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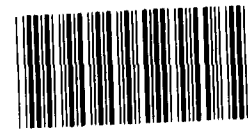
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General Accounting Office

Issues Affecting Continuation Of United States Funding Of The Gorgas Memorial Institute

Since 1928 the U.S. Government has been the primary financial supporter of the Gorgas Memorial Institute and its Panamanian-based research facility. The fiscal year 1984 budget for the National Institutes of Health, however, excluded Federal funding to this organization.

This report provides information and observations on efforts by Gorgas to broaden its financial base of support, the extent of other federally funded research activities similar to those conducted by Gorgas, the extent of pre- and post-project scientific review undertaken by Gorgas, and the possible impact on U.S. regional relations if Federal funding for the Gorgas laboratory is terminated.



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

NATIONAL SECURITY AND
INTERNATIONAL AFFAIRS DIVISION

B-206877

The Honorable Lowell Weicker, Jr.
Chairman, Subcommittee on Labor, Health
and Human Services, and Education
Committee on Appropriations
United States Senate

Dear Mr. Chairman:

As requested in your letter dated April 26, 1983, we are reporting on the United States funding of the Gorgas Memorial Institute of Tropical and Preventive Medicine, Inc., and its biomedical research arm, the Gorgas Memorial Laboratory in Panama.

As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of the report. At that time, we will send copies to interested parties and make copies available to others upon request.

Sincerely yours,

A handwritten signature in cursive script that reads "Frank C. Conahan".

Frank C. Conahan
Director



GENERAL ACCOUNTING OFFICE
REPORT TO THE CHAIRMAN,
SUBCOMMITTEE ON LABOR, HEALTH
AND HUMAN SERVICES, AND
EDUCATION
COMMITTEE ON APPROPRIATIONS
UNITED STATES SENATE

ISSUES AFFECTING CONTINUATION
OF UNITED STATES FUNDING OF
THE GORGAS MEMORIAL INSTITUTE

D I G E S T

Citing internal budgetary priorities, the National Institutes of Health has proposed that direct U.S. funding for the operation and maintenance of the Gorgas Memorial Institute of Tropical and Preventive Medicine, Inc., be terminated in fiscal year 1984. Since 1928, the Congress has provided an annual appropriation to support the Institute, a private, non-profit organization headquartered in Washington, D.C. The Institute carries out a diversified research program on tropical diseases at the Gorgas Memorial Laboratory, located in Panama. The congressional appropriation for the Institute was \$1.8 million for fiscal year 1983, which is expected to account for 84 percent of the Institute's total income for the period.

At the request of the Chairman, Subcommittee on Labor, Health and Human Services, and Education, Senate Committee on Appropriations, GAO reviewed the Gorgas Memorial Institute and Laboratory and found that:

- The Institute and Laboratory have made little effort to broaden the Laboratory's financial base of support.
- There are several U.S. Government agencies as well as international organizations--federally supported--involved in conducting research into tropical diseases similar to those studied at the Laboratory.
- There is no formalized pre- or post-project scientific review made by Gorgas. External review of the Laboratory activities is periodically provided by visiting scientists from the Fogarty International Center of the National Institutes of Health and the Gorgas Institute.
- According to the Department of State, U.S. relations with Latin America and Panama

could be affected by the perceived inconsistencies in U.S. foreign policy if the Laboratory was to close. An impact would be especially felt in Panama which receives services from the Laboratory where 86 Panamanians are employed.

The Office of Technology Assessment was requested to conduct a parallel review of the quality and relevance of research at the Gorgas Memorial Laboratory.

LITTLE HAS BEEN DONE TO EXPAND
THE INSTITUTE'S FINANCIAL BASE
OF SUPPORT

Although the Congress has consistently expressed the need for the Institute to expand its financial base of support, the Institute has made little effort to solicit additional financial assistance and remains primarily a U.S. Government-funded private corporation. One reason for this is that the Institute views the countries of Latin America as too poor to contribute and, consequently, has not asked for their assistance. The Institute did, however, contact 150 foundations and private granting organizations to determine if the Institute qualified for funding; however, the response to date has reportedly not been encouraging.

Panama is the only other country to provide funding for the Laboratory. Between fiscal years 1976 and 1982 Panama contributed about \$700,000 or 3.9 percent of the Institute's total income. Factors cited as inhibiting financial support include the adverse economic conditions in the region and the Institute's organizational structure (e.g., a private corporation, extensive U.S. military representation on the Board of Directors, and minimal Latin involvement in the decisionmaking process). The topic of increased Latin American support for the Laboratory has not been broached by Institute officials.

During GAO's review various officials suggested such alternatives to the current method of funding the Laboratory as: (1) converting the Laboratory to an international or regional research facility and (2) placing the Institute's appropriation under another Federal agency.

FEDERALLY FUNDED RESEARCH SIMILAR
TO THAT CONDUCTED AT THE LABORATORY

There are several U.S. Government departments and agencies involved in the research of tropical diseases similar to those currently studied at the Laboratory. The largest research funding organizations are:

--National Institute of Allergy and Infectious Diseases. This major Federal funder spent approximately \$34 million during fiscal year 1982 on tropical medicine research. Approximately \$24 million of this amount was directed toward external research while about \$9.5 million was for internal activities. About one-third of the total, or \$12.5 million, was for research into diseases similar to those studied at the Laboratory.

--Department of Defense. This organization plans to spend about \$15 million during fiscal year 1983 on tropical disease research. A large portion of this program is conducted internally at eight Army and Navy overseas laboratories.

--Agency for International Development. This agency will fund approximately \$15 million in tropical medicine research during fiscal year 1983, and acts as a "pass-through" agency for the \$5 million U.S. contribution to two international health research programs.

SCIENTIFIC REVIEW OF LABORATORY
ACTIVITIES IS MINIMAL

The Institute and Laboratory have neither a long-range program plan or planning process nor a formal internal review process for evaluating new, ongoing, or recently completed research projects. New projects are generated by Laboratory scientists and proposals are informally circulated within the Laboratory for review and subsequent approval by the Laboratory director. Laboratory activities are reviewed every 3 years by the Fogarty Center and, intermittently, by the Gorgas Institute. The Institute maintains a 24-member

Advisory Scientific Board to advise the president in the development and review of scientific programs; however, little use has been made of this resource to date.

THE IMPACT OF POTENTIAL
TERMINATION OF FUNDING

The Department of State believes the proposed termination of U.S. funding of the Laboratory is inconsistent with existing U.S. foreign policy and could be misinterpreted by Panama and neighboring Central American countries. Some Department of State officials also believe that terminating funding could be contrary to the intent of the current Caribbean Basin Initiative and could provide the Cuban Institute of Tropical Medicine with undue attention as it would be the only remaining Spanish-speaking reference center in the Caribbean.

Although a private corporation, the Institute is viewed by many as a U.S. Government organization. The Department of State believes that the termination of funding could thus have an impact on future U.S.-Panamanian relations. Department of State officials in Panama and Washington expressed the belief that the Laboratory's closure could strain bilateral relations.

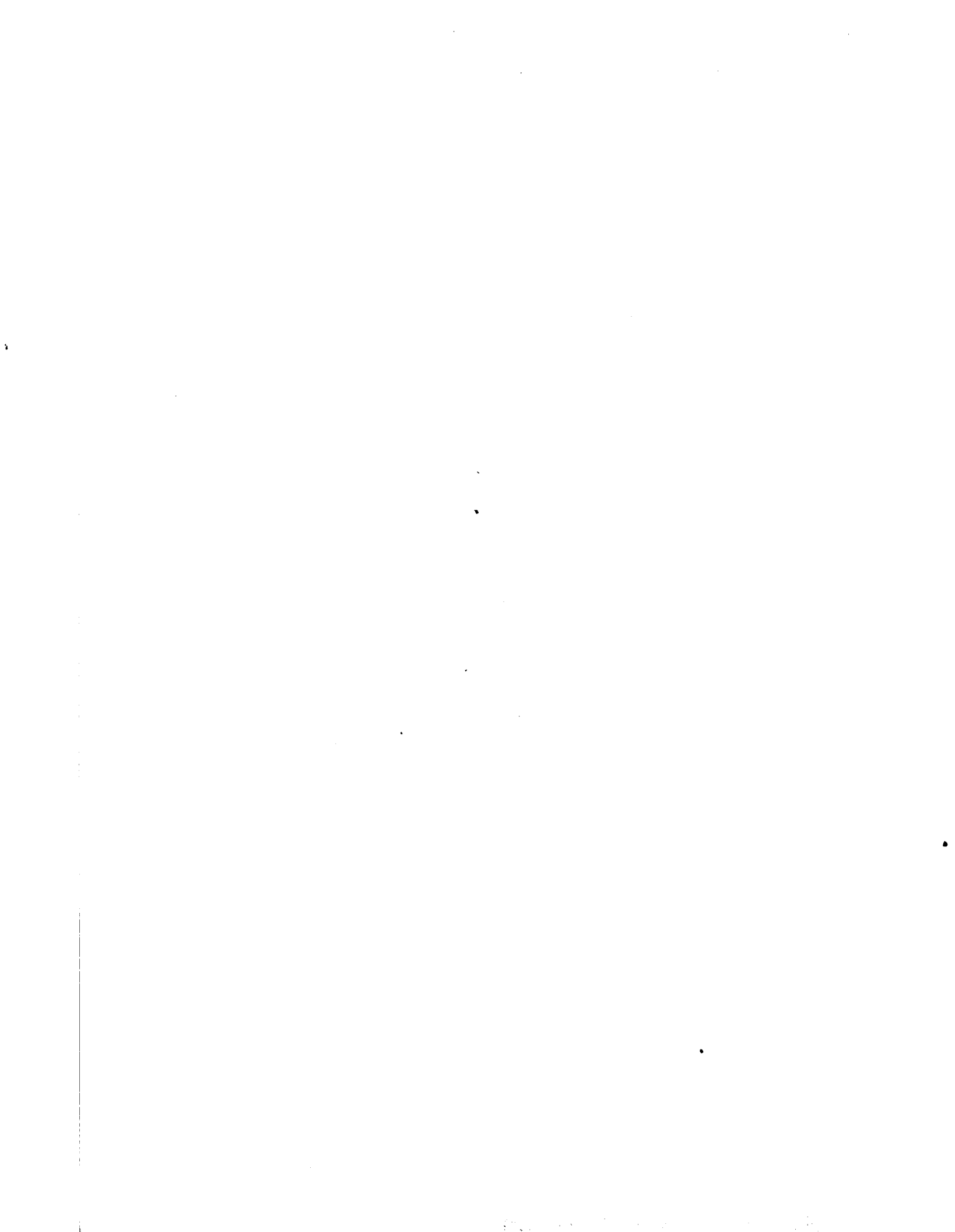
OBSERVATIONS

During GAO's review, no evidence surfaced which would support terminating U.S. funding on grounds that the Laboratory's research is not needed, duplicative, or of a poor quality. GAO takes no position on whether or not funding of the Institute should be continued. Some officials suggested that internationalization or regionalization of the Institute offers an alternative to the current organizational arrangement. If the Institute, in cooperation with the Fogarty Center, was to explore this possibility, it would want to consider the experiences of the Agency for International Development in its internationalization of the International Center for Diarrheal Disease Research in Bangladesh. GAO offers no comment on the other suggested alternative--funding the Institute through another Federal agency.

Beyond the funding question, GAO believes there is need for a formalized planning and review process at the Institute and Laboratory. While GAO recognizes the need for flexibility in Laboratory activities to respond to emergency situations, a formal planning and review process could allow for better use of Laboratory facilities and personnel. More involvement by the Advisory Scientific Board in the planning, execution, and review of Laboratory activities could enhance the quality of the scientific work done at the Laboratory.

AGENCY COMMENTS

GAO did not seek official agency comments; however, officials from the Gorgas Memorial Institute, Fogarty International Center, National Institutes of Health, and the Department of State reviewed a draft of this report and generally agreed with its content.



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ABBREVIATIONS

AID	Agency for International Development
CBI	Caribbean Basin Initiative
CDC	Centers for Disease Control
DOD	Department of Defense
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
PAHO	Pan American Health Organization
WHO	World Health Organization

CHAPTER 1

INTRODUCTION

At the request of the Chairman, Senate Appropriations Committee, Subcommittee on Labor, Health and Human Services, and Education, we reviewed the Gorgas Memorial Institute of Tropical and Preventive Medicine, Inc., and its biomedical research arm, the Gorgas Memorial Laboratory in Panama. This request was concerned specifically with

- the efforts by Gorgas to broaden the financial base of support for the Laboratory;
- the extent of other federally funded research activities similar to those conducted by Gorgas;
- the extent of internal pre- and post-project scientific review undertaken by Gorgas; and
- the possible impact on U.S. regional relations that would result from the termination of U.S. funding of the Laboratory.

THE GORGAS MEMORIAL INSTITUTE

The Gorgas Memorial Institute of Tropical and Preventive Medicine, Inc. (Institute) is a private, nonprofit organization, incorporated under the laws of the State of Delaware and registered in the Republic of Panama. Headquartered in Washington, D.C., the Institute was established in 1921 as a memorial to General William Crawford Gorgas, whose work in preventive medicine led to the control of yellow fever and malaria and made possible the construction of the Panama Canal. In recognition of the need for a research facility dedicated to the study, investigation, and prevention of tropical and other diseases, the Congress, in 1928, authorized an annual appropriation to the Institute for the operation and maintenance of a research laboratory in or adjacent to the Canal Zone, to be known as the Gorgas Memorial Laboratory (Laboratory).

The Laboratory began as a traditional tropical medicine research institute concentrating on studies of malaria, trypanosomiasis¹, and leishmaniasis.² The areas of research have been expanded and now represent a diversified program of

¹ Trypanosomiasis or Chagas' Disease is a protozoan infection which leads to severe cardiovascular disease and brain inflammation.

² Leishmaniasis is a parasitic infectious disease resulting in disfiguring skin sores.

research on tropical diseases, especially those endemic to Panama and neighboring countries. Particular emphasis is placed on virology, parasitology, and the effects of environmental change on disease vectors and transmission. In addition to the previously mentioned tropical diseases, the Laboratory has undertaken studies on other public health problems (e.g., cervical cancer and sexually transmitted diseases) and has recently been awarded \$580,000 in grants and/or contracts for additional studies of malaria and leishmaniasis, human T-cell leukemia, and childhood respiratory illnesses. In addition to research, the Laboratory also provides special diagnostic and reference services; epidemic investigations; surveillance of vector-borne diseases; and conducts formal and informal research training for scientists and technicians from the United States, Panama, and other countries. It has cooperative arrangements with several U.S. universities available to graduate and medical students. Training courses in tropical medicine are conducted several times a year for U.S. Navy medical officers. As of June 1, 1983, the Laboratory employed 93 full-time personnel--16 professional staff (6 of whom are Americans, 9 Panamanians, and one third-country national) and 77 Panamanian support personnel.

The funds received by the Institute can be broadly categorized as either "core" or "non-core." The annual congressional appropriation, which is passed through the Fogarty International Center of the National Institutes of Health, provides the Laboratory's core support. This support is essential for its operation as it provides the base of facilities, maintenance, operating support, and scientific staff that allows the Institute to successfully compete for grants and contracts.

The Laboratory director estimates that about 65 to 70 percent of the core support is used for salaries; 15 percent for maintenance, repairs, and capital investments; and 15 percent for research, travel, and materials. Research conducted with core funds is primarily limited to data collection and analysis and the maintenance of test animals and a library. Core funds are also used to support the Institute which, in fiscal year 1983, had two full-time staff members and administrative and operating expenses estimated at \$153,000. Non-core funds, on the other hand, are provided through grants, contracts, and other sources for the undertaking of a specific research activity or project.

In response to budgetary priorities (i.e., the funding of 1,324 additional investigator-initiated new and competing medical research grants), the National Institutes of Health (NIH) has proposed that direct U.S. funding for the operation and maintenance of the Institute be terminated in fiscal year 1984. The stated justification for this action was that the funds provided to the Institute were "not subject to the same peer review process as other NIH programs."

OBJECTIVES, SCOPE, AND METHODOLOGY

Our audit work was conducted in accordance with generally accepted Government auditing standards. We reviewed files and interviewed responsible officials at the Institute; NIH; Fogarty International Center; National Institute of Allergy and Infectious Diseases (NIAID); National Library of Medicine; Departments of the Army, Navy, and State; Agency for International Development (AID); Pan American Health Organization (PAHO); and Office of Technology Assessment. We contacted 13 members of the Institute's Advisory Scientific Board. Work was also performed in Panama where we met with officials of the Laboratory, Government of Panama, U.S. Embassy, and PAHO.

Our review of other federally funded research activities similar to those conducted at the Laboratory was limited to the diseases of a tropical nature studied at the Laboratory since fiscal year 1982 (i.e., trypanosomiasis, leishmaniasis, malaria, St. Louis encephalitis³, and yellow fever). Excluded from our review were such Laboratory activities as environmental impact analysis; general data collection and analysis; and cancer epidemiology. Furthermore, while we compiled information on research conducted on these diseases, we did not attempt to analyze the specific research activities being conducted within each disease category. For example, all research in malaria was broadly categorized as being similar to that conducted at the Laboratory and no distinction as to the specific types of malaria or specific types of research within this broad categorization was made.

We have also included some of the views and opinions of various officials on the value of Laboratory services and on the scientific impact of closing the Laboratory. We did not attempt to verify these statements. A concurrent Office of Technology Assessment report will address the quality and relevance of research conducted at the Laboratory.

As agreed with your office, formal agency comments were not requested on this report due to time constraints. A draft of the report was, however, provided to the Gorgas Memorial Institute, Fogarty International Center, National Institutes of Health, and Department of State. The issues identified were discussed with responsible officials and their comments are reflected in this report.

³ St. Louis encephalitis is a viral infection leading to inflammation of the brain which could result in death.

CHAPTER 2

FUNDING TRENDS AND PROBLEMS

The need for the Institute to expand its financial base of support has consistently been expressed by the Congress in recent years. However, there has been very little effort by the Institute to solicit additional funds and it remains primarily a U.S. Government-funded private corporation.

As shown by Tables 1 and 2 (pages 5 and 6), the U.S. appropriation to the Institute and Laboratory remains high--varying from 64 to 78 percent of its total support from 1976 to 1982. This trend is expected to continue in fiscal year 1983 when the U.S. contribution is expected to account for 84 percent of total support. Moreover, if grant and contract funds received from Federal agencies are included, the total Federal contribution averages over 92 percent for the period of fiscal years 1976 through 1982. Contributions from non-U.S. sources accounted for 3.1 percent of total income in fiscal year 1982 and are expected to drop to 2.6 percent in fiscal year 1983. This reduction is the result of the completion of a Panamanian contract and decreased funding levels for ongoing World Health Organization (WHO) activities.

FUNDING OF THE INSTITUTE

Over the years, U.S. funding of the Institute has been incorporated into the budgets of various larger Federal agencies. Originally provided through the budget of the Department of State, the Institute's appropriation was transferred in the mid-1950s to the budget of NIH, first to NIAID and then, in 1971, to the Fogarty Center. It should be noted that in each instance the funding was an addition to the respective agency's own budget and the agency served mainly as an administrative channel for providing the funds. Fogarty Center officials point out, however, that once the Institute's appropriation is incorporated into the Center's budget, it becomes subject to NIH and Office of Management and Budget budgetary restrictions and requirements, and, as such, loses its uniqueness and is subject to reduction. Of the Fogarty Center's \$10.1 million appropriation for fiscal year 1983, \$1.8 million was made available to the Institute for the operation and maintenance of the Laboratory. The Institute's present annual authorization under 22 U.S.C. §278, as amended, is \$2 million. Although this appropriation represents the primary source of funding for the Laboratory, approximately 26 percent of the Laboratory's fiscal year 1982 revenues were derived from separate project grants, contracts, and other sources.

In March 1983, the Administration announced a policy of annually funding 5,000 investigator-initiated new and competing medical research grants. The proposed fiscal year 1984 NIH budget, however, provided funds for only 3,676 such grants and,

Table 1

Sources of Financial Support for
Gorgas Memorial Institute and Laboratory
fiscal years 1976-83 (note a)
(dollars in thousands)

	1976	1977	1978	1979	1980	1981	1982	Estimated 1983
U.S. Appropriation	\$1,360.0	\$1,400.0	\$1,400.0	\$1,700.0	\$1,700.0	\$1,800.0	\$1,692.0	\$1,800.0
National Institutes of Health	174.8	228.1	248.4	333.3	254.9	305.1	219.2	40.5
Health and Human Services	-	-	-	4.4	4.7	0.9	-	-
U.S. Army	203.5	111.7	130.2	145.2	187.5	257.8	228.6	173.2
U.S. Navy	33.8	25.0	25.0	30.0	35.0	35.0	35.0	35.0
AID	5.5	-	-	8.1	23.3	45.2	-	-
Total Federal Support	<u>1,777.6</u>	<u>1,764.8</u>	<u>1,803.6</u>	<u>2,221.0</u>	<u>2,205.5</u>	<u>2,444.0</u>	<u>2,174.9</u>	<u>2,048.7</u>
Other U.S. Support	4.3	2.7	-	58.3	89.5	58.6	50.3	52.1
Total U.S. Support	<u>1,781.9</u>	<u>1,767.6</u>	<u>1,803.6</u>	<u>2,279.2</u>	<u>2,295.0</u>	<u>2,502.6</u>	<u>2,225.2</u>	<u>2,100.7</u>
Government of Panama	59.3	17.2	37.1	1.0	308.4	251.0	22.5	10.0
WHO/PAHO	4.4	16.0	36.9	118.2	57.0	47.8	49.0	45.5
World Bank	-	-	6.9	-	-	-	-	-
Wellcome Laboratories	-	-	(b)	1.0	-	-	-	-
Total Non-U.S. Support	<u>63.7</u>	<u>33.2</u>	<u>80.8</u>	<u>120.2</u>	<u>365.4</u>	<u>298.8</u>	<u>71.5</u>	<u>55.5</u>
Total	<u>\$1,845.6</u>	<u>\$1,800.8</u>	<u>\$1,884.5</u>	<u>\$2,399.5</u>	<u>\$2,660.4</u>	<u>\$2,801.4</u>	<u>\$2,296.7</u>	<u>\$2,156.2</u>

^a Numbers may not add due to rounding.

^b Less than \$50

at the direction of the Office of Management and Budget, NIH was required to reallocate \$140.8 million within its budget to fund the additional 1,324 grants. Consequently, most other NIH activities remained at their fiscal year 1983 level or were reduced. The largest proposed fund reallocations were made in the research center grants (centers which had previously competed for grant funds and were coming up for recompetition), where 54 of 484 research centers will not be funded and \$53.2 million has been reallocated. One such "research center" proposed to lose its funding was the Gorgas Memorial Institute. According to an agency official, it was the judgement of NIH that the funding of research centers such as the Institute was of a lower priority than investigator-initiated research activities.

The Institute's president and the Secretary of the Smithsonian Institution do not believe the NIH termination of funding is justified as the annual authorization for U.S. support of the Laboratory, Public Law 70-350, as amended, is a separate piece of legislation and not part of the overall NIH authorization. The president further believes that while NIH can recommend that the Congress not fund the Institute, it cannot unilaterally divert Institute funding to protect NIH programs and activities. An NIH official commented that the authorizing legislation allows the Executive Branch to request funds for

programs, but does not require the Executive Branch to request the funds nor the Congress to appropriate them.

The termination of Institute funding brings to light the confusion that has existed over the intended purpose of the funds provided by the Congress. The Institute views these funds as a "contribution"; the Fogarty Center and NIH consider the Institute a "research center" and the funds provided a "research grant" subject to NIH award policies and procedures; and the Comptroller General has ruled that " * * * the appropriation to the Institute is in the nature of an outright, unrestricted gift. Consequently, the usual restrictions applicable to grants do not apply * * *."

Table 2

Sources of Financial Support for
Gorgas Memorial Institute and Laboratory
fiscal years 1976-83 (note a)
(percent)

	<u>1976</u>	<u>1977</u>	<u>1978</u>	<u>1979</u>	<u>1980</u>	<u>1981</u>	<u>1982</u>	<u>Estimated</u> <u>1983</u>
U.S. Appropriation	73.7	77.7	74.3	70.8	63.9	64.3	73.7	83.5
National Institutes of Health	9.5	12.7	13.2	13.9	9.6	10.9	9.5	1.9
Health and Human Services	-	-	-	0.2	0.2	(^a)	-	-
U.S. Army	11.0	6.2	6.9	6.1	7.0	9.2	10.0	8.0
U.S. Navy	1.8	1.4	1.3	1.3	1.3	1.2	1.5	1.6
AID	<u>0.3</u>	-	-	<u>0.3</u>	<u>0.9</u>	<u>1.6</u>	-	-
Total Federal Support	<u>96.3</u>	<u>98.0</u>	<u>95.7</u>	<u>92.6</u>	<u>82.9</u>	<u>87.2</u>	<u>94.7</u>	<u>95.0</u>
Other U.S. Support	<u>0.2</u>	<u>0.1</u>	-	<u>2.4</u>	<u>3.4</u>	<u>2.1</u>	<u>2.2</u>	<u>2.4</u>
Total U.S. Support	<u>96.5</u>	<u>98.2</u>	<u>95.7</u>	<u>95.0</u>	<u>86.3</u>	<u>89.3</u>	<u>96.9</u>	<u>97.4</u>
Government of Panama	3.2	1.0	2.0	(^b)	11.6	9.0	1.0	0.5
WHO/PAHO	0.2	0.9	2.0	4.9	2.1	1.7	2.1	2.1
World Bank	-	-	0.4	-	-	-	-	-
Wellcome Laboratories	-	-	(^b)	(^b)	-	-	-	-
Total Non-U.S. Support	<u>3.4</u>	<u>1.9</u>	<u>4.4</u>	<u>4.9</u>	<u>13.7</u>	<u>10.7</u>	<u>3.1</u>	<u>2.6</u>

^a Numbers may not add due to rounding.

^b Less than 0.05 percent

Efforts to fund the
Gorgas Memorial Institute

The authorizing act for the establishment of the Laboratory, Public Law 70-350, approved on May 7, 1928, provided that Latin American governments be invited to contribute to the operation and maintenance of the Laboratory and be represented on the Institute's board or council in proportion to their contributions. Latin American contributions were limited and could not exceed 75 percent of the contribution of the United States. Invitations for contributions were extended in 1928 to Latin

American governments and in 1929 and 1931 to selected officials, educators, and physicians, as a result of which cash contributions of \$760 and \$1,150 were received from Ecuador and Venezuela in 1929 and 1931, respectively. This general lack of response and the possibility that Latin American countries, which had or were planning similar laboratories, might request U.S. contributions to their respective laboratories resulted in a 1954 amendment to the authorizing legislation. This amendment, Public Law 83-339, deleted the restrictions on Latin American contributions and the representation of nations on the Institute's governing bodies, and authorized the Institute to use its own discretion in accepting funds.

Although there are several potential bilateral donors in Latin America, Panama is the only other country currently providing funding to the Laboratory. Between fiscal years 1976 and 1982, Panama contributed \$696,538 or 3.9 percent of the Institute's total income. Panama's financial support is provided through appropriated funds, "in-kind" support, and contracted research services. The Government of Panama provides an annual contribution of \$5,000 for the maintenance of the Laboratory's library. This appropriation, which appears as a line item in the Panamanian budget, has been in place for several years and, according to a Laboratory official, there is no indication that it will either be increased or deleted.

The Government of Panama also contributes through the provision of such in-kind support as: relief from taxes and import restrictions and duties; special legal status for U.S. and other foreign scientists of the Laboratory; and permission for Laboratory physicians to work in Panamanian hospitals and scientists to work throughout Panama. In response to a condition set forth in the original Act of 1928, the Government of Panama deeded in perpetuity the original building and tract of land for the Laboratory; the property was augmented in subsequent years by the construction of three additional buildings, of which one was built with private funds. The main laboratory facility and surrounding land provided by Panama were assessed at \$126,750 on the date they were donated; however, this does not reflect the current value of this property which is in a central business location. A senior Panamanian official estimated the value of the land and facilities to be about \$20 million. We were unable to determine the dollar value of the indirect support provided by the Government of Panama; however, in 1979 the Fogarty Center estimated the value of this support to be about \$175,000 per year.

The Government of Panama also contracts for various environmental assessments and tropical research studies. For instance, the Laboratory has recently completed an environmental study of a Panamanian hydroelectric project (\$150,000) and the Ministry of Health has subcontracted for a \$168,000 study of leishmaniasis and malaria as part of an Inter-American Development Bank grant. At the time of our review the Laboratory was

negotiating with the Panamanian Government for a concessional \$500,000 loan to assist it through its current fiscal crisis. This crisis, which resulted primarily from the approximately \$400,000 expense incurred in terminating about 30 employees, has caused the Laboratory to implement such austerity measures as the proposed closing of one building. Other factors impacting to a lesser degree on this crisis include a reduction in grants and contracts, inflation, and increased building maintenance costs. Fogarty Center officials told us that the Institute knew of the substantial termination costs but was trying to reduce its future staff-size and operating costs.

The limits of Panamanian support appear to have been reached. The Minister of Health told us that while he is trying to find ways to support the Laboratory, direct Panamanian funding is at the highest level the government is able to provide due to fiscal constraints. Department of State officials added that external debt and International Monetary Fund requirements have forced Panama to "tighten its belt." The Institute's president added that Panama is providing more than its share of support and cannot realistically be asked to provide more.

Officials contacted during our review commented that the current economic conditions in Latin America prevent neighboring countries from providing financial assistance to the Laboratory. The Institute's president told us that while these countries are sympathetic and supportive, their limited resources do not allow them to provide funds. He cited the Institute's 1972 effort to create a regional medical library in which Institute representatives broached the topic with various Central American Ministers of Health. An official who participated in this project stated that the Ministers were interested in the concept, but for a number of reasons--lack of stability, personnel, resources, and concern over immediate public health problems--the library concept was never realized.

A senior official at PAHO presented a somewhat different view in stating that Latin American countries would be willing to contribute to the Laboratory and share the costs involved as long as they also shared in its decisionmaking process. At present the Laboratory is viewed by many as a strictly U.S. organization located in Panama and, according to this official, in order for it to obtain funds from other countries the image must be changed to one of an open international organization.

Although there are numerous foundations and institutions that provide funds for medical research, there is very little private sector funding available for tropical disease research. A former Institute president told us that no one granting organization can provide enough money to compensate for the loss of the congressionally provided core support. It was the consensus of opinion that without a long-term, stable base of core support the Laboratory would be forced to close.

Efforts by Gorgas to broaden
its financial base of support
have been minimal

To date efforts by the Institute and the Laboratory to broaden their financial base of support can be described as minimal. As previously discussed, the Institute views the countries of Latin America as too poor to contribute and, consequently, has not asked for their assistance. Laboratory officials told us they have informally broached the topic with the Government of Panama; however, they believe the solicitation and acquisition of funds is the responsibility of their Washington headquarters.

During late May 1983, the Institute contacted 150 foundations and other potential donors to determine if its programs qualified for funding by these organizations. The letter discussed the Institute's history, organization, and research activities, and stated that it was "exploring the possibility of seeking private funds to replace in part the reduced Federal funding available to our activities." As of August 10, 1983, the Institute had received 114 mostly negative responses with some requesting additional information. A member of the Institute's Executive Committee stated that most of the Institute's officials were inexperienced in fund raising and had little knowledge of how to go about the process of obtaining funds. Furthermore, the costs of retaining a consultant for this purpose were viewed as excessive.

According to the Institute's president neither WHO nor PAHO--two international organizations whose primary concern is health-related problems--were approached in the Institute's quest for additional funding because it is the stated policy of these organizations not to provide funds for core support (i.e., indirect costs and salary costs associated with the principal investigators).

Other agency efforts to assist the
Institute in obtaining funds

Efforts by the Fogarty Center and the Department of State to assist the Institute in broadening its financial base of support have been unsuccessful because (1) the Institute is a private corporation and, as such, the amount of Federal assistance available is limited and (2) adverse economic conditions are affecting most Latin American countries.

At the direction of the Senate Committee on Appropriations, the Fogarty Center recently addressed the question of increased Latin American support. In response to a Fogarty Center inquiry, the Department of State noted that while the Laboratory was a "worthwhile institution," funding from neighboring countries or such multilateral organizations as PAHO was not likely

in the near future. The Fogarty Center's March 1983 report concluded that while it was too early to determine whether or not neighboring countries could support the Laboratory, "the burden for obtaining additional support finally rests with the Gorgas Memorial Institute."

Department of State officials have offered to assist the Institute if it decides to approach neighboring countries. However, the amount of assistance the Department of State can provide is basically limited to introducing the Institute to prospective donor governments since the Institute is a private corporation. As of July 1983, such assistance had not been requested. A PAHO representative in Panama told us that PAHO and WHO officials had met recently in Washington, D.C., and determined that neither could provide additional funding at the present time. Furthermore, he does not think PAHO or WHO will be able to provide additional funding in the future.

Suggested alternatives to the current method of funding

During the course of this review, various officials suggested several alternatives to the current method of funding the Laboratory. These include, among others, (1) making the Laboratory an international or regional research facility and (2) placing the Institute's appropriation under another agency.

Conversion of the Laboratory from strictly a binational organization to a regional or international organization is an alternative that should not be dismissed. Views on this issue vary; however, there has been no in-depth study of this option to date.

The concept of regionalizing or internationalizing a health or research facility is not new and has occurred in the past with the establishment of a Latin American regional health center, the Institute of Nutrition of Central America and Panama, and a research center, the International Center for Diarrheal Disease Research in Bangladesh. Prior to its 1979 internationalization, the Center in Bangladesh had been predominantly U.S.-funded with the U.S. contribution estimated at about 85 percent of the Center's total funding. By internationalizing the Center, it became an independent, non-profit institution chartered under the laws of Bangladesh. The U.S. contribution, which has been reduced to about one-third of the Center's \$6 million 1983 budget, is requested by and appropriated to AID which acts as a "pass-through agent" for the funds.

Although informally discussed on several occasions, the possibility of internationalizing the Laboratory was formally proposed by the Panamanian Minister of Health in an October 8, 1982, letter to the Department of Health and Human Services. In citing Panama's difficulty in providing "large contributions to a private institution in which we have little say," the Minister

proposed establishing an international organization of regional countries with the United States and PAHO controlling the Laboratory. Although believing some of the specifics of the proposal were premature, the Institute initially supported the proposal.

A former president of the Institute now believes this proposal was hastily made and that, if implemented, the Institute would be required to make numerous administrative and organizational changes (e.g., revise existing treaties and charters, reorganize its Board of Directors, etc.) which would not remedy the Institute's primary problem--sources of funding. The Panamanian Minister of Health is of the opinion that while Latin American countries have shown some interest in the internationalization of the Laboratory, the amount of effective support they can provide is far less than the indicated interest. Furthermore, he told us the concept he previously proposed is no longer viable because, in his view, it would end up like the Institute of Nutrition of Central America and Panama in which member countries are not paying their dues but are still involved in the decisionmaking process. As of December 31, 1982, five of the six member-nations of the Nutrition Institute were in arrears and three nations had not contributed since at least 1975. Arrearages currently total approximately \$1 million.

A senior AID official who was actively involved in the internationalization of the Bangladesh Center believes that, in theory, the Institute and Laboratory can be internationalized. However, because of its existing corporate structure (e.g., the large number of active-duty and retired U.S. military officers represented on the Institute's Board of Directors and the limited Latin American/Panamanian representation), the unwillingness of the Institute's Board of Directors to change, and the lack of a firm and continuing base of financial support, the possibility of internationalizing the Institute was viewed as slim. Similar views were expressed by a senior PAHO official who has previously offered his organization's assistance in the matter. This official also believes that regional nations would be more willing to provide funds if they could also share in the decisionmaking process and research benefits associated with the Institute.

The Department of State does not believe internationalizing the Laboratory is a viable alternative since the Laboratory currently serves several interests which are not necessarily scientific in nature (i.e., assurance of environmental and health quality in Panama, political leverage in dealing with the Government of Panama, training of military physicians, etc). Consequently, according to a Department official, the small financial gains afforded the United States through the internationalization of the Laboratory are greatly outweighed by the U.S. interests that "will not be well served."

The president of the Institute believes that another alternative may be the inclusion of the Institute's funding request under the appropriation of another U.S. organization. He further believes that the termination of Institute funding to satisfy NIH budgetary policies (i.e., the funding of 5,000 NIH research grants) and not because of scientific inadequacies illustrates the adverse relationship currently existing between the two organizations. He is also of the opinion that this is a viable alternative and cited the Centers for Disease Control (CDC) as a possible alternative to NIH. The concept has not been officially broached with this or other agencies as the president believes the Congress should do so. A senior official of AID, another possible agency for the placement of the Institute's appropriation, believes the overall mission of the two organizations is compatible but, because of the Institute's existing corporate structure, such a change is not feasible.

OBSERVATIONS

GAO takes no position on whether or not funding of the Institute should be continued. Some officials suggested that internationalization or regionalization of the Institute offers an alternative to the current organizational arrangement. If the Institute, in cooperation with the Fogarty Center, was to explore this possibility, it would want to consider the experiences of the Agency for International Development in its internationalization of the International Center for Diarrheal Disease Research in Bangladesh. GAO offers no comment on the other alternative--funding the Institute through another Federal agency.

CHAPTER 3

FEDERALLY SUPPORTED RESEARCH SIMILAR TO THAT CONDUCTED BY GORGAS

Several U.S. Government departments and agencies are involved in tropical disease research. This involvement may be either direct, through conducting actual research, or indirect, through grants or contracts for such activities. Government organizations primarily involved in tropical medicine research include: NIAID, the Departments of Army and Navy, and AID. International organizations involved in tropical disease research which also receive U.S. funds include the World Health Organization, and its Central American regional office, PAHO. The following summarizes the federally funded tropical medicine research activities involving diseases similar to those studied at the Laboratory.

RESEARCH FUNDED BY THE NATIONAL INSTITUTES OF HEALTH

NIH is heavily involved in tropical medicine research. During fiscal year 1982, the various Institutes of NIH awarded over \$30 million to 314 external or extramural research projects whose primary emphasis was tropical medicine. As shown by Table 3, almost half of this amount, or \$14.6 million, was awarded for research into five of the diseases currently studied at the Laboratory.

Table 3

NIH Extramural Research Awards for Selected Diseases fiscal year 1982

	<u>Number of projects</u>	<u>Award amount</u>
Trypanosomiasis	54	\$ 5,575,850
Malaria	33	4,188,808
Leishmaniasis	33	4,074,085
St. Louis Encephalitis	5	478,657
Yellow Fever	5	241,354
Total	<u>130</u>	<u>\$14,558,754</u>

Research funded by the National Institute of Allergy and Infectious Diseases

Within NIH, the National Institute of Allergy and Infectious Diseases has primary responsibility for tropical medicine research. During fiscal year 1982 NIAID funded approximately

\$34 million in tropical medicine research, one-third of which can be broadly categorized as being similar to that undertaken at the Laboratory. NIAID funds this research through intramural and extramural programs. Intramural research in tropical medicine is carried out at the NIAID laboratories in Bethesda, Maryland, and Hamilton, Montana, and amounted to approximately \$9.5 million during fiscal year 1982. The extramural research program is carried out through research or training grants and contracts awarded to academic and research institutions. Extramural research accounted for 72 percent (\$24.3 million) of the total fiscal year 1982 NIAID budget for tropical medicine. Table 4 presents a more detailed analysis of these activities.

Table 4

National Institute of Allergy and Infectious Diseases
National Institutes of Health
Tropical Medicine Program
fiscal year 1982

<u>Program Area</u>	<u>Extramural Activities</u>		<u>Intramural Activities</u>		<u>Total</u>			
	<u>Grants</u>		<u>Contracts</u>		<u>No.</u>	<u>Amount</u>		
	<u>No.</u>	<u>Amount</u>	<u>No.</u>	<u>Amount</u>				
Research similar to Gorgas:								
Leishmaniasis	17	\$ 1,608,214	-	-	3	\$1,274,381	20	\$ 2,882,595
Malaria	15	1,419,147	-	-	8	2,147,618	23	3,566,765
Trypanosomiasis	32	3,097,248	-	-	7	792,011	39	3,889,259
ICIDR (note a)	4	1,757,630	-	-	-	-	4	1,757,630
TRU (note b)	1	406,625	-	-	-	-	1	406,625
Total similar to Gorgas	69	8,288,864	-	-	18	4,214,010	87	12,502,874
Other tropical research:								
Tropical diseases	44	3,637,829	4	280,013	9	1,413,243	57	5,331,085
General tropical medicine	87	7,659,490	-	-	13	1,990,933	100	9,650,423
General parasitology	42	3,501,526	-	-	8	1,853,580	50	5,355,106
Other (note c)	8	977,819	-	-	-	-	8	977,819
Total other tropical research	181	\$15,776,664	4	\$280,013	30	\$5,257,756	215	21,314,433
Total	250	\$24,065,528	4	\$280,013	48	\$9,471,766	302	\$33,817,307

^a International Collaboration in Infectious Disease Research Program; includes some diseases not studied at the Laboratory. See Table 5.

^b Tropical Disease Research Unit Program; includes some diseases not studied at the Laboratory. See Table 6.

^c Includes activities of a and b which have no components similar to research at the Laboratory, and tropical disease training and career development. See Tables 5 and 6.

NIAID has established four extramural award mechanisms to allow greater flexibility and coordination between U.S. tropical medicine scientists and those in developing countries. The largest of these award mechanisms, the International Collaboration in Infectious Disease Research Program, is designed to develop relationships between U.S. institutions or investigators and their developing country counterparts. During fiscal year 1982 this program was funded at a level of \$2.2 million and involved five projects in four developing countries. Four of the projects (\$1.8 million) involved some research into diseases similar to those studied at the Laboratory. Table 5 presents a more detailed analysis of this program.

Table 5

National Institute of Allergy and Infectious Diseases
National Institutes of Health
International Collaboration in Infectious
Disease Research Program
fiscal year 1982-

<u>U.S. university</u>	<u>Foreign Institution/country</u>	<u>Research Interest</u>	<u>Award amount</u>
Research similar to Gorgas:			
Harvard School of Public Health	Federal University of Bahia, Brazil	Schistosomiasis, (^a) Chagas' Disease	\$ 281,306
Cornell University Medical College	Federal University of Bahia, Brazil and University of Brasilia, Brazil	(^a) Leishmaniasis, (^a) Trypanosomiasis	674,524
Michigan State University	Central Laboratory, Ministry of Health, Khartoum, Sudan	Schistosomiasis, Onchocerciasis, (^a) Malaria	354,908
Tulane School of Public Health	Colciencias, Cali, Colombia	Filariasis, (^a) Trypanosomiasis, (^a) Leishmaniasis, Intestinal Parasites	<u>446,892</u>
Total			1,757,630
Other research:			
University of Illinois	Chiang Mai University, Thailand	Immunobiology and Epidemiol- ogy of Leprosy	<u>441,121</u>
Total			\$2,198,751 *****

^a Diseases studied at the Gorgas Memorial Laboratory.

Designed to expand NIAID's existing domestic research efforts, the second largest extramural award mechanism, the Tropical Disease Research Unit program, provides awards to outstanding U.S. institutions for multidisciplinary research in tropical medicine. This program involved the funding of \$828,025 to two institutions during fiscal year 1982 for research into tropical diseases. As shown on Table 6, one of the institutions (Robert Breck Brigham Hospital) conducted some research on diseases similar to those studied at the Laboratory.

Table 6

National Institute of Allergy and Infectious Diseases
National Institutes of Health
Tropical Disease Research Unit Program
fiscal year 1982

<u>U.S. institution</u>	<u>Research interest</u>	<u>Award amount</u>
Research similar to Gorgas:		
Robert Breck Brigham Hospital	Immunology of Chagas' Disease, Filariasis and Leishmaniasis (note a)	\$406,625
Other research:		
Case Western Reserve University	Multidisciplinary in Parasitic Infections (Schistosomiasis)	<u>421,400</u>
Total		<u><u>\$828,025</u></u>

a Chagas' Disease and Leishmaniasis are studied at the Laboratory.

RESEARCH FUNDED BY THE
AGENCY FOR INTERNATIONAL DEVELOPMENT

A senior Office of Health official in AID told us that the Agency plans to spend about \$15 million on biomedical research of tropical diseases and diarrheal disorders during fiscal year 1983. AID-sponsored research is directed at the most significant diseases of the developing world and will be primarily implemented through the five projects listed in Table 7.

Table 7

Major AID Activities in
Tropical Medicine Research
fiscal years 1983-1984

	<u>Funding level</u>	
	<u>1983</u>	<u>1984</u>
	<u>Estimate</u>	<u>Proposed</u>
	(dollars in thousands)	
Malaria Immunity and Vaccine Research	\$3,000	\$3,900
WHO Special Program for Research and Training in Tropical Diseases	3,100	2,000
Diarrheal Disease Research Program	1,900	1,900
Comprehensive Methods of Vector Control	300	500
Onchocerciasis Control (note a)	2,600	2,200

^a The primary focus of this project is the control of onchocerciasis (river blindness) in the Volta River Basin of Western Africa.

AID's support of malaria vaccine research began in the late 1960s with a project implemented by the University of Illinois. This initial project has been expanded and consists of a network of 13 research institutions which are continuing to work on the development of a vaccine. During 1978 the Laboratory was awarded a 2-year, \$81,000 AID contract to conduct research on the in-vitro cultivation of malaria parasites. At the conclusion of the project the Laboratory proposed a follow-up effort which underwent a technical review by AID and was disapproved on the grounds that it was "not of high enough priority" in relation to AID's overall revised strategy.

AID's involvement with the World Health Organization and Diarrheal Disease Research Program is limited to acting as a "pass-through" agent for the appropriated funds.

RESEARCH FUNDED BY THE
DEPARTMENT OF DEFENSE

Although the Department of Defense (DOD) does not fund tropical disease research as a separate activity, it does conduct research in various types of infectious diseases which include such tropical diseases as malaria, leishmaniasis, trypanosomiasis, schistosomiasis, and dengue. Recently consolidated, with the Army designated lead Service, DOD's infectious disease program is aimed at those diseases which are uncommon in the United States, have not been of general concern to other U.S. health research agencies, and have the capacity of hampering military operations. The center for much of DOD's tropical disease activity is the Walter Reed Army Institute for Research. DOD's infectious disease program, which emphasizes

vaccine and drug development and vector control, will be funded at a level of approximately \$55 million during fiscal year 1983 with an estimated \$15 million being directed toward research in tropical disease areas. Table 8 presents the U.S. Army and Navy infectious disease programs and funding levels for fiscal year 1983. It should be noted that the U.S. Air Force does not engage in tropical disease research.

Table 8
Infectious Disease Research
by the U.S. Army and U.S. Navy
fiscal year 1983

<u>Research Area</u>	<u>Funding level (note a)</u>		
	<u>Army</u>	<u>Navy</u>	<u>Total</u>
	<u>(dollars in thousands)</u>		
Drug and Vaccine Development	\$ 7,971	\$1,200	\$ 9,171
Military Disease, Injury, and Health Hazard	15,243	2,158	17,401
Prevention and Treatment of Diseases Affecting Mobilization and Deployment	4,124	712	4,836
Medical Defense Against Biological Warfare	17,289	1,521	18,810
Identification Base/Biological Warfare Vaccines and Drugs	<u>4,937</u>	<u>0</u>	<u>4,937</u>
Total	<u>\$49,564</u>	<u>\$5,591</u>	<u>\$55,155</u>

^a Army figures include general support costs; Navy figures include laboratory administration monies.

DOD's Drug and Vaccine Development Project includes research activities which are closely related to those conducted by the Laboratory. The objectives of this research area, in part, include the development of antiparasitic drugs and parasitic vaccines against diseases that threaten troop movements and military operations, and for which no commercial production base exists.

DOD has operated overseas medical research laboratories since 1900 and currently maintains eight laboratories throughout the world. Laboratories in Brazil, Kenya, Malaysia, and Thailand are elements of the U.S. Army and laboratories in Egypt, Indonesia, Peru, and the Philippines are U.S. Navy organizations. Research conducted in these laboratories is directed toward tropical infectious diseases that could reduce the effectiveness of military personnel operating in remote areas of the world. Staffed with 109 U.S. military, 9 U.S. civilian, and 544 local national employees, these laboratories reportedly represent the largest U.S. effort directed toward the prevention, diagnosis, and treatment of tropical infectious disease.

From 1959 to 1976 the Army maintained a research laboratory in Panama. This unit, however, fell victim to budget reductions and, upon its closure, the Army contracted with the Gorgas Laboratory for the completion of some ongoing research. According to Army officials the Laboratory was selected because it (1) was already in-place, (2) had almost 50 years of research experience, and (3) had a qualified veterinarian available.

At present, the Army has a contract with the Laboratory for the preclinical testing of potential antimalarial drugs. This project, which is funded at a level of \$173,152 for fiscal year 1983 and represents the largest contract at the Laboratory, evaluates the effectiveness of the antimalarial drugs on previously infected Aotus or owl monkeys. According to Army officials, this project is unique because (1) the Army is the only public or private organization devoting funds for the development of antimalarial drugs, (2) the Aotus monkey is the best animal model found to successfully test such drugs, and (3) this is the only malaria project in the world that has advanced to the stage of drug development in primate models.

Since 1970 the U.S. Navy has contracted with the Laboratory for the provision of a 6-week training course on tropical medicine. This course has provided advanced clinical study and research training to 350 military physicians in such areas as malaria and diarrheal illness, as well as parasitic, bacterial, viral, and nutritional problems. In a recent letter the Secretary of Defense noted that " * * * we consider the Gorgas Memorial Institute's programs to be an essential adjunct to our military health training * * *." The Navy contract for this course has recently been increased from \$35,000 to over \$65,000 per year.

RESEARCH FUNDED BY THE
CENTERS FOR DISEASE CONTROL

CDC conducts tropical disease research primarily through its Communicable and Infectious Disease Division and its Parasitology Division; and the latter is divided into malaria, helminthic, control technology, and protozoological branches. CDC also serves as a worldwide reference center and is frequently called upon by tropical countries to provide emergency assistance.

In the past CDC had financed a research station in San Salvador, El Salvador. This station was staffed with approximately 10 U.S. and 50 local national employees and acted as an "early warning station" for such diseases as malaria, dengue, typhoid fever, and Venezuelan Equine Encephalitis. Although the political situation in El Salvador forced the station's closure in the fall of 1981, CDC continues to monitor these diseases through in-country visits.

CDC currently has three personnel assigned to a university in Guatemala who are conducting research on leishmaniasis in Honduras. This study is being conducted in collaboration with the Laboratory.

RESEARCH FUNDED BY THE WORLD HEALTH ORGANIZATION

In 1975, WHO, the World Bank, and the United Nations Development Program established the Special Program for Research and Training in Tropical Diseases. This program is designed to develop new methods to control six tropical diseases (in order of priority: malaria, schistosomiasis, filariasis, trypanosomiasis, leprosy, and leishmaniasis) and strengthen the research capabilities of developing countries. During 1982 and 1983, the United States anticipates contributing \$8 million to this program. Research organizations and institutions apply for WHO-funded grants and contracts and, according to an AID official, selection is primarily based on the merits of both the proposal and the proposing organization. Although universities have been the major U.S. recipients, some awards have been made to pharmaceutical companies, NIH, and the Walter Reed Army Institute for Research. AID, which oversees U.S. participation in this program, estimates that awards to U.S. organizations exceed the U.S. contribution by approximately 25 percent.

The Laboratory conducts research on three of the six WHO-targeted diseases (malaria, trypanosomiasis, and leishmaniasis) and, as shown by Table 9, has been awarded approximately \$50,000 by WHO for several research projects. The Institute's president notes that its involvement with the WHO program has been limited because research overhead costs (e.g., salaries, equipment, etc.) must be borne by the grantee. Consequently, Institute participation has been limited to those instances where it feels a meaningful contribution can be made by the Laboratory.

Table 9

WHO Activities Conducted at the Gorgas Memorial Laboratory
fiscal year 1983

<u>Activity</u>	<u>1983 projected revenue</u>
Leishmaniasis in Honduras	\$ 2,770
Chagas' Disease (Trypanosomiasis)	15,267
Clinical Trials for Leishmaniasis Therapy	4,115
Triatomine Blood-meal Analysis	18,740
Isozyme Analysis of Lutzomia Sand Flies	<u>8,907</u>
Total	<u>\$49,799</u>

CHAPTER 4

SCIENTIFIC REVIEW OF GORGAS RESEARCH ACTIVITIES

In its justification for the termination of U.S. funding of the Institute, NIH stated that the funds provided through the NIH appropriation were "not subject to the same peer review process as other NIH programs." Our review of the scientific review applied to Laboratory activities showed the following.

- Long-range planning of Laboratory activities is lacking.
- Internal project planning and review is very informal.
- External review is periodically provided by a site visit team of government and non-government scientists organized by the Fogarty Center and the Institute.
- The Institute's Advisory Scientific Board is not being fully utilized.

NO LONG-RANGE PLANNING AT THE LABORATORY

We could not identify any formal long-range program plan or planning process at either the Institute or the Laboratory. These conditions are similar to those reported by a 1976 Fogarty Center review team which noted that the Laboratory's research efforts should be focused on one or more long-range goals with an appropriate completion schedule. A planning process of this type would reportedly permit better use of Laboratory facilities and personnel. No corrective action has been taken in response to this observation.

Although the Laboratory plans to reorganize its activities into four areas of study--microbiology, epidemiology, environmental science, and clinical therapeutics--work is generally conducted on a contract-to-contract basis or as needs arise. Activities in the latter instance are usually in response to requests for assistance during disease outbreaks. While these "studies of opportunity" enhance U.S.-Panamanian relations and add to the investigating scientists' knowledge, they do not readily allow for carefully planned research, add to the cost of the operation, and are generally not reimbursed by the Government of Panama.

A method of informally directing the Laboratory's overall research effort is accomplished through the selection of personnel. The Institute's Executive Board is responsible for the hiring of scientists who, according to the Institute's

president, generate their own work and, thereby, determine the direction of the Laboratory's research. As discussed below, the self-generated work at the Laboratory is subject to internal review.

The Institute's president believes long-range planning is not practical as scientific needs and priorities are constantly changing and the Laboratory is better able to respond to these changing requirements and attract new grants and contracts by not being restricted by a long-range plan. However, there may be potential budgetary and managerial benefits which could result from long-range planning and which also recognize the changing requirements of the Laboratory.

THE LABORATORY'S PROJECT PLANNING AND REVIEW PROCESS IS INFORMAL

The Laboratory does not have a formal internal review process for evaluating new, ongoing, or recently completed research projects. The Laboratory director told us that because of its small size, an informal process provides the necessary peer review for his organization to produce quality projects. Another Laboratory official added, however, that a more formalized review process would help to ensure that high scientific standards and productivity are maintained.

New projects, which are funded by either core, grant, or contract monies, are generated by the scientists at the Laboratory. In general, NIH grants are not solicited and the proposing investigator is responsible for developing ideas, concepts, methods, and approaches for the proposed project. Contracts, on the other hand, are solicited and the awarding institution establishes the plans, parameters, and detailed requirements for the project. The Laboratory makes no distinction between the review of proposals for grants or contracts. Staff-generated proposals are developed at a rate of about one per month and are circulated to other Laboratory scientists for their review. Proposals may also be circulated to outside experts to obtain analyses based on scientific, ethical, and fiscal considerations. Scientists reportedly are aware of the required informal review before a project is undertaken, although there have been unusual instances where, because of a short time-frame, this informal review process has been bypassed.

The Laboratory director is responsible for approving all proposals funded with core monies while the Institute's president approves all grant and contract proposals prior to their submission to the funding agency. Once a project is submitted to a funding agency it undergoes that agency's review and that agency determines, through its own process, whether or not to fund the Laboratory's work. The funding agency is then responsible for monitoring and evaluating the work done at the Laboratory.

Other projects are informally monitored by the Laboratory director and are presented to Laboratory staff and outside experts in Laboratory-sponsored periodic presentations--forums about every 2 weeks and seminars about once a month. If the project's director or Laboratory director recognizes a need for redirection of a project, the matter is discussed between the director and staff person and a solution is reached.

According to a Laboratory official, another way in which ongoing projects are monitored and evaluated is when each scientist develops a report of the work he or she has been doing--whether paid for by grant, contract, or core funds--for inclusion in the Laboratory's annual report. The director reviews these reports and goes over them with the individual scientist. These reports are then compiled to form the annual report to the Congress. This process allows individual scientists to annually review their work.

Finally, the Institute's president told us that there is no formal internal post-project review process.

EXTERNAL REVIEW OF LABORATORY ACTIVITIES

The Institute is not subject to the managerial controls of the Fogarty Center; however, the Fogarty Center maintains general program oversight of the U.S.-provided funds through periodic site visits to the Laboratory. Scientists chosen by the Fogarty Center review all programs for quality, adequacy, and relevance to the Laboratory's mission, including any administrative factors that may affect its programs. Reviews were made in 1976 and 1980, and are scheduled approximately every 3 years. A review is scheduled for fall, 1983. The 1980 site visit team reported that the Laboratory's studies were of scientific importance to the United States, Panama, and the region; the overall research quality was of a high standard; and the scientific value and benefits derived from the Laboratory were a worthwhile investment of U.S. funds.

In addition to these Fogarty Center-sponsored reviews, the Laboratory is also reviewed by teams selected by the Institute's Executive Board. In 1973 and 1974 Institute-sponsored scientists reviewed the Laboratory's virology and parasitology programs, respectively, and in 1978 a review team consisting of representatives from the Fogarty Center and the Institute's Executive Committee and Advisory Scientific Board reviewed the Laboratory's scientific programs. According to the Institute's president these reviews occur between Fogarty Center visits; however, there have not been any since 1978.

Indirect external review of completed projects occurs during the publication process. A traditional measure of research quality and productivity in the scientific community is the number of reports published in scientific journals. Scientists peer review these reports to determine whether they are of

sufficient significance and quality to be published. Laboratory scientists published over 100 reports between fiscal years 1978 and 1982 which, according to a member of the Institute's Advisory Scientific Board, is a tribute to the Laboratory's excellence. The Fogarty Center reported in 1980 that, considering the Laboratory's size, the 30 reports published during fiscal year 1979 represented "a very good record." The scientific quality of the material published by the Laboratory is being addressed in more detail by the related Office of Technology Assessment review.

LITTLE USE IS MADE OF THE INSTITUTE'S
ADVISORY SCIENTIFIC BOARD

The Institute has a 24-member Advisory Scientific Board to advise the president on matters involving the development and review of scientific programs. We contacted 13 of the 19 Board members located in the United States and were told the Board had been rarely utilized in the past, had never met as an entity, and, overall, had not been involved in the activities of the Institute. It should be noted that most members contacted did not know why they were chosen to be on the Board although they assumed they were considered experts in their field. However, two of the members contacted were considered experts in fields in which the Laboratory did not work.

In the past the Institute has made little use of the Board as its members have not been asked to comment on proposed or ongoing projects at the Laboratory. Some members, however, have accompanied the Laboratory review teams sponsored by the Fogarty Center and the Institute. In addition, some members have informally advised the Laboratory on project proposals, but this is dependent upon personal relationships with Laboratory staff or other professional affiliations.

The only formal contact between the Institute and Board members is the members' receipt of the Institute's annual report and invitations to its annual meeting. However, very few Board members attend the annual meeting--two in 1981, three in 1982 and one in 1983--since, according to some members, all travel costs must be borne by the member; those who did attend did so because they either live or work near Washington, D.C. (where the meetings are held) or were in the area on other business.

A 1976 Fogarty Center review team recommended that the Board have an active role in the planning and review process and work closely with the Laboratory's director. The Institute's president responded to this recommendation in 1977 by stating: "We plan to use the GMI (Gorgas Memorial Institute) Advisory Scientific Board actively in program development and evaluation." This has not happened. Some Board members believe increased involvement can be accomplished either by circulating project plans or creating a smaller Board which would meet biannually with the Institute paying the costs.

The Institute's current president told us that, although the Board has not been used in the past, it will be used in the future. He believes members can be utilized in a number of ways, including generating project ideas, examining projects developed by the Laboratory staff, helping identify new scientists to be hired at the Laboratory, and functioning as an editorial board to critique project papers before they are submitted for publication in scientific journals. The president believes greater use of the Board will enhance the quality of the scientific work done at the Laboratory.

OBSERVATIONS

We believe there is a need for a more formalized planning and review process at the Institute and Laboratory. The need for flexibility in Laboratory activities to respond to emergency situations is recognized; however, we believe a more formal planning and review process could allow for better use of Laboratory facilities and personnel. Also, more involvement by the Advisory Scientific Board in the planning, execution, and review of Laboratory activities could enhance the quality of the scientific work done at the Laboratory.

CHAPTER 5

IMPACT OF POTENTIAL TERMINATION OF U.S. FUNDING

According to the Department of State, the major impact that would result from the closure of the Laboratory would be the "adverse political messages about both U.S. consistency and the relative priority of our interest in humanitarian activities in Panama, in Central America, and in the U.S." In general, views on the extent and type of other impacts varied; however, most officials we spoke with felt the Institute and Laboratory served a useful purpose and should continue to receive U.S. funding. The termination of U.S. support would have an adverse impact on those U.S. organizations having programs and/or activities at the Laboratory.

REGIONAL RELATIONS

In a July 23, 1983, letter to the Secretary of Health and Human Services, the Secretary of State asked that the termination of U.S. support be reevaluated "with a view to continuing adequate funding" for the Laboratory. The Secretary of State further noted the following:

"***the Laboratory is one element in a complex relationship between our country and Panama, and between our country and a region in turmoil. Failure to continue to adequately fund the Laboratory ***would be quite inconsistent with our posture of constructive engagement with Panama, and with the Administration's policy of strong support for the troubled Central American region. It could easily be misinterpreted by our neighbors in the region at a time when confusing signals should be avoided."

This letter, according to the Department of State, presents "an authoritative reflection of the Department's views" on the impact topic.

A Department of State official contacted prior to the above cited letter told us that the termination of U.S. funding for the Laboratory would be viewed in some circles as indicating a lack of concern for the Latin American region by the United States. The official further believes that such an action could be seen by various countries in the region as illustrative of general U.S. indifference toward the health of poorer populations.

Other than the Department of State's recent letter, there was no consensus as to the regional impact that would result if U.S. support of the Laboratory was withdrawn. This can primarily be attributed to the fact that, while its research may be

applicable to various countries in the region, the Laboratory's research initiatives have a Panamanian rather than regional focus.

Possible funding termination is viewed by some as inconsistent with the current Caribbean Basin Initiative (CBI). The CBI is an integrated package of trade, investment, and aid measures designed to assist the countries of the region in coping with an unfavorable international economic environment and in implementing more effective economic policies. A Department of State official told us that while the CBI is primarily aimed at trade and finance, the termination of funding for the Laboratory is in "definite conflict with the intent" of the CBI. Another Department official added that "any decline in U.S. funding in Central America, especially when infrastructure activities are involved, goes against the entire CBI concept. This is especially true when projects or activities involving local funding are concerned." In citing NIH's concern for domestic rather than international issues, a Department official told us that the proposed termination of funding resulted from a lack of coordination within the Administration.

One possible outcome resulting from the proposed termination of funding for the Laboratory, according to Department of State officials, could be increased attention being paid to the Cuban Institute of Tropical Medicine. Located in Havana, this institute is an 80-bed hospital for patients suffering from tropical diseases and, other than the Laboratory, represents the only Spanish-speaking tropical disease reference center in the Caribbean. The primary advantages of the Cuban facility are the abundance and variety of tropical diseases available for study. According to a senior PAHO official, that organization discourages the use of the Cuban facility because some of its patients have been exposed, through various activities in Africa, to diseases not found in this hemisphere and visiting doctors could unknowingly introduce such diseases into Central America. The official added that the potential teaching and educational void resulting from the Laboratory's closure could result in increased training at the Cuban Institute. A Department of State official added that the closure of the Laboratory would give Cuba the opportunity to attract undue attention to its institute which could be disadvantageous to the United States.

U.S.-PANAMANIAN RELATIONS

Department of State officials in Washington and Panama advised us that if U.S. funding was terminated and the Laboratory was closed, some "hard feelings" would result and the United States would lose some of the diplomatic "tools" or leverage currently at its disposal.

Although a private corporation, the Laboratory is viewed by many Panamanians as a U.S. Government organization. Consequently, according to Department of State officials, termination of

funding would directly reflect upon the United States and would be noticed out of proportion to its actual scientific impact. Such an action would, according to one official, be seen as "another case of the U.S. not caring about its past commitments to Panama" and could have an impact on future U.S.-Panamanian relations. Department of State officials also noted that while Panama is relatively better off economically than some of its neighbors, the country is experiencing some severe economic problems (e.g., massive layoffs in the sugar industry).

A Department of State official told us that the Laboratory serves many U.S. interests which are not necessarily scientific in nature. For instance, the Laboratory greatly influences Panamanian environmental policies, especially those outlined by the World Bank and the Joint Committee on the Environment of the Panama Canal Commission, and serves a unique, unofficial role because the Government of Panama has no such agency or facility of its own. The official further noted that the views and opinions of the Laboratory are greatly respected by all parties since they are impartial. Consequently, the closure of the Laboratory would deprive the United States of this diplomatic "tool."

Department of State officials also emphasize the "symbolic" and "memorial" aspects and the commitment made by the United States in establishing the Laboratory. Overall, Department of State officials believe the Laboratory should continue to be funded because U.S. environmental, medical, military, and regional interests are all served by the continued operation of the Laboratory.

VIEWS ON THE SCIENTIFIC IMPACT

During our review many officials provided opinions on the value of the Laboratory's scientific work and the potential impact of the proposed termination of funding. We were told the Army, Navy, Yale University, and CDC have programs and/or activities at the Laboratory which would be affected if it were forced to curtail operations. The information below has not been verified and should be used in concert with the related Office of Technology Assessment report on the relevance of research conducted at the Laboratory.

This report by the Office of Technology assessment has concluded the following.

"* * * the only benefit to the U.S. of defunding Gorgas would be a saving of perhaps significantly less than \$2 million per year. The negative consequences would include loss of one of the few, high quality, broadly relevant, tropical research institutions located in a tropical country."

The report further concludes that the "positive consequences of U.S. core support of Gorgas appears to greatly outweigh the amount of funds involved."

Since the 1976 closure of its research facility in Panama, the Army has contracted with the Laboratory for the testing and evaluation of antimalarial drugs on previously infected Aotus monkeys, the best and standard primate model for such testing. Army officials believe antimalarial drugs will take at least 10 to 15 years to develop and, because of the need for the Aotus monkey model, closure of the Laboratory would require them to either establish a military laboratory in Panama or import the monkey and accompanying malaria strains for research in the United States. Based on their most recent experience in creating an overseas laboratory in Kenya, Army officials estimated that it would cost about \$2 million to establish such a facility in Panama. It is important to note that this cost exceeds the combined total of the fiscal year 1983 Institute appropriation (\$1.8 million) and the Army contract (\$173,200). Army officials added, however, that there is some question as to whether or not the Government of Panama would allow the U.S. military to re-establish an in-country research laboratory.

Importation of the Aotus monkey for research within the United States is not viewed as a feasible alternative because (1) the monkey is classified by the Fish and Wildlife Service as an animal which could become endangered by international trade and (2) special facilities would be required for the research activities. The Aotus monkey is indigenous to Panama and northern South America and each exporting country has unique requirements. Recent U.S. importation of this monkey has been 187 in 1979, 472 in 1980, and 356 in 1981. Panama, which according to Army officials has embargoed exportation of the Aotus monkey, shipped 4 such monkeys to the United States in 1979, 51 in 1980, and none in 1981. A senior PAHO official added that if the Aotus monkey were imported for drug research, then extensive costs would be incurred in (1) constructing a security facility for the imported malaria parasites and conduct of the research and (2) developing a natural habitat for the test animals. Facilities and conditions for malaria drug research, according to this official, already exist at the Laboratory.

The Navy currently contracts with the Laboratory for the annual training of about 24 Navy doctors in tropical medicine which, according to a senior Naval official, satisfies existing Naval contingency requirements. Closure of the Laboratory would require the Navy, which recently increased its contract from \$35,000 to over \$65,000 annually, to develop an internal program at a location similar to its Philippine or Egyptian laboratories. These alternative locations lack the "abundance" of diseases found in Panama, the tropical rainforest environment, and the qualified teachers and researchers that are available

at the Laboratory. We were also told that the student transportation costs would be excessive and, therefore, fewer Naval physicians would be able to attend and contingency requirements would not be met.

Yale University is completing the fourth year of a contract with the Laboratory (\$52,084 during fiscal year 1983) for research on yellow fever. This project is the result of a grant awarded to Yale by NIAID and, according to its project director, cannot be conducted in the United States. Furthermore, the project director believes that closure of Laboratory would result in the loss of a critically important research site as the Laboratory fulfills an invaluable role as a place where students are able to receive high quality training in tropical disease research.

The Centers for Disease Control utilizes the Laboratory as a reference laboratory and for disease surveillance which, according to a senior CDC official, is important for the health of the U.S. and middle America. For example, Laboratory analysis on insects is used in studies of arboviruses¹ and their vectors. Further, through the surveillance of disease, the Laboratory has prevented the spread of yellow fever to the United States and alerted CDC to epidemics such as Venezuelan Equine Encephalitis. The importance of the Laboratory's disease monitoring function was also reiterated by the Fogarty Center in recent congressional testimony.

During a 1982 National Academy of Sciences-sponsored seminar, international experts in vector biology concluded that the number of field-oriented vector biologists was below the critical level required to address the worldwide problems of vector-borne diseases. Reportedly, effective training in field entomology requires repeated periods of working abroad in different environments to gain practical field experience, and the Laboratory was cited as one of the more important facilities for such research. Members of the Institute's Advisory Scientific Board we contacted reiterated the importance of the Laboratory as a place for field research and training. Eleven of those contacted are professors at universities that have specialties in tropical medicine and eight of these identified the Laboratory as an important place for tropical disease research training and said if it closed there would be a loss to the scientific community.

¹ Arboviruses or Arthropod-Borne Viral Diseases are a large group of diseases caused by viruses defined by ecological, epidemiological, and clinical parameters. Arboviruses replicate in and are transmitted by such arthropods as mosquitoes, ticks, sandflies, and gnats.

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United States Senate

COMMITTEE ON APPROPRIATIONS

WASHINGTON, D.C. 20510

April 26, 1983

J. KEITH KENNEDY, STAFF DIRECTOR
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Mr. Charles A. Bowsher
 Comptroller General
 U.S. General Accounting Office
 441 G Street, N.W.
 Washington, D.C. 20548

Dear Mr. Bowsher:

I am writing to request that the General Accounting Office provide my Subcommittee on Labor, Health and Human Services, and Education with a report on the Gorgas Memorial Institute of Tropical and Preventive Medicine, Inc., and its biomedical research arm, the Gorgas Memorial Laboratory in Panama.

In the months ahead, the Subcommittee will be faced with the question of whether to agree to a recent Administration request to terminate direct federal funding of the Gorgas Institute in fiscal 1984. The Administration's original January budget had requested \$1,899,000 for Gorgas in the new fiscal year.

In developing its report to the Subcommittee, GAO should cover all aspects of Gorgas' activities and financing.

In particular, it is requested that GAO determine what scientific review is applied to Gorgas' research both before it is undertaken and after it is completed; and what other research similar to the work performed at Gorgas is conducted elsewhere with federal support. GAO also should advise the Subcommittee on the extent of efforts to broaden the international base of financial support for the Laboratory.

Since the proposed termination of federal support for Gorgas could result in closure of the Laboratory, the Subcommittee wishes to have information on the implications of such a step for American international relations in the region.

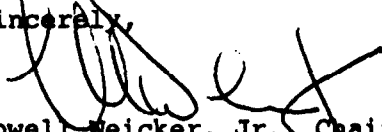
In order to assist the Subcommittee in making its fiscal 1984 funding decision on Gorgas, it is necessary to receive your

Mr. Charles A. Bowsher
April 26, 1983
Page Two

report by early August of this year. The information will be used in conjunction with a related request to the Office of Technology Assessment for a report on the scientific benefits of the Gorgas Laboratory's research.

Your assistance in this matter is appreciated.

Sincerely,



Lowell Weicker, Jr., Chairman
Labor-HHS-Education Appropriations Subcommittee

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