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DRAFT

Acting Director, Agent Orange Projects

Agent Orange Study Contract Issues

James O. Mason, M.D., Dr.P.H., Director, CDC

Through: Vernon N. Houk, M.D. _____
Director, CEH

Issue:

What options exist to resolve the impact on CDC's contractors related to the conduct of a validation study and continued delay in the decision concerning the conduct of the Agent Orange Study component of CDC's Epidemiologic Studies of the Health of Vietnam Veterans?

Background:

CDC directed its health interview contractor, Research Triangle Institute (RTI), and the medical examination contractor, Lovelace Medical Foundation (LMF), to stop all work related to the Agent Orange Study on January 15, 1986.

Current Status:

The health interview contractor has since been maintained in a "state of readiness" at a total cost of \$395,000 for the five month period - January 15 through June 14, 1986. During these months the contractor has continued to work on the remaining Vietnam Experience Study participant lists. It will, however, be necessary to inform RTI on June 1 about future work for the time period beginning June 15.

LMF made a formal written request on March 27 for financial consideration resulting from the inability of the Government to provide Agent Orange Exposure Study participants for medical examinations as required under the terms of the existing contract with CDC. CDC has responded in writing on May 8, 1986. Negotiations are expected to be held with the contractor in June.

The following options represent possible alternatives to the resolution of issues involving the Agent Orange Exposure Study.

NOTE: The size and scope of the medical examination contract make delay beyond July 15 expensive. An added burden effecting any decision is the fact that a substantial portion of the outlay will involve payment for non-performance by the contractors.

Contract Status

| <u>Contractor</u> | <u>Original Contract Cost</u> |
|--|-------------------------------|
| RTI (Health Interview) | \$ 7,505,000 |
| Lovelace Medical Foundation (Medical Examinations) | <u>35,892,498</u> |
| Total | \$43,397,498 |

| | <u>RTI</u> | <u>Lovelace</u> | |
|---|------------------|-------------------|---------------------|
| * <u>Estimated Cost</u> VES Study (40%) | \$3,001,370 | \$14,357,629 | \$17,359,000 |
| Estimated Cost AOS Study (60%) | <u>4,503,630</u> | <u>21,534,869</u> | <u>\$26,038,499</u> |
| Total | \$7,505,000 | \$35,892,498 | \$43,397,498 |

*RTI contract awarded 8/84 - LMF contract awarded 2/85. If the Agent Orange Study is not done the unit cost of the Vietnam Experience study examinations will go up because the medical contractor (LMF) has amortized their fixed costs over a minimum of 10,000 completed examinations.

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OPTION 1: CDC WOULD MODIFY THE HEALTH INTERVIEW (RESEARCH TRIANGLE INSTITUTE (RTI)) AND THE MEDICAL EXAMINATION (LOVELACE MEDICAL FOUNDATION (LMF)) CONTRACTS TO CONDUCT A VALIDATION STUDY. THE TWO CONTRACTS WOULD BE TERMINATED AFTER THIS DATA IS COLLECTED.

PRO:

None, except the possibility that this option might cost less than other options if there is a long delay from the completion of data collection for the validation study to the decision on the conduct of the Agent Orange Study.

Con:

1. Current contractors will not understand the logic of this approach.
2. There would be no incentive for outstanding performance and the contract would terminate regardless of the outcome of the validation study.
3. Current contractors would probably not be willing to participate in a validation study if contract is terminated after their data collection activities are complete.
4. An extensive procurement process (six to nine months) would be required to select contractors for the Agent Orange Study if it is conducted.
5. New pricing plans would be contained in new proposals and could be considerably higher than in current contracts.
6. Consistency of data collection methods for VES and AOS may not exist if new contractors were selected. Current contractors might not bid for a new procurement.
7. Experience gained by contractors in completing over 15,000 interviews and 4,000 medical exams could be lost if AOS is conducted by different contractors.

NOTE: Option 1 requires the active participation of ESC in the qualification of participants to be included in the validation study.

Cost: Option 1
 (In providing cost estimates an assumption has to be made about when the contractors would start work. We have used October 1, 1986 as this date. Further delay beyond that date could cost up to \$90,000 per month for RTI and up to \$630,000 per month for LMF.)

RTI

| | |
|---|----------------|
| 1. State of Readiness from June 15 to September 30 @ \$90,000 per month | \$315,000 |
| 2. Payment for Interviews (600) in Validation Study October 1 - December 31 (estimated time period) plus associated fixed costs | 120,000 |
| 3. Negotiated Final Settlement | <u>Unknown</u> |
| Subtotal: Estimated Known Costs | \$435,000 |
| Plus Final Unknown Negotiated Settlement | |

LMF

| | |
|--|----------------|
| 1. State of readiness July 15 - September 30 (estimated to be negotiated) | \$1,500,000 |
| 2. 400 medical examinations @ \$2,400 | 960,000 |
| 3. Negotiated final amount for termination | <u>Unknown</u> |
| Subtotal - Estimate known costs | \$2,460,000 |
| Plus Final Unknown Negotiated Settlement | |

Additional Costs: Laboratory CEH

| | |
|--|----------------|
| 1. Phase I | \$ 120,000 |
| The maximum estimated cost of Phase I is \$120,000, which would pay for the performance of 60 TCDD measurements in adipose tissue and 60 TCDD measurements in serum, @ \$1,000 each. Estimate would be reduced by number of "high" group who have already had adipose tissue measurements. | |
| 2. Laboratory CEH - Phase II | <u>400,000</u> |
| TCDD measurement: 400 veterans @ \$1,000 each | |
| Subtotal | 520,000 |

Cost Summary

| | | |
|----------|--|----------------|
| Summary: | RTI | \$ 435,000 |
| | LMF | 2,460,000 |
| | Laboratory TCDD measurements | 520,000 |
| | Plus negotiated amount for termination | <u>Unknown</u> |
| | Total (plus negotiated settlement costs) | \$3,415,000 |

OPTION 2: CDC TO MODIFY RTI AND LMF CONTRACTS TO DO A VALIDATION STUDY AND RETAIN BOTH CONTRACTORS IN A STATE OF SUSPENSION/DORMANCY UNTIL A DECISION IS MADE REGARDING THE AGENT ORANGE STUDY.

PRO:

- 1. Current contractors might be willing to do Validation Study if they know they will do AOS if conducted.
- 2. Same contractors would collect data for AOS if conducted. Experience and expertise from VES would be utilized.
- 3. Start up time for AOS (if conducted) would be considerably shorter if current contractors are utilized.
- 4. Probably less costly than Option 1. This depends on how long it takes to do a validation study and the time period between completion of data collection and decision on AOS.

CON:

- 1. This option could cost more than Option 1 if there is an extensive delay between the end of data collection and a decision on AOS.

NOTE: Option 2 requires the active participation of ESG in the qualification of participants to be included in the validation study.

COST: Option 2

RTI

| | |
|--|----------------|
| 1. Validation Study starts October 1 State of Readiness - same as Option 2 | \$315,000 |
| 2. Payment for Interviews (600) in Validation Study plus associated fixed costs | 150,000 |
| 3. Shutdown into state of suspension awaiting decision on AOS | 40,000 |
| 4. Restart of work based on decision to conduct AOS | <u>120,000</u> |
| Subtotal - Estimated costs if AOS is conducted | \$625,000 |

In the event the AOS is not conducted, Item 4, or \$120,000 for restart would not occur. However, an unknown negotiated settlement cost would be expected.

LMF

| | |
|--|----------------|
| 1. State of readiness July 15 - September 30 | \$1,500,000 |
| 2. Cost of performing 400 medical examinations @ \$2400 | 960,000 |
| 3. State of suspension/dormancy (\$630,000 maximum per mo) times number of months to AOS decision | <u>Unknown</u> |
| Subtotal | \$2,460,000 |

Laboratory CEH

| | |
|----------------------|---------|
| 1. TCDD measurements | 520,000 |
|----------------------|---------|

Cost Summary

| | |
|---|----------------|
| RTI | \$ 625,000 |
| LMF | 2,460,000 |
| Laboratory CEH | 520,000 |
| Suspension/Dormancy | <u>Unknown</u> |
| Total(plus negotiated settlement costs) | \$3,605,000 |