURY CLAIMS

While the risk of harm from flu vaccine is small, those who believe they have been injured by this vaccination may have a claim. The law provides that a claim may normally be filed against the United States Government. Information on how to file a claim may be obtained by writing to the U.S. Public Health Service Claims Office, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

IF YOU HAVE ANY QUESTIONS ABOUT FLU OR FLU VACCINE, PLEASE ASK

CONSENT

I have read the above information about Victoria and swine flu, the vaccine, and the special precautions. I have had an opportunity to ask questions, and I understand the benefits and risks of flu vaccination as described in this document. I request that it be given to me or to the person named below for whom I am authorized to consent.

INFORMATION ON PERSON TO RECEIVE VACCINE

Name (Please Print) _____ Birthdate _____ Age _____

Address _____ County of Residence _____

Signature of person to receive vaccine or Parent or Guardian _____ Date _____

FOR CLINIC USE

Clinic Ident. _____

Date Vaccinated _____

Manufacturer and Lot No. _____

U.S. Department of Health, Education, and Welfare / Public Health Service / Center for Disease Control / Atlanta, Georgia 30333

CDC 7.32

APPENDIX V

COMPARISON OF CLINICAL TRIAL POTENCY TEST RESULTS ON MONOVALENT AND BIVALENT SWINE FLU VACCINE

Lot	Designated value (CCAs)	Manufacturer test results	FDA test results
A	200	228	132
B	200	300	180
C	200	208	180
D	200	216	192
E	200	312	194
F	200	252	204
G	200	252	228
H	400	480	300
I	400	396	312
J	400	470	324
K	400	636	348
L	400	420	360
M	400	600	392
N	800	984	660
O	800	861	684
P	800	1,008	696
Q	800	1,224	720
R	800	880	732
S	800	948	768

APPENDIX VI

PRINCIPAL HEW OFFICIALS RESPONSIBLE FOR ACTIVITIES DISCUSSED IN THIS REPORT

	Tenure of Office	
	From	To
SECRETARY OF HEALTH, EDUCATION, AND WELFARE:		
Joseph A. Califano, Jr.	Jan. 1977	Present
David Mathews	Aug. 1975	Jan. 1977
ASSISTANT SECRETARY FOR HEALTH:		
James F. Dickson III (acting)	Jan. 1977	Present
Theodore Cooper	May 1975	Jan. 1977
DIRECTOR, NATIONAL INFLUENZA IMMUNIZATION PROGRAM:		
W. Delano Meriwether	Apr. 1976	Present
DIRECTOR, CENTER FOR DISEASE CONTROL:		
William H. Foege	May 1977	Present
David J. Sencer	Feb. 1966	May 1977
COMMISSIONER, FOOD AND DRUG ADMINISTRATION:		
Donald Kennedy	Apr. 1977	Present
Sherwin Gardner (acting)	Dec. 1976	Apr. 1977
Alexander M. Schmidt	July 1973	Dec. 1976
DIRECTOR, BUREAU OF BIOLOGICS:		
Harry M. Meyer	July 1972	Present
DIRECTOR, NATIONAL INSTITUTES OF HEALTH		
Donald S. Fredrickson	July 1975	Present
DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES:		
Richard M. Krause	Nov. 1975	Present