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Report to the Chairman, Committee on Governmental Affairs, U.S. Senate

December 1991

BIOLOGICAL WARFARE

Role of Salk Institute in Army's Research Program

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National Security and
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December 19, 1991

The Honorable John Glenn
Chairman, Committee on Governmental Affairs
United States Senate

Dear Mr. Chairman:

As you requested, we reviewed work performed for the Army by the Salk Institute, a private nonprofit organization in Swiftwater, Pennsylvania. In carrying out the medical component of its Biological Defense Research Program (BDRP), the Army began in 1978 to contract with Salk to develop, produce, test, and store vaccines to protect U.S. forces against biological warfare threats. The objectives of our review were to determine whether

- Salk had developed and produced vaccines to protect U.S. forces against biological agents that had been validated, that is, determined as being developed or produced as a weapon;
- contracting with Salk is the Army's only viable means of developing and producing these vaccines; and
- the fees paid to Salk for the use of its facilities were in accordance with applicable federal regulations.

Results in Brief

Most of the Salk Institute's work has not been devoted to developing and producing vaccines to protect U.S. forces against validated biological warfare threat agents. Though the mission of the medical component of the BDRP is to develop countermeasures against only validated agents, the Army has directed Salk to use the bulk of available funds for work on non-validated biological threat agents. Some program officials believe that the BDRP should not be restricted to validated threat agents. Of the $17.7 million spent under the 5-year 1988 contract (through March 31, 1991), only $3 million, or 17 percent, was used for work clearly related to validated biological warfare threat agents. The Salk Institute provided no vaccines for Operation Desert Shield/Storm.

The Army has limited commercial alternatives to using the Salk Institute to develop vaccines because Salk has a unique vaccine production facility. However, the Army could improve and expand its in-house vaccine production facilities to meet its needs, although the cost of such expansion is unknown.

The Army has paid Salk about $5.5 million more in fees for the use of its facilities than what is authorized by regulation. In determining the fees, the Army followed cost principles established for commercial organizations rather than for nonprofit organizations. Other contracts may be similarly affected.

Background

The mission of the medical component of the BDRP is to develop medical defenses, such as vaccines and drugs, to defend against biological warfare. The Department of Defense (DOD) defines a "biological warfare threat" as a biological agent that is assessed (or "validated") by the intelligence community as being developed or produced as a weapon. The Assistant to the Secretary of Defense for Atomic Energy provided DOD's definition to the Senate Committee on Governmental Affairs in a written response to questions raised during a May 17, 1989, congressional hearing. Medical defenses against these threats include preventive vaccines, drugs, therapy, and patient treatment and management. The Department of the Army executes the medical component of the BDRP through research and development projects. For fiscal years 1984 through 1991, the Congress appropriated about $445 million for the medical component of this program.

As part of the BDRP, the U.S. Army Medical Research and Development Command has awarded Salk three multiyear contracts valued at $75.4 million to develop, produce, and test biological vaccines and to produce other biological products such as cell cultures and diagnostic reagents. Salk's current contract extends from April 1, 1988, through September 15, 1993.

The Armed Forces Medical Intelligence Center, in conjunction with other intelligence agencies, develops the list of validated biological warfare threat agents. This list includes biological agents that are in various stages of research and development and will be completed in the near-term (in the next 5 years), in the mid-term (in the next 5 to 10 years), and in the far-term (in the next 10 to 20 years). Agents in the near-term category include those that are ready to be used as a weapon or will be ready soon. Agents included in the mid-term category are those assessed as currently under development for use as a weapon. The far-term category includes agents that are undergoing research and development to determine whether they are good candidates for development as a biological weapon. The list also indicates the degree of certainty of the threat based on available intelligence information (for instance, threats are categorized as virtually certain, probable, or possible).

The Army's Deputy Chief of Staff for Intelligence is responsible for validating this list. The list is then used by the Academy of Health Sciences, a component of the Army's Health Services Command, to establish vaccine requirements needed to counter biological warfare threat agents.

Funds Used on Agents Not Validated as Threats

As of March 31, 1991, about $3 million, or 17 percent, of the $17.7 million the Army paid Salk under its 1988 contract had been spent on work that was clearly related to biological agents validated by the Armed Forces Medical Intelligence Center as warfare threats. Another $5.8 million, or 33 percent, had been spent to fund work that often applied both to validated biological warfare threat agents and diseases not related to warfare. The remaining 50 percent of the total, or $8.8 million, had been spent to develop and produce medical products for diseases not related to warfare.

In responding to issues raised during our last review of the BDRP, U.S. Army Medical Research and Development Command officials acknowledged that some research projects did not address validated threats.[1] The officials believed that the Intelligence Center's interpretation of threat agents is too narrow and that program officials are in a better position than the Center is to determine what agents should be researched. Consequently, program officials have been spending BDRP funds to research biological agents whether they have been validated by the Center or not.

Vaccine Development and Production Alternatives

The Army awarded a contract to Salk in 1988 after receiving no other response to its solicitation for vaccine production research. Although we found no evidence that commercial interest in this work has increased, an in-house option may exist.

Our discussions with five commercial vaccine producers indicated that shifting from Salk to other commercial vaccine producers would not be a viable alternative. In part because there is no commercial market for biological warfare vaccines in the United States, vaccine producers lack the facilities needed to produce them.

The Army's current in-house capabilities are not sufficient to meet the demand for biological warfare vaccines. However, officials at one Army

[1]Biological Warfare: Better Controls in DOD's Research Could Prevent Unneeded Expenditures (GAO/NSIAD-91-68, Dec. 27, 1990).

research and development laboratory told us that in-house facilities could be improved and expanded to meet vaccine production needs. Our analysis of three current renovation projects at government laboratories indicated that the facilities could be expanded to meet future needs.

In the absence of competition, the Army has limited assurance that the estimated cost of performance negotiated with Salk is reasonable. Comparison of Salk's proposed cost of performance on future solicitations with the estimated cost of performing the required work at government laboratories could provide an additional measure of the reasonableness of Salk's proposed costs.

Excessive Payments for the Use of Salk Facilities

The Army's last two contracts with Salk have permitted paying fees to Salk for the use of its facilities that did not comply with applicable cost principles contained in Office of Management and Budget (OMB) Circular A-122. The Army paid Salk $5.5 million more in fees than permitted by the circular basically because the Army followed cost principles for commercial organizations instead of those for nonprofit organizations. Although other contracts may be involved, the extent of the problem is unknown.

Recommendations

In our 1990 report on the BDRP, we recommended that the Secretary of the Army direct the Medical Research and Development Command to review all ongoing research projects to determine whether they addressed validated threats agents and discontinue all projects that did not. We believe this recommendation also applies to the work being conducted by Salk. The Department has not officially responded to this recommendation.

We recommend that the Secretary of the Army direct the Commander of the Medical Research and Development Command to take the following actions.

- Determine, prior to the negotiation of another contract with Salk, whether changed conditions, such as the discontinuation of work not related to validated threats, would materially change Salk's cost of performance. Specifically, in the absence of commercial competition, Salk's estimated cost of performance should be compared to the cost of performing the work at government laboratories.

- Ascertain whether there is a basis to recover from Salk past overpayments for the use of facilities and reduce any remaining facility use payments otherwise due under the 1988 contract to amounts allowed by OMB Circular A-122.
- Determine whether the appropriate cost principles were followed in contracting with other nonprofit organizations and, if not, ascertain whether recovery action should be undertaken and what changes should be made to internal controls to ensure that the proper cost principles are followed in the future.

As requested, we did not obtain official agency comments on this report. However, we did discuss the report's contents with Army and DOD officials and have incorporated their comments where appropriate. The results of our review are discussed more fully in appendix I. The information you requested on various aspects of the BDRP is included in appendix II. Our scope and methodology are discussed in appendix III.

Unless you publicly announce this report's contents earlier, we plan no further distribution of this report until 30 days after its issue date. At that time, we will send copies to the Secretaries of Defense and the Army; the Director, Office of Management and Budget; and other interested parties.

Please contact me at (202) 275-4141 if you or your staff have any questions concerning this report. Other major contributors to this report are listed in appendix IV.

Sincerely yours,

Richard Davis

Richard Davis
Director, Army Issues

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Abbreviations

BDRP	Biological Defense Research Program
DOD	Department of Defense
EEE	Eastern equine encephalitis
GAO	General Accounting Office
NIH	National Institutes of Health
OMB	Office of Management and Budget
RVF	Rift Valley fever
VEE	Venezuelan equine encephalitis
WEE	Western equine encephalitis

The Army's Relationship With the Salk Institute

Background

In March 1977, the Army issued a request for proposal to Merrell National Laboratories for a follow-on 5-year contract to conduct vaccine production research and establish techniques to make vaccines against biological weapons. The Army had decided the proposed contract should be sole source because Merrell had the only facility capable of making vaccines that were not commercially available. Merrell had received similar Army contracts since 1960.

Before the request for proposal's closing date, Merrell National Laboratories notified the Army that it was donating its Swiftwater, Pennsylvania, facilities, where the work would be performed, to the Salk Institute. Army contract officials told us that Merrell had given the Army the opportunity to purchase the Swiftwater facility, but the Army declined for reasons not now known by them. The donated facilities included a laboratory building where Merrell had performed research under the Army contracts. The Army had fully paid for this laboratory through depreciation charged to these contracts. After receiving the Swiftwater facilities, Salk sold the commercial biological manufacturing operation to Connaught Laboratories. Salk retained the laboratory building, including some adjoining land, and established a separate nonprofit entity—Government Services Division—to operate the facility.

In October 1977, Salk submitted a proposal in response to the Army's solicitation. The Army accepted Salk's proposal and awarded Salk a 5-year contract, effective January 1, 1978. Subsequently, the Army awarded Salk two additional 5-year contracts to operate the Swiftwater facility. The Army has spent or plans to spend about $75.4 million for the three Salk contracts, as shown in table I.1.

Table I.1: Salk Contracts

Dollars in millions

Contract period	Actual and planned expenditures
January 1978 through March 1983	$10.45
April 1983 through March 1988	25.52
April 1988 through September 1993	39.41[a]
Total	**$75.38**

[a]Through April 15, 1991, Salk had submitted contract expense vouchers totaling $19.16 million.

The Army considers Salk's vaccine production facility a vital part of the Biological Defense Research Program (BDRP). In supporting the need for additional facilities at Salk, the former Commander of the U.S. Army Medical Research and Development Command in 1989 stated that Salk

was a national resource. The Commander also said that Salk was vital to the defense of the United States and its allies against potential biological warfare weapons. Even though the Salk-owned (and, previously, Merrell-owned) facility has been operating for about 31 years, it produced none of the vaccines used to protect U.S. military personnel involved in Operation Desert Shield/Storm against biological weapons. Salk has developed and produced some vaccines directed at validated biological threats, but an Army official told us that these were not the vaccines needed for this theater of operations. Salk did produce materials that were used in diagnostic kits for the operation.

Funds Used to Develop Vaccines Against Agents Not Validated as Warfare Threats

In our December 1990 report on the BDRP, we stated that of all the ongoing or recently completed biological projects we had examined, only about 50 percent were related to agents determined by the Academy of Health Sciences and the Armed Forces Medical Intelligence Center to represent biological warfare threats. The 1988 contract awarded to the Salk Institute was one of the 218 projects we examined. The Academy and the Intelligence Center identified the 1988 Salk contract as a project related to validated biological warfare threat agents because it had been awarded for the production of vaccines countering biological warfare threat agents. However, with the assistance of Academy personnel, we analyzed the various project/task orders the Army directed Salk to work on under the 1988 contract and found that only 17 percent, or $3 million, of the $17.7 million expended as of March 31, 1991, was clearly related to the development of vaccines to protect U.S. forces against validated biological warfare threat agents. Another 33 percent, or $5.8 million, was used to fund activities relating to both validated biological warfare threat agents and diseases not related to warfare. The remaining 50 percent, or $8.8 million, was expended for protection against various diseases not related to warfare, rather than for protection against validated biological warfare threat agents. See table I.2 for a breakdown of our analysis.

Table I.2: BDRP Development Funding by Validated Threat and Nonvalidated Biological Agent

Type of work	Expenditure	Percent
Threat		
Cell culture production	$727,400	4
Vaccine work	2,300,804	13
Subtotal	**3,028,204**	**17**
Nonthreat		
Cell culture production	2,125,148	12
Vaccine work	6,721,064	38
Subtotal	**8,846,212**	**50**
Other		
Vaccine storage/shipping	1,369,200	8
Immune surveillance/ immunization	259,760	1
Expansion of facilities	2,042,824	12
Diagnostic reagents production	1,616,791	9
Cell production/ miscellaneous	538,090	3
Subtotal	**5,826,665**	**33**
Total	**$17,701,081**	**100**

Alternative to Using Salk's Vaccine Facility

The Army has had limited options for obtaining vaccine development and production services. Other contractors, for example, have declined to compete for the work being done by the Salk Institute. Our discussions with five commercial vaccine producers confirmed the lack of contractor interest. However, even though Army officials told us that the Army has no in-house capability to develop and produce biological warfare vaccines, our discussion with officials at a government research facility indicate that the in-house vaccine production capability is improving.

In part because there is no commercial market for biological warfare vaccines in the United States, commercial vaccine producers have not constructed the containment facilities needed to produce them.[1] Vaccine manufacturing officials explained that such facilities are costly to construct; therefore, they would seek a guarantee from the Army that they would recoup their investments. One official estimated that it would cost about $25 million to construct a facility to produce one to two million doses of seven or eight vaccines a year.

[1]The Centers for Disease Control establishes advisory standards for vaccine production and laboratory facilities. It has established four biosafety containment levels. The required level depends on the disease to be worked on. Diseases are categorized by the required containment level.

We found that the Army could expand its in-house capabilities to perform the limited biological warfare vaccine work currently being done at the Salk Institute. The Walter Reed Army Institute of Research is currently remodeling a facility to meet the Food and Drug Administration's requirements to produce human vaccines. This facility is intended to produce small amounts of infectious disease vaccines for use in clinical trials.

However, to develop and produce vaccines to protect against biological warfare threat agents, the Walter Reed facility would need to be expanded and upgraded to the same containment level as that of the Salk facility. Walter Reed officials stated that after such improvements, their facility could produce sufficient quantities of live virus vaccines to meet Army requirements.

Other government facilities are also potentially available. For example, the Army has renovated two laboratory suites at the Medical Research Institute of Infectious Diseases at Fort Detrick to meet the Federal Drug Administration's requirements for the production of bulk botulism toxoids. This facility will be operated by Salk under its current Army contract. Also, the Army has an agreement with the National Institutes of Health (NIH) to reimburse it for renovating and operating a wing of an existing NIH-owned, contractor-operated drug production facility. The Army will use this facility to have the current NIH drug production contractor produce bulk anthrax vaccine. The bulk botulism toxoids and anthrax vaccine will be shipped to a commercial supplier—Michigan Department of Public Health—for testing, final processing into individual doses, and packaging.

The Army took these actions to increase production capabilities because it had insufficient quantities of botulism toxoids and anthrax vaccines for Operation Desert Shield/Storm.

Excessive Payments for the Use of Salk's Facilities

In determining contract costs for the 1983 and 1988 contracts with the nonprofit Salk Institute, the Army inappropriately followed the cost principles for commercial organizations rather than for nonprofit organizations. The Army has therefore paid Salk $5.5 million in excess fees over the past 9 years to use Salk's original building and two additions.

Office of Management and Budget (OMB) Circular A-122, "Cost Principles for Nonprofit Organizations," dated July 8, 1980, applies to contracts and grants awarded after its publication date. The circular prohibits the

payment of fees for the use of facilities previously paid for by the federal government. Specifically, section 9 of attachment B of Circular A-122 states that the computation of a "use allowance" should exclude any portion of the cost of buildings and equipment borne by or donated by the federal government regardless of where the title was originally vested or where it currently resides. Even so, the Army included in the Salk contracts the provisions of the Federal Acquisition Regulations that pertain to fees paid to commercial organizations. These regulations allow commercial organizations to charge reasonable fees for the use of fully depreciated property.

In its 1983 and 1988 contracts with Salk, the Army improperly agreed to pay an annual fee of $150,000, or about 5 percent of the appraised value of the property, which had been donated to Salk by the previous owner. In total, the Army paid Salk $1.35 million ($150,000 a year times 9 years) to use the donated facilities. According to OMB Circular A-122, the Army should not have paid these fees because it had previously fully paid for the facilities.

In addition, the Army's 1983 and 1988 contracts with Salk provide excessive fees for the use of two additions to Salk's facility. Circular A-122, section 9, attachment B limits the use fee to no more than 2 percent of the building's acquisition cost.

Salk added a $3.4 million cell culture facility under its 1983 Army contract. The Army allowed Salk to recover the entire amount over the 5-year contract period. As of April 1991, the Army had paid Salk $2.8 million ($3,400,000 minus $612,000 [($3,400,000 times 2 percent times 9 years]) more for the 9-year contract use of this facility than would be allowed under the use fee provisions of Circular A-122.

Additionally, Salk has spent or plans to spend a total of $6 million to construct an animal test facility and a research and development laboratory. The Army agreed to pay Salk for the use of these facilities over an 8-year period through an annual fee of $1.12 million. This amount compares to the $120,000 a year the Army would be paying if it were using the 2-percent use fee allowed by Circular A-122. As of April 1991, the Army had paid Salk about $1.5 million to use this facility, or about $1.3 million ($1.5 million minus $160,000 [$6 million times 2 percent times 1-1/3 years]) more than the use fee allowed by the OMB Circular. Further, if fully carried out, this agreement will result in a total payment of about $9 million, or $8 million ($8.96 million minus $960,000

[$6 million times 2 percent times 8 years]) more than is provided for under the use fee provisions of Circular A-122.

A summary of the Army's use allowance payments that exceeded what is permitted under OMB Circular A-122 is shown in table I.3.

Table I.3: Use Allowance Payments That Exceeded What Is Permitted by OMB Circular A-122

Facility	Army use payment	Use payment allowed by OMB Circular A-122	Excess payment
Original building	$1,350,000	0	$1,350,000
Cell culture	3,397,000	611,460	2,785,540
Animal test/ research and development	1,493,333	160,000	1,333,333
Total	**$6,240,333**	**$771,460**	**$5,468,873**

While the Army has used cost principles for commercial organizations in its contracts with Salk, the NIH follows OMB Circular A-122 cost principles for nonprofit organizations when contracting with Salk. An OMB official told us that the Army had not requested a waiver to OMB Circular A-122 for the Salk Institute and, accordingly, the Army should be following the circular in establishing contract costs for work performed by the Salk Institute.

Responses to Your Questions About the Salk Institute

What Biological Warfare Vaccines Are Being Stored at the Salk Institute?

Fifty-seven million doses of biological vaccines are stored at Salk's Swiftwater facility. Salk produced the majority of these vaccines, but some were produced by the prior Army contractor. Fifty million doses are in bulk form and would require additional processing before use.

Academy of Health Sciences personnel advised us that 7 million doses of the stored vaccines are for use against diseases that are infectious in nature, rather than against validated biological warfare threat agents.

Table II.1 lists the vaccines in storage at Salk as of March 31, 1991.

Table II.1: Vaccines Stored at Salk

Type of vaccine	Doses[a]
Biological warfare vaccines	
Tularemia, dried	497,610
Tularemia (fermentor)	4,789,320
Q fever, phase 1, inactivated, dried	63,050
Q fever, chloroform and methanol residue, inactivated, dried	39,220
Venezuelan equine encephalitis (VEE), TC83, live, attenuated, dried	44,076,398
VEE, C84, inactivated, dried	434,870
Eastern equine encephalitis (EEE), inactivated, dried	109,830
Smallpox	52,300
Western equine encephalitis (WEE), inactivated, dried	24,700
Subtotal	**50,087,298**
Nonbiological warfare vaccines	
Chikungunya, live, attenuated, dried	5,213,524
Junin candidate #1, live, attenuated, dried	457,300
Rift Valley fever (RVF), live, attenuated, mutagenized ZH548, MP-12	1,099,095
RVF, inactivated, dried	222,195
Hepatitis A virus, inactivated liquid	10,680
Subtotal	**7,002,794**
Total	**57,090,092**

[a]Included are doses now stored as frozen bulk for the following diseases: VEE, TC83, 43.6 million doses; Chikungunya, 5 million doses; Junin, 288,000 doses; and RVF, live, 1 million doses.

What Are the Length of Storage and Frequency of Stock Rotation?

Salk has a potency testing program, but it does not rotate stock. All Salk-produced vaccines are freeze-dried and stored in freezers at the Salk facility. Salk's policy is to test vaccines before they are shipped unless previous stability testing has been performed within 1 year of the shipping date. Stability testing measures residual vaccine potency after a period of storage. The oldest vaccine in storage was manufactured in 1962. Table II.2 shows the dates of manufacture for the vaccines in storage at Salk.

Table II.2: Dates of Manufacture for Stored Vaccines

Vaccine	Dates of manufacture
Tularemia	1962, 1964, and 1985
Q Fever, phase 1, inactivated	1970
Q Fever, chloroform and methanol residue, inactivated	1988
Chikungunya, live, attenuated	1985
Junin candidate #1, live, attenuated	1988 and 1989
RVF, live, attenuated	1988
Smallpox	Unknown
RVF, inactivated	1978, 1979, and 1989
Hepatitis A	1990
VEE, TC83, live, attenuated	1968, 1970, 1971, and 1972
EEE, inactivated	1969, 1970, and 1989
WEE, inactivated	1981
VEE, C84, inactivated	1980 and 1981

How Much Has the Army Expended Under Contracts With Salk?

The Army's cost to support Salk's Swiftwater facility has steadily increased over the time covered by the three contracts. The Army has spent or plans to spend about $75.4 million for these contracts. Cost information by only broad categories exists for the first two Salk contracts. For the 1988 contract, cost information is available by project/task order. Table II.3 shows the cost information for the first two Salk contracts.

Table II.3: Salk Contract Costs

	Contract	
Cost category	**1978**	**1983**
Personnel	$3,544,825	$8,230,963
Equipment	971,369	2,449,120
Supplies	1,245,192	3,617,742
Facilities	1,425,015	2,694,749
Purchased services	1,390,615	1,572,970
Use allowance	787,500	4,145,666
Other	402,071	984,669
Performance fee	685,237	1,827,809
Total	**$10,451,824**	**$25,523,688**

Starting with the 1988 contract, the Army began to track costs by project/task orders. As of March 31, 1991, Salk had incurred expenses of $17.7 million in performing these orders. Table II.4 shows a breakdown of Salk's costs under the 1988 contract by type of work.

Table II.4: Salk's Cost by Type of Work

Activity	**Amount**
Cell culture production	$3,355,939
Vaccine scale-up and development	1,062,525
Vaccine production	6,833,233
Vaccine inventory and storage and shipping	1,369,200
Vaccine phase I clinical trials	1,160,809
Immune surveillance and immunization	259,760
Diagnostic research reagents	1,616,791
Expansion of facilities	2,042,824
Total	**$17,701,081**

Scope and Methodology

To evaluate the work being performed by Salk, we obtained and reviewed Army project/task orders, including cost data, given to Salk under the current contract. The Army did not use project/task orders to direct work under the 1978 and 1983 contracts. Costs were not accumulated by project under these earlier contracts. Therefore, detailed cost information before April 1, 1988, was unavailable for our review. Although little detailed information was available concerning the first two Salk contracts, we were able to obtain and review Salk's annual reports for these contracts to determine the general nature of the work performed. We also discussed the work performed under these contracts with Army and Salk officials.

To determine whether the vaccines produced by Salk are for the protection of U.S. forces against validated biological warfare threat agents, we discussed these vaccines with officials from the Academy of Health Sciences and the Armed Forces Medical Intelligence Center. To determine available alternatives to the Army's reliance on Salk, we discussed with personnel of five commercial vaccine companies the extent of commercial interest in producing biological warfare vaccines. We discussed Army in-house vaccine production capabilities with officials from Army research and development laboratories. To determine whether the fees for the use of Salk's facilities are in accordance with federal regulations, we obtained and reviewed the applicable sections of the Federal Acquisition Regulations and OMB Circular A-122 and held discussions with Army, OMB, and National Institutes of Health personnel.

To determine the historical relationship between the Army and Salk, we reviewed contract files and held discussions with Army and Salk officials. To determine the types and amounts of biological warfare vaccines already stored at Salk and the length of storage and frequency of vaccine stock rotation, we obtained and reviewed a vaccine inventory and discussed it with a Salk official.

To accomplish our objectives, we visited and obtained information from the following military organizations at Fort Detrick in Frederick, Maryland:

- U.S. Army Medical Research and Development Command,
- U.S. Army Medical Research Institute of Infectious Diseases,
- U.S. Army Medical Materiel Development Activity,
- U.S. Army Medical Research Acquisition Activity, and
- The Department of Defense's Armed Forces Medical Intelligence Center.

We also visited and obtained information from the following military organizations:

- U.S. Army Academy of Health Sciences, Fort Sam Houston, Texas;
- Defense Contract Audit Agency, Mid-Atlantic Region, York Branch Office, York, Pennsylvania;
- Food and Drug Administration, Rockville, Maryland;
- National Institutes of Health, Bethesda, Maryland;
- Salk Institute, Headquarters, San Diego, California;
- Salk Institute, Government Services Division, and the Connaught Laboratories, Inc., Swiftwater, Pennsylvania; and
- Wyeth-Ayerst Laboratories, Marietta, Pennsylvania.

We reviewed the Army's 1990 Financial Integrity Act report to determine whether any management control weaknesses had been identified concerning the BDRP program.

We conducted our review from August 1990 to July 1991 in accordance with generally accepted government auditing standards. Because of the technical nature of the program, our Medical Consultant assisted us in this review.

Major Contributors to This Report

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