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PD-AAI-543
ISM-577

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Auditor General

AN ASSESSMENT OF THE AID-FINANCED
RESEARCH PROGRAM WITH
WASHINGTON UNIVERSITY, ST. LOUIS, MO.

An AID-Financed research program entitled, "A Study of the Side Effects and Mechanism of Action of Prostaglandins" will have little, if any, use for AID's bilateral development assistance program. As of December 1979, AID spent \$1.2 million on this research project which is directly related to abortion activities. While research into abortion-related activities is not prohibited, AID's use of abortion activities in its development assistance programs is prohibited. Nonetheless, the research continues with no defined plans by AID for using the results of the research.

Audit Report Number 80-49
Issue Date April 11, 1980

Area Auditor General, Washington
Agency for International Development
Washington, DC 20523

**AN ASSESSMENT OF THE AID-FINANCED
RESEARCH PROGRAM WITH
WASHINGTON UNIVERSITY, ST. LOUIS, MO.**

**"A Study of the Side Effects and Mechanism of
Action of Prostaglandins"**

Contracts AID/csd-3160 and AID/PRA-C-1193

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RESEARCH PROGRAM WITH
WASHINGTON UNIVERSITY, ST. LOUIS, MO.

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EXECUTIVE SUMMARY

INTRODUCTION

AID justified its research into prostaglandins on the basis that the present surgical means of pregnancy termination made demands on manpower and clinical resources impossible to meet in many settings. Accordingly, AID entered into two consecutive contracts with Washington University, St. Louis, Mo., that covered the period from June 1971 through September 1980. The value of the contracts amounted to \$1.6 million of which \$1.2 million was spent as of December 1979 (page 1).

The purpose of the program was to conduct research into prostaglandins in order to develop a chemically, self-administered means of fertility control. That is, an abortion-related research activity (page 1).

Purpose and Scope of Review

Our review was directed toward evaluating (1) the extent to which the abortion-related research was applicable to AID's development program, (2) the coordination between this research effort with similar prostaglandin research, and (3) the effectiveness of AID's monitoring and evaluation of the program. Our examination included a review of pertinent records in AID Washington and at the contractor's facility at Washington University in St. Louis and discussions with appropriate AID and contractor officials (page 2).

Questionable Use of Research Results

The potential programmatic use that AID can make of the research being conducted by Washington University is questionable because the research is directed toward abortion activities. While research into abortion-related activities is not prohibited, AID's use of abortion activities in its development assistance programs has been legislatively prohibited since June 1974 (page 3).

We found that AID does not have specific plans to apply the research directly to its bilateral assistance program. Nevertheless, AID continued with the program and obligated about \$1.2 million after the legal restrictions prohibiting AID's use of abortion activities in its development program came into being (page 5).

Similar Research Being Done by Others

The AID-financed research program into prostaglandins at Washington University is similar to research programs financed by the World Health Organization in Sweden and a locally-financed program at the University of Singapore. For example the AID-financed prostaglandin research focused on menstrual induction methods of abortion through the use of a vaginal suppository and an injectable chemical compound called sulproston. The World Health Organization research was directed toward the vaginal administration of prostaglandin to terminate early first trimester pregnancy and the research at the University of Singapore was directed at clinical trials of prostaglandins for termination of first and second trimester pregnancy. (page 6).

Summary of Management Comments

The Bureau for Development Support (AA/DS) expressed the view that the major criticism of the audit seems to be that this kind of abortion-related research is of little use since AID cannot support abortion-related programmatic activities. They felt that while this point was reasonable to raise, it ignored the fact that the real objective of AID activities is to help the poorest of the poor in developing countries, not just to develop something for use in AID bilateral assistance programs. Furthermore, it was believed that the results of work done under the project could well have application in AID service delivery programs such as health.

As a research project, AA/DS said that this contract had provided valuable basic principles and demonstrated valuable practical application; capitalized on scientific leads developed over the course of the project; it has not been superfluous to work in the same field by WHO and others and in their opinion, its monitorship and evaluation efforts have been appropriate.

The current contract expires in September 1980, and the investigator indicated to AA/DS that he does not intend to seek another contract with AID. It was stated that it, therefore, was appropriate to finalize the project and maximize its "fruition."

Conclusions and Recommendations

Notwithstanding the rationale expressed by the principal investigator and AID population officials as to the possible uses that might be made of the results of the abortion-related prostaglandin research, the fact remains that legislation prohibits the use of AID funds for abortion activities. Moreover, the extent of similar research being done by others may have satisfied AID's research objectives.

In our view, basic research into abortion-related activities that do not have a direct programmatic impact on AID's bilateral development assistance efforts should be curtailed. This is especially true in light of the financial constraints confronting AID. We believe, it is questionable to use limited Agency funds and resources for abortion-related research programs unless specific plans have been formulated and approved to effectively apply and use the research results to meet AID's authorized development objectives.

Accordingly we are recommending that AA/DS:

- (1) Identify all ongoing abortion-related research that does not have a direct impact on AID development assistance programs with a view toward curtailing further expenditures.
- (2) Justify to a higher AID authority the continuation of ongoing abortion-related research or the initiation of any new research that does not have a direct impact on AID development assistance programs.
- (3) Evaluate the system of collaboration and sharing of research results with WHO and other researchers with views toward promoting closer collaboration and coordination for more timely sharing of research results.(pages 10,11).

Other Audit Matters

Other matters requiring Agency management attention are presented in the report and include the need to (1) improve project monitoring and evaluative efforts, (2) require the submission of progress reports by the contractor and (3) require complete accountability and determination as to the disposition and use of equipment. A list of recommendations is presented as Exhibit B.

INTRODUCTION

Background

The rationale for AID's involvement with research into prostaglandins was presented in a project statement dated March 1971. It was stated, in part, that present surgical means of pregnancy termination make demands on manpower and clinical resources impossible to meet in many settings. Therefore, development of a chemical, self-administered means of fertility control would have great significance to the efficiency and success of AID-assisted family planning programs.

In effect, this research effort was directed at finding a safe and more efficient way of allowing self-administered abortion. To accomplish this objective, AID entered into two sequential contracts with the Washington University of St. Louis, Missouri. In total these contracts amounted to \$1.6 million for research to be conducted over the period June 1971 through September 1980.

First Contract AID/csd-3160 (1971-1977)

This first contract to finance the program was awarded in June 1971. It was initially intended to be effective for a three-year period until June 1974; however, it was later extended by contract amendments through September 1977 and in total amounted to \$865,957.

The contract "Statement of Work" called for the Principal Investigator to "Perform a research and development program directed toward a study of side effects and mechanism of action of prostaglandins." The program was to include but not be limited to these general objectives:

1. Conduct controlled clinical trials to examine the efficacy, acceptability and side effects of prostaglandins, focusing upon the simplest, safest, and most predictable method of therapeutic administration;
2. Examine the physiological, endocrinological and structural changes of the reproductive organs so as to determine their mechanism of action. Such studies would be complimented by basic experiments in animals; and
3. Develop a bio-assay technique using the excised uterus.

Five specific services were to be performed additionally as called for in the contract.

Follow-on Contract AID/pha-C-1193 (1977-1980)

The follow-on contract to finance the research program was awarded on September 30, 1977 and amounts to \$757,139. The statement of work of this contract is essentially the same as that of the previous contract. The general objectives are to develop and utilize biological assay

procedures for screening prostaglandin analogues to allow selection of compounds with most promising characteristics for clinical studies and to develop and test safe, effective and acceptable delivery systems for human use.

AID Policy Determination fifty-six (PD-56)

The Agency had more flexibility under this type of population program when the project was initiated in June 1971 and until June 1974. At this point the Helms Amendment came into play and the Agency developed and promulgated its PD-56 dated June 10, 1974. This became AID's policy relative to abortion-related activities.

The policy addressed "limiting use of funds for abortion." It stated, "None of the funds made available" to AID "shall be used to pay for the performance of abortions as a method of family planning or to motivate or coerce any person to practice abortions."

The policy allowed the Agency to continue to support research in this area, and it stated, "AID will continue to support research programs designed to identify safer, simpler, and more effective means of fertility control. This work includes research on both foresight and hindsight methods of fertility control." Under this Research provision, therefore, the Agency has continued to finance this research program in prostaglandins.

Purpose and Scope

We have reviewed AID's population research project, "A Study of the Side Effects and Mechanism of Action of Prostaglandins," from project inception, June 30, 1971, through December 31, 1979. At the time of our visit to the contractor's office in St. Louis in November 1979, \$1.2 million of grant funds had been expended. The purpose of the review was:

- to determine whether goals and objectives of the project are being achieved, and are applicable to AID's development program,
- to ascertain the extent of coordination between this research effort and similar research, and
- to determine the effectiveness of AID's monitoring and evaluation of the program.

Our review included an analysis of document and discussions with appropriate AID officials in Washington, and site visits to the contractor's research office at Washington University in St. Louis. At the site we reviewed appropriate documentation, observed project activities, and held discussions, as necessary, with responsible contractor officials. The review was performed between October 1979 and January 1980.

Staff members of the U.S. Senate Committee on Foreign Relations expressed special interest in this review.

FINDINGS, CONCLUSIONS AND RECOMMENDATIONS

THE POTENTIAL APPLICATION AND USE OF RESEARCH RESULTS SHOULD BE DEFINED BEFORE LIMITED AID FUNDS AND RESOURCES ARE COMMITTED

The potential programmatic use that AID can make of the research being conducted by Washington University is questionable because the research is directed toward abortion activities. While research into abortion-related activities is not prohibited, AID's use of abortion in its development assistance programs is prohibited.

We found that (1) AID does not have specific plans to apply the research directly to its bilateral assistance programs, (2) similar abortion-related research into prostaglandins is being done by others, and (3) the statement of work requirements in the contract required revision to the actual work being performed. Nevertheless, AID obligated about \$1.2 million on abortion-related research after the legal restrictions prohibiting AID's application of abortion activities in its development program came into being. These matters are discussed below in greater detail.

Plans to use research program results lacking

The AID Office of Population (DS/FOP) has no definite or documented plans to use the results to be derived from the Washington University research program. A major objective of this program from its inception was to support the use and application of the research results in less developed countries (LDCs).

When this program started in June 1971 there was no legal impediment to the use of AID funds for abortion related activity. However, with the enactment of the Helms Amendment to the Foreign Assistance Act in 1974, the Agency was estopped from using funds for abortion. AID policy determination No. 56 dated June 10, 1974 stated that none of the funds made available shall be used to pay for the performance of abortions as a method of family planning or to motivate or coerce any person to practice abortions. The policy did, however, allow the Agency to

continue to support research on abortion-related activity. It stated in pertinent part that AID would continue to support research programs designed to identify safer, simpler and more effective means of fertility control.

These elements have been an integral part of the Washington University research program and the bases for providing continued support and AID funding. The Principal Investigator said that by September 1980, convincing clinical evidence should be achieved on the results of two menstrual induction - abortion medical procedures, namely, through the use of a vaginal suppository and the injectable use of sulproston.

The Investigator said that an 85% success rate had been achieved through the use of a vaginal suppository in 40 cases; 10 completed at Washington University and 30 at Turku University in Finland. This rate was considered clinically acceptable for a suppository that could be self-administered although the side effects (nausea, vomiting and diarrhea) were frequently found unless patients were premedicated.

The use of injectable sulproston was completed in 44 cases; 20 performed at Washington University, 10 by researchers in Finland and 14 cases by associates in Hungary. The results achieved were felt to be unique in that the success rate was 100%, and in the opinion of the researchers, this therapeutic procedure was considered effective, acceptable to patients and physicians and could be recommended for routine clinical usage.

Principal Investigator's professional opinions on
use of research results

The Principal Investigator of this program has devoted his lifetime to research; the last nine years were spent on this program. He has become a world renowned expert and scientific authority in the field of obstetrics and gynecology. We asked him for his professional expert opinion on how these newly discovered medical techniques and methodologies could best be used and applied by AID to further the purposes of foreign assistance objectives in less developed countries. He stated:

- Benefits from this program depend on whether current legal restrictions on abortion are modified. It also depends on whether AID makes legal efforts to separate - menstrual induction - from abortion.
- The clinical symptoms of menstrual induction are those of menstruation rather than abortion and could be performed at the expected time of the menstrual period when current pregnancy tests are negative.

MISSING PAGE
NO. 5

Need for closer collaboration of AID, WHO and other researchers
in prostaglandins and timely sharing of research results

The AID-financed research program in prostaglandins at Washington University, St. Louis, Mo., is similar to research programs financed by WHO in Sweden, and a locally-financed program at the University of Singapore. We believe that closer collaboration among these researchers and timely sharing of research results could be more economical and enhance earlier achievement of program objectives. This is especially true where common drug compounds are being used and objectives and goals of the programs are the same.

Washington University research

The two most advanced and promising research activities at the Washington University are menstrual induction with a vaginal suppository, and menstrual induction with an injectable chemical compound called sulproston.

The AID-financed vaginal suppository studies were conducted at the Washington University and at the Turku University in Finland. Forty successive cases were completed as of November 1979. The success rate was about 85%. However, there were frequent side effects in patients, such as nausea, vomiting and diarrhea, unless premedication was used. For greater credibility and acceptance for this method of menstrual induction the Principal Investigator for the AID-financed research wanted at least 200 or more cases.

The injectable sulproston studies were conducted at Washington University, Turku University in Finland, and associate institutions in Hungary. AID funds are not used to cover any direct program costs from Hungary.

At the end of November 1979, 44 cases were completed using injectable sulproston. This study produced a success rate of 100%. It was the Principal Investigator's opinion that this therapeutic procedure is effective, acceptable to patients and physicians, and can be recommended for routine clinical use. He indicated that patients who had surgical abortion previously prefer this non-surgical method of injectable sulproston. But he wants 200 or more cases to assure greater credibility and acceptance of this method for menstrual induction.

Other research into prostaglandins

Based on our review of the World Health Organization (WHO) annual report for 1978 and our discussions with AID population officials, we believe that WHO's program in Sweden is similar to the AID-funded prostaglandin research program at Washington University.

According to their annual report for 1978, WHO supported research in prostaglandins focused on new methods for the termination of pregnancy. The program objectives stated in the report were concentrated upon the development of a non-invasive medical method for the termination of pregnancy which in the case of first trimester pregnancy would be an outpatient procedure and possibly self-administered. To this end WHO continued the development and clinical testing of a vaginal suppository for the termination of both first and second trimester pregnancy.

The WHO report included a study of 201 healthy women with a normal pregnancy. This study used the vaginal administration of prostaglandins to terminate early first trimester pregnancy. The frequency of complete abortion varied between centers. However, the results were sufficiently encouraging to justify further efforts in this new approach to fertility regulation. The aim was to develop a non-surgical outpatient, possibly self-administered, method. Another study of 438 patients conducted in eight centers in the United Kingdom, Sweden, Norway, Zambia, India and Yugoslavia using a single-dose vaginal suppository showed a success rate of 81%.

AID population officials stated that scientific research, especially biomedical research, has many facets, from the biochemical/pharmaceutical development of a new compound on through to the final clinical testing. The programs of WHO and Washington University share a common medication--prostaglandins. The research at Washington University has been aimed at understanding mechanisms of action of prostaglandins through laboratory and animal studies. At the same time, WHO conducted field trials in different countries with varying dosages of prostaglandins, routes of administration and timing.

They further stated that the contractor's work at Washington University often suggests changes in protocols used by WHO. As with all scientific research, the major communication of scope, status and results are exchanged through publications and through personal communication. In this case, communication is further facilitated through a series of inventories and meetings. Each organization (WHO and AID) prepares and exchanges an annual research inventory and report. In addition, the annual WHO meeting of biomedical research on contraception provides a format for further exchange. Whereas administrative aspects of each program may not be fully communicated to each other, the scientific protocols and research results are openly published and information frequently exchanged by the persons involved.

The Principal Investigator stated that the major difference in his program and the WHO program is conceptual. Since 1972 the Washington University research primarily focused on menstrual induction while the

WHO researchers worked mostly on abortion and only in recent years on menstrual induction. However, now that there are indications that WHO modified their concepts and protocols, the two independent programs may have a greater overlap in the next few years.

He further stated that in 1976 WHO had already published the outcome of hundreds of clinical trials using prostaglandins. Thus he was knowledgeable of the WHO program from articles and WHO reports, but he lacked specific information on the projected duration of their program.

AID also started funding the University of Singapore prostaglandin research program with the Makerere University at Kampala, Uganda, in June 1971. Because of political events in Uganda, the Principal Investigator moved to the University of Singapore in June 1973 under contract AID/CM/PHA-C-73-36.

The contract work plan called for the researchers to conduct clinical trials of prostaglandins for termination of first and second trimester pregnancy; explore the use of prostaglandins for termination of very early pregnancy; investigate the mechanism of action of prostaglandins; conduct studies of the side effects of prostaglandins; and train fellows and collaborate with scientists.

The expected end results of the program were similar to the Washington University contract - to develop a simple, safe and practical method for the termination of pregnancy throughout the gestation and to find a better understanding of the mechanism of action of prostaglandins.

AID's contract terminated in September 1976 and at that time the Principal Investigator obtained funding to continue research activities from local sources. The Principal Investigator continued his prostaglandin research activities, but actual status of the research results are not immediately available in AID's Office of Population.

In addition to the research described above, which is similar to the Washington University AID-financed research into prostaglandins, the U.S. Government is also financing other research into prostaglandins. For example, the U.S. Department of Health, Education and Welfare publication dated November 1979 entitled, "Inventory and Analysis of Federal Population Research - Fiscal Year 1978," shows 26 separate grants or contracts for research into prostaglandins. The total value of these grants and contracts is about \$12 million.

Need for more specificity in research objectives

The contract scope of work needs to be refined to give effect to changes that have transpired in program goals and contractual requirements that are not expected to be accomplished. Research should focus specifically on those activities that can be more effectively and reasonably achieved under the AID contract before its scheduled termination in September 1980.

This program had a broad statement of work from its inception in June 1971. The broad scope of work allowed the researchers a great deal of flexibility which the Principal Investigator considered necessary in a research program of this nature.

The present contract statement of work is composed of numerous research activities including the injectable prostaglandin and the prostaglandin vaginal suppository methods for menstrual induction (abortion). The general objectives of this contract were to develop and use biological procedures to allow the selection of chemical compounds with most promising characteristics for clinical studies, and to develop and test safe, effective and acceptable delivery systems for human use.

Other significant research called for comparative screening of new prostaglandin compounds produced by the Upjohn Company and the Warner-Lambert Company. An abortion screening test was to be performed also.

Other research called for the development of vaginal delivery systems through the use of melting suppositories. This research called for studies in animal models and coordinated human trails to determine the most effective and acceptable treatment schedule, studies of a controlled release system for vaginal suppositories, as an abortion is progressing, and pilot studies by injecting patients intravaginally by pump infusion when menstrual periods were delayed two weeks. Extensive clinical studies were also required to be made during various stages of pregnancy with the use of prostaglandin compounds.

During discussions with the Principal Investigator about the program during our visit to the project office at Washington University, we pointed out the need for a clear definition of expected goals to be achieved under the AID contract. We were concerned about research that had been completed to date, the identification and status of the most promising advanced research in the program, and the additional research that could realistically be expected to be completed during the contract period.

The Principal Investigator acknowledged that the contract statement of work requirements needed revision because the primary aims of the contract had been achieved. However, additional clinical data using the guinea pig as a predictive model for testing the potential of compounds in postconceptional therapy is the most promising research activity that is needed to be focused on during the remaining contract period. However, there is reason to question if all ongoing research can be accomplished before the now scheduled date of contract termination.

AID Office of Population (DS/POP) officials stated that they are basically in agreement with the need to modify the contract scope of work, but they emphasized the importance of distinguishing between the broadness of what the contract now requires and what it permits.

They described as one example that the contract currently calls for the Principal Investigator to test a certain prostaglandin compound (WX 13,426). However, because of unfavorable early test results the drug company abandoned its testing. This compound is not now available to the Principal Investigator. Therefore, it would be meaningless to continue to require a specific exercise that could no longer be carried out.

They also cited as an example research that was permitted and allowed to be made but that was never specifically mentioned in the contract. This research with the prostaglandin compound sulproston now appears to be the most directly applicable work achieved under the contract. The DS/POP officials concluded that this was the nature of research and, while the Investigator proposed to focus primarily on the guinea pig and sulproston for the remaining year of the contract, he should continue to be allowed to pursue other related relevant leads as they arise.

Conclusions and Recommendations

Notwithstanding the rationale expressed by the principal investigator and AID population officials as to the possible uses that might be made of the results of the abortion-related prostaglandin research, the fact remains that legislation prohibits the use of AID funds for abortion activities. Moreover, the extent of similar research being done by others may have satisfied AID's research objectives.

In our view, basic research into abortion-related activities that do not have a direct programmatic impact on AID's bilateral development assistance efforts should be curtailed. This is especially true in light of the financial constraints confronting AID. We believe it is questionable to use limited Agency funds and resources for abortion-related research programs unless specific plans have been formulated and approved to effectively apply and use the research results to meet AID's authorized development objectives. Accordingly, the following courses of action are recommended:

Recommendation No. 1

AA/DS identify all ongoing abortion-related research that does not have a direct impact on AID development assistance programs with a view toward curtailing further expenditures.

Recommendation No. 2

AA/DS justify to a higher AID authority the continuation of ongoing abortion-related research or the initiation of any new research that does not have a direct impact on AID development assistance programs.

Recommendation No. 3

AA/DS evaluate the system of collaboration and sharing of research results with WHO and other researchers with views toward promoting closer collaboration and coordination for more timely sharing of research results.

AID MONITORING AND EVALUATION OF THE RESEARCH PROGRAM HAS BEEN SPORADIC

This research project has been ongoing for more than eight years and AID's monitoring and evaluation of the program needs to be improved to assist AID's management in their assessment of project accomplishments. For example, only three Research Advisory Committee (RAC) reviews were made, including a pre-project review. AID population officials made only three project site visits which were documented by field trip reports, and only one formal outside evaluation had been made of the program. This evaluation was performed only recently during October and November, 1979. Our comments on these subject activities are presented below.

Research advisory committee (RAC) reviews

Although three RAC reviews were made on the program, only the most recent RAC review, performed on December 10, 1976, addressed the need for an evaluation of the program.

The first RAC review of the program was a pre-project review made April 15 and 16, 1971. AID presented the RAC with a general statement on prostaglandin research including the background, the progress to date, and a request for a very careful study of the side effects of prostaglandins. AID/DS/POP officials presented the Washington University's proposal. They emphasized that the research needs were clearly stated and that the researchers were well qualified and experienced. The RAC approved the program for AID support as presented, for a three year period from 1971 to 1974.

The second RAC review was performed on May 6 and 7, 1974. The issue was whether AID would extend the program for three more years from July 1974 to June 1977. The RAC reviewed available information and elicited comments on questions regarding: project accomplishments to date; rationale for extension of program under the contract; and other program related matters. In its meeting on May 6 and 7, 1974, the RAC recommended that the requested extension be approved. RAC made no mention of a need for a comprehensive evaluation of the program, but

recommended that AID give serious consideration to making this a terminal grant if technology suitable for wide-scale use had not been developed by the close of the extension period.

On September 30, 1976, the AID contract was modified by Amendment No. 14 to extend the program under the contract an additional three months from June 30, 1977, to September 30, 1977, to coincide with the new fiscal year. The AID contract records indicated that the three month extension did not have RAC approval, but a proposal for continuation of work through FY 1980 would be reviewed by RAC during the fall of 1976.

A third RAC review of the program was held on December 10, 1976. Again, RAC analyzed the various data presented for review. Even though the RAC generally favored extending the program, it was concerned that the project seemed to be going on and on more or less indefinitely. A technology suitable for wide-scale use had not been developed at that time. They stated that over-optimism appeared to be a chronic feature of projects in this area. The RAC discussed other problems related to the policy and political issues raised, and discussed ethical and clinical controls over experimentation for inputs to the program from researchers in Finland and Hungary. The RAC members were apprehensive about the apparent lack of progress to date, but they wanted to see a product developed as a result of these research efforts.

AID population officials stated that the complexity of the problems encountered in population research cause one to give up, and all of the questions raised have been given serious consideration. They further stated there is real concern about the apparent lack of speed, but the drug regulatory requirements demand time for extensive testing of new compounds, formerly stated in terms of months, now requiring years. Also that all U.S. sponsored research overseas must be approved by appropriate Human Ethical Committees, and a single standard of ethical concerns and practices is used in both the U.S. and abroad.

The RAC recommended extension of the prostaglandin project with the understanding that AID staff review the budget with the objective of reducing it wherever possible and with the commitment to terminate the project at the end of two years if it is judged that a technology suitable for wide-scale use will not be developed by the end of the three years.

The prior RAC review of the program in May 6 and 7, 1974, ended with a recommendation that AID give serious consideration to making this a terminal grant if technology suitable for wide-scale use has not been developed by the close of the extension period. RAC restated the same recommendation more than two years later in its meeting on December 10, 1976.

One significant action took place subsequent to the December 1976 RAC approval of the three year extension. A provision included in the new contract #1193 required that technology suitable for wide-scale use will be developed by the end of three (3) years. The contract also required an evaluation of progress toward the objectives. This evaluation was to be undertaken at the end of the second year of the contract (September 29, 1979). The purpose was to determine the likelihood that contract objectives will be fulfilled within the three year period. The next RAC review of the program is scheduled for May 1980.

Conclusion and Recommendation

We believe the RAC reviews of the program would provide greater utility to AID if they stressed the need for timely independent evaluations of the program, and addressed the questions regarding proposed utilization of research results.

Section G.1 of the Manual Order No. 1531.1 states the RAC is established by the Administrator to evaluate all research proposals eligible for implementation under central funding sources and to advise appropriate action.

Section G.2 of the Manual Order states in part that the RAC also reviews proposed extensions of active research projects involving major changes in substance or funding and evaluates project progress reports. The Manual Order, Section G.3, states in part that in addition to evaluation and advice on individual proposals and ongoing research projects, RAC undertakes a broader advisory role on such matters as long-range research directions and priorities, participation on Agency sector or key problem committees, and utilization of research results in field technical assistance programs.

In view of the facts in this case and the above AID requirements, it is evident that the Agency relies heavily on the RAC evaluations and their recommendations. We believe it is significantly important, therefore, that the RAC reviews stress the need for timely independent evaluations of the programs and address proposed utilization of research results.

Recommendation No. 4

AA/DS should reassess the RAC review procedures and ensure that all future RAC reviews of the Agency's research projects address all significant areas, including the need for timely independent evaluations and proposed utilization of research results, in accordance with AID's requirements.

Project management and monitoring deficiencies

AID/DS/POP needs to strengthen its management and monitoring practices to assure more effective implementation of research activities.

Three project site visits were made which were documented, and although frequent informal contacts were indicated, these were seldom documented. These gaps, we believe, do not provide an historical overview of the program activities and progress achieved against project goals. Consequently, most of AID's management and monitoring practices were restricted to the AID Population Office's review of published reports and its informal contacts with the Principal Investigator.

Even though the program was initiated in June 1971, the AID Population Office records indicated that the first site visit was not made until November 1974. A field trip report covering the first visit was prepared in January 1975. A second field visit was made in late September 1976 and a covering field trip report was prepared in December 1976. A new project officer was designated in the fall of 1978 and he made a two-day site visit to the project in late November 1978. A trip report was prepared in December 1978. The project officer made another two-day visit to the project site in early October 1979 to accompany two outside consultants engaged to evaluate the program, but a covering field trip report was not prepared.

We believe that the first trip report provided an excellent overview of research activities at that time. There was ample evidence that the AID population official held in-depth discussions on the program with the Principal Investigator. The report clearly indicated that the AID official was well versed in the program. He was able to ascertain and report precisely the status of the program. His review appeared to cover all significant aspects including: what research activities were completed; the research activities in process; techniques and drug compounds used in the research; as well as the directions envisioned in conducting future research from that point. There was also evidence that this official's background and knowledge enabled him to provide constructive suggestions on problems that needed to be resolved.

The second field trip report was prepared by the same AID official. However, the trip report did not provide an overview of the program at that point. But the report did show that in-depth discussions were held with the Principal Investigator on research progress and related matters.

The report indicated that other research activities were discussed including clinical studies to be carried out in the U.S., Finland and in Hungary. It indicated that all of these sites have approved human

experimentation committees, but AID would not provide any financial support for studies carried out in Hungary. The AID official generally concluded that the research group was energetic, focused on the development of improved fertility control technology and operated a high quality program.

The third trip report was prepared to cover a site visit to the project on November 28 and 29, 1978. This field visit was made by the newly designated AID project officer and it was a get-acquainted visit with the Principal Investigator. While the report did not give any details of discussions, it did provide brief sections on: the basic research; current clinical work with prostaglandins; progesterone synthesis inhibitor; and other health related spin-offs. The AID project officer concluded that he found the Principal Investigator's work very much on track with regard to the objectives of his contract and the work could well lead to useful improvements in several areas of fertility regulation.

The project officer made another field visit to the project in October 1979. The purpose of this visit was to accompany two outside consultants engaged by AID to evaluate the program. The project officer stated that the consultant team report when submitted will constitute the greater part of his trip report.

DS/POP officials indicated they believed that the technical monitoring of this project has been sufficient. It was their view that good technical monitoring of such a project primarily involved understanding the project, how it fits into an overall research and population program, and keeping track of the scientific aspects of the project to help maximize the benefits derived from it.

They rely heavily on the published literature, reports and informal communication, and only a moderate amount of site visiting.

Conclusion and Recommendation

We believe that project management and monitoring can be improved upon, and that formal documentation of these activities and informal contacts would strengthen the project management and monitoring of this research program. Guidelines contained in AID Manual Order No. 1531.1, Section V identify project manager responsibilities. These responsibilities in part are to assure: that required reports are prepared and submitted on time; that adequate work plans exist and that satisfactory progress is being made in the research to assure optimum utilization of interim and final research findings; that he prepares his own evaluation of the research project for others in the Agency and for the project files; and that on-site visits to evaluate the project are made and documented. This lack of documented site visits indicates a clear need, in our opinion, for the Bureau for Development Support to assess the

Population Office project management activities and implement procedures aimed to strengthen its oversight management and monitoring of the research program area.

Recommendation No. 5

AA/DS should require that an evaluation be made of the Office of Population project management activities to implement controls and procedures to strengthen its oversight management and monitoring of research projects. The requirements of AID Manual Order 1531.1, Section V, should be analyzed and implemented, as a minimum, in connection with this assessment.

First on-site evaluation of the program by outside consultants

The first on-site evaluation of the program by outside consultants was performed in October 1979. The AID Population Office had this evaluation made to comply with the present contract provisions.

In accordance with the contract, the AID Population Office, through the American Public Health Association (APHA), contracted for the services of two outside consultants to evaluate the program. One of the consultants was an M.D. in OB-GYN and the other was a Ph.D., Reproductive Endocrinologist. A requirement was for the OB-GYN to have experience and knowledge of animal work, and the Reproductive Endocrinologist to have some experience in human clinical work.

The AID Population Office developed a scope of work for the consultants to follow in conducting the evaluation at Washington University. The scope of work document gave a brief background for the project and indicated the overall objectives have been: to elucidate the basic mechanism of action of prostaglandins and other related compounds in initiating and maintaining uterine contractions; and to screen various synthetic prostaglandins and other compounds for use in fertility regulation including menstrual regulation and abortion. Compounds are sought for use in both a clinical setting and for self-administration.

The Population Office listed twelve questions for the consultants to provide answers for regarding the program, and provided them with copies of the AID contract work scope, copies of available progress reports, and recently published articles. Although the project dates back to 1971, the consultants were to focus on results of the current three year contract.

The evaluation team performed their review at Washington University in a two-day period, October 1 and 2, 1979. We were provided with a copy of their draft evaluation report in early November 1979. The report noted that it was limited to the AID DS/POP official's questions. We were concerned about the apparent limitations imposed upon the evaluators as to the time frame for field work, and that their review was limited only to questions raised by the Population Office. It appears to us that such restrictions precluded an independent evaluation of the program.

Furthermore, no provision was made for the consultants to meet with researchers in Finland and Hungary for discussions and to review records. Consequently, their evaluation was limited to available data in AID, at Washington University and through discussions with AID population officials and the Principal Investigator at Washington University. Moreover, neither the AID population officials nor the evaluators made on-site visits to associate's institutions in Finland and Hungary.

In their report, the evaluators stated that self-administration of compounds for menstrual induction should be and is a goal of this project. The present development of a 2-compartment fast and slow release vaginal suppository for the delivery of sulproston will be a likely candidate for this drug-delivery system. They stated the goal for a once-a-month suppository for self-administered early abortion, although certainly possible, would be dependent upon social factors outside the realm of this project.

The evaluation was initiated by the AID Population Office mainly to comport with the recommendation of the last RAC review in December 1976. This recommendation was carried over to the condition that AID would terminate the project at the end of two years if it was judged that a technology suitable for wide-scale use will not be developed by the end of the three years.

For the AID Population Office to fully comply with the RAC recommendation and the contract provision, an independent comprehensive evaluation should have been made sooner so that it could have determined whether the contract should be terminated in September 1979, the end of the first two years. This particular point was not answered by the consultants' report. Moreover, the AID Population Office already had available information to answer its own questions posed for the consultants to answer.

The AID DS/POP officials indicated that their March 1979 internal review of the project budget was in accordance with the December 1976 RAC recommendation. At that time, they judged that a technology suitable for wide-scale use would be developed in three years as recommended. They expressed that such a judgment made as late as September 1979 would have been too late to make a judgment for third year funding.

However, they stated that the draft report prepared by the consultant team had already been of definite utility.

Conclusion and Recommendation

The population officials indicated the outside evaluation was quite beneficial, but we question the real benefits of this limited type of evaluation to AID for reasons we have stated earlier. Moreover, although a great deal of the research program inputs were from research sources in Finland and Hungary, the Principal Investigator is the only project researcher who has visited these facilities.

Even so, the AID population officials concluded that a trip to visit the Principal Investigator's collaborators in Finland and Hungary would have been of very low utility. Consequently, the evaluators were limited to available data in AID and at Washington University, discussions with AID population officials, and a two day project site visit. These limitations are significant, given the fact that it was a first outside and on-site evaluation of the research program that has continued for almost nine years.

We believe it is now important for the AID Bureau for Development Support to assess the overall evaluation of this research program. We believe the Bureau for Development Support needs to make sure that this program is scheduled and reviewed again by the RAC committee, and that appropriate measures are taken to finalize the project.

Recommendation No. 6

AA/DS should determine the extent to which this research program should be continued or establish a final termination date, and ensure, if it is to continue, that the program is scheduled and reviewed by the RAC in its Spring 1980 session.

DEFICIENCIES IN THE RESEARCH PROGRAM PROGRESS REPORTING

The contractor's required semi-annual and annual progress reports on the research program have not been submitted throughout the contract period. Moreover, the reports when submitted generally did not provide an overview of progress achieved against overall research objectives. These are considered basic elements to facilitate effective AID monitoring and evaluation of the program.

Of the 17 program reports required during the period June 1, 1971, through September 30, 1979, the contractor submitted only nine reports. The initial contract was active from June 1971 through September 1977, and required that semi-annual progress reports be submitted on July 15th

and January 15th to cover the preceding six months period. Four semi-annual reports were not received for the periods ending December 1974, December 1975, December 1976 and June 1977. However, the annual reports were received as well as the final report which covered the contract through its completion date of September 30, 1977.

The follow-on contract became active on October 1, 1977, and its scheduled completion date is September 30, 1980. The first progress report under this contract was received in February 1979, about one year late. The report covered an eighteen-month period. The latest semi-annual report was received in September 1979.

Some of the reports submitted consisted of abstracts of research which had appeared in obstetrics and gynecology publications and were not always related to activities which had occurred in the reporting period. We believe this fragmentary reporting contributes to difficulties in monitoring and evaluating research activities.

In January 1972 AID developed new guidelines for the preparation of research annual reports. These guidelines were incorporated in this contract and were to be used to prepare progress reports on all AID research contracts. Reports were to be submitted in a prescribed format that could be used to improve annual project reviews, and provide information on the effectiveness of research resources in producing research results.

Report topics to be covered included:

- A concise statement of the background and rationale that led to the initiation of the project,
- A statement of the initial program objectives and any changes made,
- An explanation of the continued relevance of project objectives,
- A discussion of the significant findings and other accomplishments for the reporting period as they relate to the anticipated results in the work plan,
- A description of the efforts to disseminate and utilize research results, and evidence and cases known that the research findings are being used in developing countries,
- A statement of expenditures and obligations related to the budget plan,
- A work plan and budget forecast for the coming year, and

- Any pertinent reports of technical data and analyses, abstracts of papers and publications and other research findings and reports, as appropriate.

Reports when submitted did provide information on the current research activity, but failed to provide an overview of research progress against program objectives. Therefore, we could not measure research accomplishments as they related to project objectives as stated in the contract. A more meaningful evaluation of research activities could be made by AID's management if reports were submitted in the format prescribed in the contract.

AID population officials acknowledged that the Principal Investigator had not submitted progress reports timely and in the format required by the contract. They believed, however, that written reports submitted since the beginning of the current contract No. 1193 permitted sufficient professional monitorship.

They stated that for their purposes the crucial information is the accomplishments to date which they believe had been addressed by the Principal Investigator. They also felt that their two site visits, the Principal Investigator's published literature, a recent formal evaluation, our own audit activities, and numerous verbal interchanges had allowed good information exchange.

They stated, however, they will take steps to see that progress reports related to the contract, particularly the final report, are filed at the AID reference center when received.

The Principal Investigator's most recent semi-annual report, dated September 6, 1979, covered research activities from February to September 1979. A current semi-annual progress report is due shortly.

Conclusion and Recommendation

We believe the AID Population Office officials should require the Principal Investigator to submit subsequent research reports in the prescribed format as outlined in the contract. Furthermore, the AID Population Office should ensure that all progress reports are filed with the AID reference center as required by the Agency regulations (AID Handbook 18).

Recommendation No. 7

AA/DS should require the Principal Investigator to submit a current progress report on the research activities under the "refined" contract scope of work in accordance with the contract guidelines, and have all of the contract research progress reports recorded and filed at the AID reference center in accordance with AID Handbook 18 requirements.

NON-UTILIZATION OF AID-FINANCED EQUIPMENT

The research equipment purchased with AID contract funds has amounted to almost \$35,138. Our on-site verification of the items in November 1979 indicated that most of the equipment was in storage and not presently used. Title to the equipment is vested with AID under the contract terms.

Six major items of equipment valued at approximately \$17,496 were in storage, and these items had not been utilized since October 1978 when the laboratory was moved to other facilities. According to the Principal Investigator, four of the items were previously used, but the other two, a transducer and transmitter with accessories valued at \$2,911 had not yet been utilized in the program. The transducer was purchased October 7, 1979, and the transmitter was purchased April 11, 1978.

Three items valued at approximately \$726 could not be located at the time of our site visit. The Principal Investigator said that this equipment became inoperable and was destroyed. This equipment was purchased during the period September 25, 1973, to February 26, 1976.

An Eppendorf centrifuge with accessories valued at \$492 was missing. We were told that this equipment was taken by a former researcher when he relocated to another institution. This equipment was purchased June 17, 1976.

A survey meter with accessories valued at \$279 could not be located and there was no additional information about it at the time. It was purchased August 24, 1976.

The non-utilization of the above equipment and related matters was discussed with the Principal Investigator. We asked for his plans for recovering the missing equipment and for utilizing the items held in storage. We were advised that the six items of equipment in storage will be installed in a new 4th floor laboratory facility in early 1980. Also that the three items which could not be located were accessories to

a fluoroscope. After they became non-functional because of a technical failure the items were left behind when the laboratory was moved to its present location.

At the end of our audit field work, the Principal Investigator had requested the former researcher to return the missing centrifuge. The Principal Investigator stated if the missing survey meter was not located it would be replaced by the University.

A request has been made to the Department of Health, Education and Welfare (HEW) to confirm the above actions taken or planned on the equipment when they perform their forthcoming audit of AID contract costs. The audit has been scheduled to begin early in 1980.

Conclusion and Recommendation

The contracting officer should determine whether all the equipment is still required for the program and direct that appropriate disposition be made of the equipment in accordance with provisions of the AID contracts.

The contracting officer concurred with our findings.

Recommendation No. 8

AA/SER/CM should initiate action to require full accountability and disposition of AID-financed equipment in accordance with the AID contract provisions.

FINANCIAL AND ADMINISTRATIVE MATTERS TO BE RESOLVED

Our review of financial records and reports at Washington University showed a need for various financial and administrative matters to be resolved:

A current audit of AID contract costs is needed. The HEW audit agency has the cognizant audit responsibility of Washington University overhead and costs under all AID and other U.S. Government-funded programs at this institution.

We reviewed the HEW's audit report dated May 1978. Their report covered costs of \$372,917 claimed by the University under AID contract #3160 through June 30, 1975. Their audit did not question any costs at that time. We noted cumulative costs through August 31, 1979, amounted to \$1,220,934 under contracts #3160 and #1193, leaving a balance of \$848,000 unaudited as of that date.

The most recent HEW audit at Washington University was conducted during June and August 1979. The results of this audit were furnished to AID on January 28, 1980. The audit related to costs claimed under AID sub-grant P-5 of grant AID/pha-G-1064. This grant was awarded to Johns Hopkins Program for International Education in Gynecology and Obstetrics (JHPIEGO).

At the close of their audit in August 1979 the University and HEW had not yet reached a final decision on the steps required to bring the University's labor certification and distribution systems into compliance with the requirements of OMB Circular A-21. In addition they questioned travel costs that were not fully supported in accordance with terms of the subgrant.

We communicated with HEW audit officials and requested a final audit of costs under contract #3160 which terminated September 30, 1977, and a current initial audit of contract #1193 which became active October 1, 1977, and is scheduled to terminate September 30, 1980.

Although our audit did not address contract costs we did selectively relate contract budget line items to procurement documentation records maintained by the Principal Investigator's staff at the research laboratory. Certain apparent deficiencies were noted relating to equipment, procurement source waiver, travel costs and payments to consultants.

As commented upon heretofore, some equipment was not utilized, and some relatively minor items of equipment could not be located at the university.

The contractor, exceeded the AID approved amount for procurement of consultant services from non-U.S. sources. An AID waiver approved \$156,000 for this procurement, but the expended amount was approximately \$164,000.

The AID contract required travel on U.S. flag carriers unless U.S. carriers were unavailable, and, deviations from this requirement required a certification to justify any exceptions. Travel reports did not identify the air carriers utilized.

Internal controls are lacking in the preparation of billings for consultants services and the distribution of check payments for these services. This is primarily applicable to services performed by the Principal Investigator's research associates in Finland. The Principal Investigator reviews their services inputs and instructs them in their billings. He indicated this enabled him to stay within the budget because the researchers usually performed more services than they were paid for, and this is the reason the billings are prepared in this manner.

The university's check payments for these services are made out to the associate researcher in Finland instead of that individual's institution, and these checks are routed through the Principal Investigator to be

forwarded to Finland. The Principal Investigator explained the reason this is done is to avoid delays which were experienced in the past. We believe that normal internal controls are lacking under these billing and payment procedures.

In addition to our request to the HEW audit agency for current audits of the AID contract costs at the university, we formally communicated the above cited deficiencies to them on November 30, 1979. They indicated their audit of the AID contract costs and above related points is scheduled to be made in January-February 1980.

The AID Contracting Officer, SER/CM, needs to close the AID-terminated contract #3160 and other contract matters once the HEW audit report is received and reviewed.

The Contracting Officer SER/CM stated that appropriate action would be taken to finalize a close-out of contract #3160 and related matters once the HEW audit report has been received and reviewed.

Recommendation No. 9

AA/SER/CM, should finalize close-out settlement of contract #3160 upon receipt and review of the HEW audit agency's final report on contract costs and related matters.

Washington University
 Summary of Contract Budget, Expenditure, and Balance Remaining
 Contracts AID/csd-3160 and AID/pha-C-1193
 June 1, 1971 through August 31, 1979

EXHIBIT A

	<u>AID/csd-3160</u>			<u>AID/pha-C-1193</u>			<u>Total</u>		
	<u>Budget Amount</u>	<u>Expenditures to Date</u>	<u>Balance Remaining</u>	<u>Budget Amount</u>	<u>Expenditures To Date</u>	<u>Balance Remaining</u>	<u>Budget Amount</u>	<u>Expenditures To Date</u>	<u>Balance Remaining</u>
Salaries	\$ 265,687	\$ 265,272	\$ 415	\$ 251,812	\$ 137,029	\$ 114,783	\$ 517,499	\$ 402,301	\$ 115,198
Fringe Benefits	20,130	14,039	6,091	23,957	11,247	12,710	44,087	25,286	18,801
Consultants' Fee	167,092	158,420	8,672	115,850	36,200	79,650	282,942	194,620	88,322
Consumable Supplies and Other Expenses	146,966	147,061	(95)	138,742	91,516	47,226	285,708	238,577	47,131
Travel	25,760	24,335	1,425	29,790	18,764	11,026	55,550	43,099	12,451
Equipment	45,250	28,703	16,547	5,000	2,934	2,066	50,250	31,637	18,613
Overhead	195,072	187,498	7,574	191,988	97,916	94,072	387,060	285,414	101,646
Total	\$ 865,957	\$825,328	\$40,629	\$ 767,139	\$ 395,606	\$ 361,533	\$1,623,096	\$1,220,934	\$ 402,162

LIST OF REPORT RECOMMENDATIONS

Recommendation No. 1

AA/DS identify all ongoing abortion-related research that does not have a direct impact on AID development assistance programs with a view toward curtailing further expenditures.

Recommendation No. 2

AA/DS justify to a higher AID authority the continuation of ongoing abortion-related research or the initiation of any new research that does not have a direct impact on AID development assistance programs.

Recommendation No. 3

AA/DS evaluate the system of collaboration and sharing of research results with WHO and other researchers with views toward promoting closer collaboration and coordination for more timely sharing of research results.

Recommendation No. 4

AA/DS should reassess the RAC review procedures and ensure that all future RAC reviews of the Agency's research projects address all significant areas, including the need for timely independent evaluations and proposed utilization of research results, in accordance with AID's requirements.

Recommendation No. 5

AA/DS should require that an evaluation be made of the Office of Population project management activities to implement controls and procedures to strengthen its oversight management and monitoring of research projects. The requirements of AID Manual Order 1531.1, Section V, should be analyzed and implemented, as a minimum, in connection with this assessment.

Recommendation No. 6

AA/DS should determine the extent to which this research program should be continued or establish a final termination date, and ensure, if it is to continue, that the program is scheduled and reviewed by the RAC in its Spring 1980 session.

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Recommendation No. 8

AA/SER/CM should initiate action to require full accountability and disposition of AID-financed equipment in accordance with the AID contract provisions.

Recommendation No. 9

AA/SER/CM, should finalize close-out settlement of contract #3160 upon receipt and review of the HEW audit agency's final report on contract costs and related matters.

LIST OF REPORT RECIPIENTS

	Copies
Deputy Administrator	1
Assistant Administrator, Bureau for Development Support (DS)	5
Director, Office of Population (DS/POP)	1
Audit Liaison Officer, Bureau for Development Support (DS)	1
Bureau for Program and Management Services, Office of Contract Management (SER/CM)	1
Office of Legislative Affairs (LEG)	1
Office of Financial Management (FM)	1
Office of the General Counsel (GC)	1
Office of Development Information and Utilization (DS/DIU)	4
Office of the Auditor General (AG)	1
Office of Policy, Plans and Programs (AG/PPP)	1
Communications and Records Office (AG/DMS/C&R)	12
Area Auditor General/Washington (AAG/W)	1
Office of Inspections and Investigations (AG/IIS)	1