DOCUMENT RESUME

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[EPA Pesticide Research Contract for Determining Pesticide Residues in Fetal Tissue]. CED-78-112; B-133192. May 9, 1978. 11 pp. + enclosure (1 pp.).

Decision re: Rep. Harold L. Volkmer; by Henry Eschwege, Director, Community and Economic Development Div.

Issue Area: Environmental Protection Programs: Harmful Pesticides and Toxic Substances (2211).
Contact: Community and Economic Development Div.
Budget Function: Natural Resources, Environment, and Energy: Pollution Control and Abatement (304).
Organization Concerned: Environmental Protection Agency; Automated Medical Services of Ohio, Inc.
Congressional Relevance: Rep. Harold L. Volkmer.

Several deficiencies were alleged concerning an Environmental Protection Agency (EPA) contract for the testing of human fetuses for pesticide residues. The allegations concerned: EPA's monitoring of the contract; the source, condition, and legality of the fetus samples; the usefulness of the data obtained under the contract; and continuation of the contract over objections. EPA awarded a firm fixed-price contract to Automated Medical Services of Ohio, Inc. (AMSO) for $175,213 which was subsequently amended upward to $320,687. EPA monitored the contract primarily by reviewing written reports submitted by AMSO and by single visits to AMSO and to the subcontractor, the University of Utah. The EPA Deputy Administrator noted that the large number of contracts that EPA administers makes onsite visits to all contractors virtually impossible. The Federal Government has no laws prohibiting research on dead fetuses or the products of conception; AMSO believed that it complied with State requirements concerning such research. The issues raised regarding compliance with State procedures and the adequacy of consent forms should be referred to the States involved. Statistically significant data were not generated, and EPA does not plan to use the analytical method developed. As a result, contract benefits to EPA are quite limited. The contract should not have been awarded because of: possible large cost differences in doing the study under contract rather than in-house, the fact that a detection method already existed, and realization that data would not be developed in a timely manner. (RRS)

6329

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

COMMUNITY AND ECONOMIC
DEVELOPMENT DIVISION

B-133192

May 9, 1978

The Honorable Harold L. Volkmer
House of Representatives

Dear Mr. Volkmer:

In response to your August 1, 1977, letter, we reviewed several alleged deficiencies concerning an Environmental Protection Agency (EPA) contract for the testing of human fetuses for pesticide residues.

We reviewed (1) EPA monitoring of the contract, (2) how the fetuses were obtained and their physical condition, (3) the usefulness of data obtained from the tests, (4) changes in the original purpose of the contract, and (5) why the contract has been continued despite objections from some EPA officials. You also asked us to determine whether the contract should be terminated. However, at the time of your request, all but $1,187 had already been paid to the contractor, and we did not pursue this alternative.

We reviewed EPA's policies and practices and examined pertinent legislation, documents, reports, and records on obtaining and analyzing fetal tissue for pesticide residues. We also interviewed responsible EPA officials and a contractor representative about contract implementation and execution.

This report contains no recommendations because our work was limited to one contract which had been essentially completed at the time we began our review. We did, however, note certain matters which warrant the consideration of the Administrator, EPA. A letter transmitting this report to EPA details these matters, which include the adequacy of (1) contract funds retained by EPA to insure satisfactory contract completion, (2) coordination within EPA to accomplish work at least cost and to avoid duplication, and (3) contract monitoring to assure the quality of contract work.

CED-78-112
(08711)

EPA CONTRACT 68-01-1930--FETAL TISSUE ANALYSIS FOR PESTICIDE RESIDUES

EPA's decision to award a contract for determining the levels of certain pesticide residues in fetal tissue resulted from an earlier Agency decision to seek cancellation of chlordane and heptachlor registrations because of unreasonable adverse health and environmental effects. One of the adverse effects noted in EPA's November 26, 1974, notice of intent to cancel was the high accummulation of these pesticides in the tissues of stillborn babies. The contract was intended to derive statistically significant data on accumulation of chlordane, heptachlor, their metabolites, and up to 16 chlordane and heptachlor substitute chemicals in human embryos and fetuses which were then related to the mothers' probable exposure to pesticides, and the age of the embryo or fetus.

On March 27, 1975, EPA advertised Request for Proposal 75X-183 in Commerce Business Daily. According to EPA records, only Automated Medical Services of Ohio, Inc. (AMSO), and Technological Resources, Inc. of New Jersey responded. Technological Resources asked to be considered for subcontract work but declined to bid on the overall contract stating:

> "The main reason for declining is due to the delicate and controversial nature of obtaining aborted fetuses and tissues. We have consulted with some highly respected obstetricians and pathologists. They have serious doubts that such a study could be successfully completed because of the conflicting policies in various hospitals and the highly controversial political, moral, religious and ethical issues involved. However, they recognize the scientific value and need for the desired information."

Therefore, EPA entered negotiations with AMSO. During a visit to AMSO in Mansfield, Ohio, a contract specialist determined that AMSO was not capable of performing the required EPA tissue analysis for pesticide residues. EPA concluded that the analysis must be performed at a subcontracted laboratory. As a result, they negotiated a firm fixed-price contract of $175,213 with an effective date of June 27, 1975. Subsequently, the contract was amended by six change orders, including a subcontract, which increased the total price to $220,687. AMSO awarded the $89,500

subcontract to the University of Utah to develop a more sensitive method of detecting pesticides. AMSO sent one of its employees to Utah to work with the subcontractor to improve AMSO's capabilities in tissue analysis.

As of January 1978, EPA had made progress payments to AMSO as follows:

Date	Amount
1-13-76	$ 34,000
3-10-76	34,000
3-18-76	34,500
4-30-76	34,500
5-26-76	34,500
8-12-76	34,500
11-18-76	34,500
1-18-77	34,500
4- 4-77	34,500
6- 6-77	10,000
	$319,500

The $1,187 balance was to be paid upon EPA's acceptance of the contractor's completed report. The final report date, originally June 26, 1976, was extended by contract change order no. 6 to December 30, 1977. However, it had not been received as of May 1, 1978.

NEWSPAPER ALLEGATIONS CONCERNING CONTRACT DEFICIENCIES

A number of alleged contract deficiencies were reported in newspapers. Our review of these allegations is detailed below.

EPA monitoring of contract

EPA monitored the contract primarily by reviewing written reports submitted by AMSO. In addition, the EPA project officer visited the subcontractor on November 22, 1976. The project officer also visited AMSO at the same time we did on September 2, 1977.

An EPA official told us that he believed the contract was adequately monitored through the periodic progress reports submitted by AMSO. The EPA Deputy Administrator has

said that the large number of contracts that EPA administers makes onsite visits to all contractors virtually impossible.

Although it is desirable that project officers make periodic onsite visits to review contract work, there may be other satisfactory means of monitoring. Guidelines for monitoring could ensure that it is adequately performed.

Source, condition, and legality of fetus samples

The contract specified that human embryos and fetuses should be collected from legal abortion clinics and from private physicians performing legal abortions. Samples were to be analyzed to determine the concentration in various tissues of chlordane, heptachlor, their metabolites, and up to 10 other pesticides which may be used as chlordane or heptachlor substitutes. The contractor was also responsible for obtaining pesticide exposure histories from the mothers and for complying with all Federal, State, and local requirements for tissue collection.

During our September 1977 visit to AMSO's office in Mansfield, Ohio, we observed that the specimens--tissue samples, not complete fetuses--were stored in a laboratory freezer in small glass bottles with screw-on lids. The lid of each specimen bottle was marked with the specimen number and tissue type.

An AMSO official told us that all specimens were obtained from legal abortion clinics and that no entire fetuses or embryos were collected. The official also stated that AMSO did not pay either the women or the clinics who provided specimens. AMSO collected 43 samples from a clinic in San Francisco, California, and 46 from a clinic in Cincinnati, Ohio. Signed consent forms and exposure histories were available for 33 of the 43 San Francisco specimens; the remaining 10 could not be located. The EPA project officer told us in December 1977 that AMSO now had all documents on file. Exposure histories were available for all 46 specimens collected in Cincinnati; however, signed consent forms were not available. Instead, AMSO had a list of 46 signatures which AMSO said were obtained from participating women after they were read a statement similar to the one on the California consent forms. (A copy of the consent form is included as enclosure I.) We did not contact the

women to verify that AMSO fully informed them about its use of the tissue samples because of the confidentiality promised when consent was obtained.

During our visit to AMSO in September 1977, we asked to see documentation regarding the consent forms (or signatures) and exposure histories for fetus samples taken. We were shown data on 79 of the 89 tissue samples. After our visit we became aware that the contractor had collected 12 additional fetus samples in Cincinnati during December 1975. AMSO did not tell us about or show us the consent forms (or signatures) or exposure histories for these 12 cases. At our request, the EPA project officer called and was told that AMSO had the appropriate documents on file.

The Federal Government has no laws prohibiting research on dead fetuses or the products of conception; however, California and Ohio do have laws restricting the use of such tissues. AMSO believed that it complied with State requirements, but State laws are not clearcut and a California State Department of Health official and knowledgeable members of the legal profession raised questions as to AMSO's compliance with State laws.

California law states:

"The rights to medical treatment of an infant prematurely born alive in the course of an abortion shall be the same as the rights of an infant of similar medical status prematurely born spontaneously.

* * * * *

"It is unlawful for any person to use any aborted product of human conception, other than fetal remains, for any type of scientific or laboratory research or for any other kind of experimentation or study, except to protect or preserve the life and health of the fetus."

AMSO did take samples of the aborted product of human conception other than fetal remains--the placenta and the decidua--for its analysis work. A California Department of Health official told us that the Department of Health was not familiar with the project and that the project had not been cleared as required through its Human Subject Review Committee. The official said that the Committee was quite concerned about such projects because abortion procedures

might be changed to avoid contaminating the tissue and because the clinic primarily served women on welfare. He said it was necessary that the Committee assure that

--standard therapeutic procedures were used in the abortions,

--women were advised of any increased risks that might result from changes in the therapeutic procedures,

--appropriate consent forms were used and thoroughly explained to participants,

--participants were notified if harmful levels of pesticide residues were found in fetus samples, and

--all available measures were taken to sustain the life of live fetuses, as required by California law.

The official said that all these issues need to be addressed. In this regard, AMSO said that it was not involved in any clinical procedures involving the mothers or obtaining the fetal tissue.

The Ohio law is also not clear. It states that:

"No person shall experiment upon or sell the product of human conception which is aborted. Experiment does not include autopsies * * * [or post mortem examinations]."

In discussing this law with a State official and experts on human testing law, we received different opinions. A case was made that the contract work was typical of post mortem examinations and, therefore, would be permitted if appropriate consent forms were obtained. A case was also made that the primary objective of the contract was to develop a new method for detecting pesticides and, therefore, the work was experimentation which is not permissible. AMSO told us that chemical analysis of the fetus tissue would be incidental to the autopsy of the specimens and, therefore, should not be considered experimentation.

We believe the issues raised regarding compliance with State procedures and the adequacy of the consent forms are matters which should be referred to the States involved.

Usefulness of data obtained under contract and changes in the contract

As previously noted, the EPA contract was originally intended to derive statistically significant data on the levels of chlordane, heptachlor, their metabolites, and up to 16 chemicals that could be used as substitutes for chlordane and heptachlor. The data was to be used in hearings on chlordane and heptachlor. The scope of the contract was formally changed by change order no. 3, dated March 3, 1976, by adding methodology development work and by stipulating that this work should take precedence. In addition, another important change was made in deleting the 16 chlordane and heptachlor substitute chemicals and replacing them with 9 chemicals that are on EPA's list of suspect chemicals, that may require suspension or cancellation action.

Consequently, AMSO developed a new method for detecting chlordane and heptachlor which, according to AMSO, is much more sensitive than previous methods. However, statistically significant data was not obtained. For example, an early AMSO proposal indicated that over 675 fetus samples would be analyzed--a much larger number than the 89 actually analyzed under the contract. Additionally, the original 12-month term of the contract was extended to 30 months, which precluded using the data in the chlordane and heptachlor hearings.

A former EPA lawyer who had worked on the chlordane and heptachlor case during 1975 told us that he could not recall the AMSO contract. There is documentation indicating that the lawyer reviewed the request for proposal but only for compliance with legal requirements. Another lawyer currently working on the case told us that he

--was not aware of the contract until October 1976,

--could not use the data because, when a summary of AMSO findings first became available in May 1977, the hearing had entered a stage which would not permit introduction of new data, and

--would not use the data because he was not sure it could be defended adequately under cross examination, and might thereby cast doubt over other EPA information.

An equally important measure of contract usefulness is how EPA plans to use the data generated. EPA National Human Monitoring Program officials said that they would not use the AMSO method because it had not undergone collaborative testing by a recognized group, such as the Association of Official Analytical Chemists, and because other methods which have undergone such testing are available. They added that these approved methods existed in 1975 when the contract was awarded. AMSO told us that an article on the detection methodology is being prepared for publication and it hopes the methodology will undergo collaborative testing.

Because statistically significant data was not generated for use in the chlordane and heptachlor hearings and because EPA does not plan to use the analytical method developed, contract benefits to EPA are quite limited.

Continuation of contract over objections

Opinions within EPA regarding the contracting out of the study differed almost from the beginning. Initially, differences apparently stemmed from which of two divisions--Technical Services or Criteria and Evaluation--within EPA's Office of Pesticide Programs should have performed the work. About 3-1/2 months after the effective date of the contract (October 15, 1975), the Director, Technical Services Division, wrote the Deputy Assistant Administrator for Pesticide Programs that in-house study efforts could have resulted in considerable savings as well as high quality results. The Director also noted that the chlordane and heptachlor hearing would most probably be completed before data from the AMSO study becomes available.

The Division prepared a more critical memorandum on November 3, 1976, supporting termination of the contract for the following reasons:

> "The contractor has spent the first phase of the contract in a methods development mode to develop methods for the * * * determination of certain chemicals in human tissues. Unfortunately neither the contractor nor the project officer knew that these methods already exist and could easily have been adapted for their purposes. This represents a totally wasted effort.

"The contractor is already behind schedule. The project will be finished (final report available) sometime after June 1977. The public hearings are scheduled to end long before this date. A realistic estimate by OGC [Office of General Counsel] is that the hearings will be completed by April 1977. Therefore, none of the data will be available, thereby nullifying the entire purpose of the project.

"Analytically, the contractors appear to be weak. Limits of detectability have not been established yet. There is no externally moderated quality assurance program. This deficiency acutely jeopardizes the use of these data in any future regulatory proceedings. Additionally, another index of exposure to chlordane and heptachlor, trans-nonachlor was omitted from the analytical protocol."

The memorandum also noted that the tissues were to be collected in only two cities, presenting severe statistical problems because of the extremely small sample size.

The recommendation to terminate the contract was also apparently based on the premise that because a great deal of work yet remained--fetus samples had not been collected--a significant portion of contract funds had not been paid. This, however, was not true. At that time EPA had already paid out $206,000 of the $320,000 contract; within 15 days the amount paid out had increased to $240,500. Analysis of fetal tissue, the original objective of the contract, was not started until after January 1977. Experience has shown that if EPA had terminated the contract, settlement costs could have eliminated much of the remaining unpaid funds without benefit to EPA. At this late point in the contract, we agree that the funds were better used in obtaining more data, rather than committing them to unproductive contract termination or settlement costs.

The Technical Services Division requested $30,000 in the fiscal year 1978 budget to collect and analyze tissue samples of 100 fetuses. Although the project was not funded, the estimated cost was in line with average EPA costs for analyzing other types of tissue. This was considerably less than the $231,000 paid AMSO for analyzing tissues of 89 fetuses, exclusive of the $89,500 subcontract with the University of Utah for methodology development. The substantial difference in the AMSO cost and the

Division's estimated cost seems to support the validity of the Technical Services Division's conclusion that a collaborative effort would have resulted in substantial EPA savings.

AMSO did not agree with many of the Technical Services Division comments. AMSO said:

--It performed the work stipulated by the contract and the modifications thereto.

--The analytical methodology was developed by a world renowned analytical chemist at the University of Utah.

--Quality assurance of AMSO analytical work was provided by the University of Utah.

We believe that the contract should not have been awarded because of (1) the possible large cost difference in doing the fetus study under contract rather than in-house, (2) the fact that a chlordane and heptachlor detection methodology already existed, and (3) early realization that data would not be developed in time for use in the chlordane and heptachlor hearing.

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We obtained comments on our draft report from the EPA project officer and the President, AMSO. Their comments were considered in finalizing our report.

The results of our review were discussed with your office on December 20, 1977. Although we performed additional work through February 28, 1978, questions still remain concerning whether California and Ohio laws on obtaining and testing fetus materials were properly followed. As agreed with your office, copies of this report will be

made available to interested congressional committees, Members of Congress, AMSO, the Environmental Protection Agency, and others upon request.

Sincerely yours,

Henry Eschwege

Henry Eschwege
Director

Enclosure

ENCLOSURE I

COPY

Dear Patient,

Today we have two visitors in our clinic, Dr. _____ and his wife ____. Dr. _____ is a pathologist from Ohio and _____ is a registered nurse.

It is their wish to do a study of the products of conception to get more information on the following questions:

1. If a woman is exposed to pesticides or other chemical agents, does it have an effect on even an early pregnancy?

2. Can a doctor determine the exact length of a pregnancy by examining the tissue?

If you agree to participate, it means that the specimen we obtain in surgery, which is usually examined by our pathologist, will also be examined by Dr. _____ for study purposes. You will also have a discussion with Mrs. _____ while you are in the clinic; this will be about your possible exposure to pesticides etc. The interview is very short and usually quite interesting. Your name will not be used, and Dr. _____ will keep no record of you by name. You may ask not to participate in the study if you wish.

___ welcomed the chance to work with Dr. _____. We strongly urge your participation as we feel this study will contribute to better medical care for all of us in the future.

I do wish to participate. Signed

Date

GAO NOTE: Underscoring indicates material was deleted from the original.