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

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BIOLOGICAL WARFARE

Better Controls in DOD's Research Could Prevent Unneeded Expenditures

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

Dear Mr. Chairman:

This report responds to your request that we review the medical component of the Department of Defense's Biological Defense Research Program. It discusses, among other things, the need for the Department to implement better program controls to ensure that all medical research and development efforts are directed toward validated biological warfare threat agents. It contains recommendations to the Secretary of the Army aimed at improving the management of the program.

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

This report was prepared under the direction of Richard Davis, Director, Army Issues, who may be reached on (202) 275-4141. Other major contributors are listed in appendix III.

Sincerely yours,

Frank C. Conahan
Assistant Comptroller General

Executive Summary

Purpose

In 1972, over 100 countries signed the Biological and Toxin Weapons Convention, which prohibits the development, production, and stockpiling of biological and toxin weapons. Since 1972, however, the number of nations having or suspected of having offensive biological warfare programs has increased from 4 to 10, with some of these countries being located in the Middle East, according to the Army's senior biological warfare analyst. U.S. military forces facing the threat of biological warfare must have medical countermeasures to defend against a biological weapons attack. The Department of Defense, through its Biological Defense Research Program, is responsible for developing these countermeasures, and the Congress has appropriated about $370 million since fiscal year 1984 for this purpose.

The Chairman of the Senate Committee on Governmental Affairs requested that GAO determine whether the program's medical research and development projects were (1) directed at validated biological warfare threat agents, (2) used to develop medical products for the defense of U.S. forces, and (3) coordinated with other federal research organizations to avoid unnecessary duplication.

Background

The mission of the medical component of the research program is to develop medical defenses, such as vaccines and drugs, to defend against biological warfare. The Department of Defense defines a "biological warfare threat" as a biological agent that the intelligence community has assessed as being developed or produced as a weapon. The Armed Forces Medical Intelligence Center, in conjunction with other intelligence agencies, validates the biological agents that present a bonafide threat to U.S. forces. The Academy of Health Sciences, a component of the Army's Health Services Command, determines the requirements for drugs and vaccines needed to counter these validated threats. The Army's Medical Research and Development Command, at Fort Detrick, Maryland, executes the medical component of the research program through research and development projects. The Command reports to the Army Surgeon General.

Results in Brief

The Army, because it did not have adequate internal controls in its medical research program, unnecessarily expended funds on research and development efforts that did not address validated threats and may have duplicated research efforts of other federal agencies. GAO's review showed that

- 49 research projects, valued at about $47 million, were directed at biological agents that the Armed Forces Medical Intelligence Center had not assessed as warfare threat agents;
- an additional 57 projects, valued at about $48 million, were questionable because neither GAO nor the Army could readily determine whether these projects addressed validated biological threat agents;
- research projects were not independently reviewed by the Academy or the Intelligence Center to ensure that the research addressed validated threat agents;
- 3 of the 10 medical products already developed for the defense of U.S. forces and 2 of the 6 products under development do not address validated warfare threat agents; and
- the Army and at least two other federal agencies were conducting medical research on many of the same agents.

Principal Findings

Millions Allocated for Research on Agents Not Validated as Threats

The Army's medical research program included research on biological agents that had not been assessed by the Armed Forces Medical Intelligence Center as warfare threats. In April 1990, GAO reviewed 218 ongoing or recently completed medical research projects, valued at about $239 million. GAO determined, with the assistance of the Academy and the Intelligence Center, that 49 projects were not directed at validated threat agents. Neither GAO nor the Army could readily determine whether an additional 57 projects addressed validated threat agents because the Army project summaries did not contain sufficient information. The combined cost of the 106 projects was about $95.3 million of the $239 million, or about 40 percent.

The U.S. Army Medical Research and Development Command officials acknowledged that some research projects did not address validated threat agents. These officials believed that the Intelligence Center's interpretation of threat agents was too narrow because it did not include agents that were (1) highly infectious by aerosol or other means, (2) stable in the environment, and (3) of low to moderate communicability. Using this broad criteria, the Medical Command could conduct research on virtually all biological agents.

All proposed research projects are reviewed by Medical Command personnel for methodology, scientific merit, and military need. However,

neither the Command nor independent organizations such as the Academy or the Intelligence Center assessed projects to ensure that they were directed at validated biological warfare threat agents.

Some Medical Products Do Not Address Validated Threat Agents

Since 1965, nearly one third of the medical products that the Army has developed or is developing address agents not validated as warfare threats. Three of 10 products already developed and 2 of 6 products under development fall into this category. Of the $45 million the Army spent on all 16 products by the end of fiscal year 1990, $19 million, or 43 percent, was spent on the 5 products not addressing validated threat agents. In addition, the Army plans to continue to spend funds for the 2 products under development that do not address validated threats.

Some Medical Command Research May Duplicate Research of Other Agencies

The Medical Command may unnecessarily duplicate medical research, either in whole or in part, that is being performed by federal civilian agencies. Army regulations require a search of the Department of Defense's technical data base before a research project is initiated to prevent unnecessary duplication of effort but do not require Command personnel to search other federal research data bases. Command personnel responsible for conducting these searches told GAO that they did not access other federal data bases.

GAO's search of the Federal Research in Progress data bases disclosed that both the Army and the National Institutes of Health or the Centers for Disease Control were conducting medical research on about 23 of the same agents. For example, both the Army and the National Institutes of Health were conducting research to develop an improved anthrax vaccine. In addition, the Army, the National Institutes of Health, and the Centers for Disease Control were researching dengue fever. While GAO recognizes that duplication of research is not always inappropriate, the Army, to get the most from its research, needs to coordinate its research projects with those of other federal agencies.

Recommendations

GAO recommends that the Secretary of the Army direct the Medical Research and Development Command to

- review all ongoing medical research projects to determine whether they address validated warfare threat agents, and discontinue all projects that do not;

- arrange for independent reviews of all proposed research projects by officials from the Armed Forces Medical Intelligence Center and the Academy of Health Sciences to ensure that all future projects address validated warfare agents, and report the results of each review to the Army Surgeon General; and
- discontinue development of all products that do not address a validated threat.

To avoid unnecessary duplication of effort and improve coordination, GAO also recommends that the Army amend its regulations to require the systematic coordination of its medical biological research projects with those of other federal research agencies.

Agency Comments

As requested, GAO did not obtain official agency comments on this report. However, it discussed information obtained during the review with agency officials and included their views where appropriate.

Contents

Abbreviations

BDRP	Biological Defense Research Program
DOD	Department of Defense
GAO	General Accounting Office

Chapter 1

Introduction

The Biological Defense Research Program (BDRP) is aimed at ensuring the sustained effectiveness of U.S. military forces in biological warfare by providing medical countermeasures that deter, constrain, or defeat biological warfare threats. The Department of Defense (DOD) defines a "biological warfare threat" as a biological agent that is assessed by the intelligence community as being developed or produced as a weapon. Medical defenses against these threats include preventive vaccines, drugs, therapeutic measures, and patient treatment and management procedures. The Department of the Army, serving as DOD's executive agent, executes the medical component of the BDRP through research and development projects.

Program Funding History

In response to DOD's information about the growing number of countries having or suspected of having offensive biological warfare capability, the Congress steadily increased funding for medical biological defense research from $29.2 million in fiscal year 1984 to a high of $69.9 million in fiscal year 1989. The fiscal year 1990 appropriation declined slightly to $66.4 million. This appropriation included $55.4 million for technology base funding categories—basic, exploratory, and advanced (nonsystems) research projects—and $11 million for product development and testing.[1] (Appendix I describes the research program categories.) Total program funding allocated to medical research for fiscal years 1984 through 1990 was $369.7 million, as shown in table 1.1.

Table 1.1: Program Funding for the BDRP Medical Component

Dollars in millions

Fiscal year	Funding appropriated
1984	$29.206
1985	36.463
1986	52.031
1987	56.976
1988	58.798
1989	69.857
1990	66.398
Total	**$369.729**

The Army's fiscal year 1991 budget request totaled $66.3 million.

[1]Advanced nonsystems development includes preparation for full-scale production and advanced testing of a medical product.

Management Structure of the BDRP Medical Component

The U.S. Army Medical Research and Development Command, at Fort Detrick in Frederick, Maryland, manages the medical component of the BDRP, directing the research and development of drugs and vaccines needed to defend against biological warfare agents. The Commander of the Medical Command reports to the Army Surgeon General. Within the Command, the U.S. Army Medical Research Institute of Infectious Diseases, also at Fort Detrick, serves as the lead medical laboratory for the BDRP.

Other organizations play a vital role in the BDRP. The Academy of Health Sciences, a subordinate command of the U.S. Army Health Services Command, has responsibility for preparing requirements documents for medical research against biological warfare threat agents for the U.S. Army Training and Doctrine Command. Under a memorandum of understanding with the Training and Doctrine Command, the Academy establishes the requirements for medical products (drugs and vaccines) that are needed to counter biological warfare threats.

The Armed Forces Medical Intelligence Center, a tri-service organization at Fort Detrick, is responsible, in conjunction with other intelligence agencies, for analyzing and validating information on biological agents that present a warfare threat to U.S. forces. This intelligence information is intended for use by the Academy of Health Sciences in setting requirements needed to counter the threats.

Objectives, Scope, and Methodology

The Chairman of the Senate Committee on Governmental Affairs asked us to evaluate DOD's Biological Defense Research Program. As arranged with the Committee, our work included only the medical component of the program because the Army has allocated the majority of BDRP funds to this component since 1984. Our objectives were to determine whether the program's medical research and development projects were (1) directed at validated biological warfare threat agents, (2) coordinated with other federal research organizations to avoid unnecessary duplication, and (3) used to develop medical vaccines, drugs, and other products for the defense of U.S. forces.

We reviewed 218 ongoing or recently completed BDRP projects, as of April 1990, to determine whether the Army's policies and procedures, including internal controls, were adequate to ensure that research and development was directed at only biological warfare threats. Because of the technical nature of the projects, the Academy of Health Sciences, with the help of the Armed Forces Medical Intelligence Center, assisted

us in determining which projects involved research on agents identified by the Intelligence Center as warfare threats. We did not, nor did the Academy, attempt to assess the scientific merit or value of the research.

To evaluate the adequacy of the Army's coordination with civilian agencies, we obtained information on the program's use of data bases for federal civilian research on the same biological agents. Through a limited literature search, we determined whether other federal agencies, such as the National Institutes of Health and the Centers for Disease Control, were conducting research on the same biological agents being researched by the Army. In addition, we obtained and analyzed documentation and interviewed officials from the Centers for Disease Control in Atlanta, Georgia, and from the National Cancer Institute, the National Institute of Allergy and Infectious Diseases, and the National Institute of Neurological Disorders and Stroke, all in Bethesda, Maryland, to determine whether these agencies had an interest in the same biological agents as did the BDRP.

Further, we examined the Army's use of independent reviews for research proposals, discussed the use of independent reviews with program officials, and reviewed applicable Army regulations.

To determine the number of medical products produced for the defense of U.S. forces against biological warfare, we obtained and reviewed Army documentation from 1965 to the present. We discussed this information with officials from the Army and the Department of Health and Human Services' Food and Drug Administration, in Rockville, Maryland, which approves the Army's use of new drugs and vaccines. Given the expense and sometimes long-term nature of medical research, we did not attempt to assess the adequacy of the number of medical products developed by the Army relative to the resources invested.

To accomplish our objectives, we interviewed officials from the Department of the Army and the Army's Training and Doctrine Command, Fort Monroe, Norfolk, Virginia, and the Army's Academy of Health Sciences, Fort Sam Houston, San Antonio, Texas. We also obtained and analyzed documentation and interviewed officials from the following military activities 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 Material Development Activity, and
- DOD's Armed Forces Medical Intelligence Center.

We reviewed Financial Integrity Act reports submitted by the Army to the Secretary of Defense for fiscal years 1987 through 1989 to determine whether any management control weaknesses were identified concerning the Army's implementation of the program.

We conducted our review from September 1989 to October 1990 in accordance with generally accepted government auditing standards. Because of the technical nature of the program, our Chief Medical Adviser assisted us in this review. As requested, we did not obtain official agency comments, but we discussed the information in this report with agency officials. Their views are included in the report where appropriate.

Army Management of the Medical BDRP Can Be Improved

The Army, because it did not have adequate internal controls in the BDRP's medical component, allocated at least $47 million to research and development that did not address validated biological warfare threat agents. Further, the Army's review of proposed research did not include an assessment of whether the research was directed at validated warfare threats. Moreover, some of the Army's research may duplicate research of federal civilian agencies because Medical Command personnel were not required to conduct searches of those agencies' data bases.

Funds Allocated for Research of Agents Not Validated as Warfare Threats

The Army was conducting research on biological agents that were not assessed by the Intelligence Center as warfare threats. In April 1990, the Army had 218 ongoing or recently completed BDRP research projects valued at about $239 million. We determined that 49 projects, valued at $47.4 million, or about 20 percent of the total funds, were not directed at validated biological threats. For another 57 projects, valued at about $48 million (another 20 percent of the total funds), we could not determine whether the projects were directed at validated biological threats because the Army project summaries did not contain sufficient information. Table 2.1 shows the results of this analysis.

Table 2.1: BDRP Funding by Threat and Non-Validated Threat Projects

Type of projects	Number of projects	Percentage of total projects	Dollar value	Percentage of total dollars
Non-threat	49	22.5	$47,390,468	19.8
Unknown	57	26.1	47,966,716	20.1
Threat-related	112	51.4	143,633,474	60.1
Total	**218**	**100.0**	**$238,990,658**	**100.0**

The U.S. Army Medical Research and Development Command acknowledged that it was conducting research on biological agents that have not been validated by the Intelligence Center as warfare threats. Medical Command officials told us that they believed that the Intelligence Center's interpretation of threat agents was too narrow because the Intelligence Center identifies only those biological threat agents that are being developed or produced as weapons. In addition to the biological agents assessed by the Intelligence Center as potential warfare agents, the Medical Command believed that other agents must be researched if they were (1) highly infectious by aerosol or other means, (2) stable in the environment, and (3) of low to moderate communicability. Using this

broad criteria, the Medical Command could conduct research on virtually all biological agents.

The Medical Command's interpretation of what constitutes a threat agent contradicts DOD's definition—that is, an agent assessed by the intelligence community as being developed or produced as a weapon.[1]

Technical Review Did Not Ensure That Proposed Research Addressed Validated Threat Agents

The Medical Command's in-house review of proposed projects did not require that research be directed at validated warfare threats. All projects are subject to an in-house technical review by Medical Command personnel for methodology, scientific merit, and military need. However, neither the Command nor independent organizations such as the Academy or the Intelligence Center assessed projects to ensure that they were directed at validated threat agents.

Medical Command Does Not Search Other Federal Research Data Bases to Prevent Duplication

Army regulations require a search of the Defense Technical Information Center's data bank prior to initiating a research project in order to prevent unnecessary duplication of effort. However, there is no similar requirement for the Medical Command to search other federal research data bases, and we found that it did not perform such searches. Accordingly, the Medical Command was unaware of research being done that could benefit the BDRP.

Army regulation 70-9, "Research Information Systems and Reports," dated May 1981, requires a thorough search of the Defense Technical Information Center data base before new research is started to prevent unnecessary duplication among DOD components. We found that these searches were generally conducted. The personnel responsible for conducting the search of the Defense Technical Information Center's data base told us that they do not access other data bases. Medical Command officials told us that BDRP scientists are experts in the field, who keep abreast of the latest scientific developments by attending seminars and reading professional publications pertaining to their areas of expertise.

Our literature search of the Federal Research in Progress data bases disclosed that both the Army and the National Institutes of Health or the Centers for Disease Control were conducting research or had an interest

[1]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.

in the detection, treatment, or prevention of about 23 of the same diseases.[2] For instance, both the Army and the National Institutes of Health were conducting research to develop an improved anthrax vaccine. Also, the Army, the National Institutes of Health, and the Centers for Disease Control were researching dengue fever. Appendix II contains a list of the agents we identified for which both the Army and the National Institutes of Health or the Centers for Disease Control had one or more research projects underway involving the same biological agents. While the research methods and goals may differ, the list shows that civilian health agencies are concerned about many of the same biological agents as the Army.

Further, our literature search disclosed that other federal agencies, such as the U.S. Department of Agriculture and the National Science Foundation, also had ongoing research on some of the same agents as the Army. For instance, both the Army and the Department of Agriculture were conducting research on botulism and Venezuelan equine encephalitis. We recognize that duplication of research is not always inappropriate. However, the Army, because it does not coordinate its research with federal civilian agencies, cannot ensure that its research is not unnecessarily duplicating other agencies' research on the same agents.

Conclusions

The Army's medical BDRP program unnecessarily expended millions of dollars on research projects that did not address validated biological warfare threat agents. The Medical Command was aware of the Armed Forces Medical Intelligence Center's validated list of warfare threat agents, but believed that this information was interpreted too narrowly. Therefore, the Medical Command researched biological agents that it assessed as threats, in addition to those validated by the Intelligence Center. Further, the Command did not determine whether proposed research projects addressed validated threat agents. Moreover, the Command did not systematically query the data bases of federal civilian agencies involved in similar research to avoid duplication. The Army and at least two other agencies were conducting medical research on as many as 23 agents.

Recommendations

We recommend that the Secretary of the Army direct the Medical Research and Development Command to (1) review all ongoing medical

[2]Federal Research in Progress data bases provide access to information about ongoing federally-funded research projects in the fields of physical sciences, engineering, and life sciences.

research projects to determine whether they address validated warfare threat agents, and discontinue all projects that do not; and (2) arrange for independent reviews of all proposed research projects by officials from the Armed Forces Medical Intelligence Center and the Academy of Health Sciences to ensure that all future projects address validated warfare agents, and report the results of each review to the Army Surgeon General.

We also recommend that the Army amend its regulations to require the systematic coordination of its medical biological research projects with those of other federal research data bases.

Some of the Army's Medical Products Do Not Address Validated Threat Agents

The Army has developed and is developing several biological vaccines and drugs for U.S. military forces who might encounter biological warfare. However, nearly one third of these products did not address validated biological warfare threat agents. Since 1965, the Army invested about $45 million in development and initial production costs for about 16 medical products. Of the $45 million, over $19 million, or 43 percent, was spent for 5 medical products that did not address validated threats. Moreover, the Army continues to develop medical products that do not address validated threats.

Medical Products Developed Since 1965

Over the past 25 years, the Army completed the development of 10 medical products, costing about $24.6 million. However, 3 of the 10 products did not address validated biological warfare threats. Of the $24.6 million, about $17.1 million, or 70 percent, was spent to develop the 3 products that did not address validated threats. Table 3.1 shows the 10 products developed since 1965.

Table 3.1: BDRP Products Developed Since 1965

Dollars in millions

Product	Fiscal year	Development and initial production costs	Directed at validated threat
Vaccine, Venezuelan equine encephalitis	1965	$0.234	Yes
Vaccine, tularemia	1966	0.242	Yes
Vaccine, eastern equine encephalitis	1968	0.437	Yes
Vaccine, rift valley fever[a]	1969	12.351	No
Vaccine, Venezuelan equine encephalitis	1975	1.138	Yes
Drug, ribavirin	1979	2.702	Yes
Vaccine western equine encephalitis	1984	0.243	Yes
Vaccine, Argentine hemorraghic fever[a]	1986	4.086	No
Vaccine, chikungunya	1986	0.722	No
Vaccine, Q fever	1989	2.479	Yes
Total		**$24.634**	

[a]The Army used BDRP funds to develop this product, even though this disease is not a biological threat agent but a naturally-occurring, or "infectious," disease that affects large numbers of people in various parts of the world.

Medical Products Under Development

The Army's six additional medical products under development are for either the identification of, protection against, or treatment for various biological agents.[1] These include four products for use against validated warfare agents and two products for agents that are not validated by the intelligence community as threats. The two products not directed at validated threats accounted for $2.1 million of the total developmental costs, or about 10 percent. The products under development are shown in table 3.2.

Table 3.2: BDRP Products Under Development

Dollars in millions

Product	Development cost[a]	Directed at validated threat
Toxoid, botulinal polyvalent	$3.006	Yes
Immune globulin, lassa fever	1.915	No
Vaccine, anthrax recombinant DNA	0.015	Yes
Vaccine, vaccinia vectored Venezuelan equine encephalitis	0.737	Yes
Vaccine, vaccinia vectored Korean hemorraghic fever	0.190	No
System, rapid identification	14.492	Yes
Total	**$20.355**	

[a]These costs are as of the end of fiscal year 1990.

Conclusions

The Army has developed several medical countermeasures against biological warfare since 1965. However, of the $45 million invested in the development of 16 products, about 43 percent of this amount has been spent on products that do not address valid biological threat agents. So far, the Army has spent about $2 million on products still being developed that do not address valid threats.

Recommendation

We recommend that the Secretary of the Army direct the Medical Research and Development Command to discontinue development of the two products that do not address validated threats.

[1]Products selected for development, but not funded, were excluded from this analysis.

Medical Research and Development Program Categories

Technology Base Research

Basic research (funding category 6.1):

- identification and isolation of infecting agents and
- characterization of agents.

Exploratory development (funding category 6.2):

- definition of animal models,
- preparation of vaccine and drug candidates,
- improvement of disease diagnosis and agent identification, and
- epidemiological studies.

Advanced nonsystems development (funding category 6.3A):

- scale-up production and
- advanced testing.

Product Development

Advanced systems development (funding category 6.3B):

- safety and efficacy testing.

Engineering development (funding category 6.4):

- large-scale field trials and
- initial purchase of product.

Research Conducted by the Army and Other Agencies Involving the Same Biological Agents

	Agencies involved	
Biological agent	**National Institutes of Health**	**Centers for Disease Control**
Anthrax	X	
Venezuelan equine encephalitis	X	X
Lassa fever		X
Ebola virus		X
Hemorraghic fever with renal syndrome		X
Congo Crimean hemorraghic fever		X
Dengue fever	X	X
Yellow fever	X	
Alphaviruses	X	
Eastern equine encephalitis	X	
Arboviruses	X	X
Q fever	X	
Tetanus	X	
Plague	X	
Tetrodotoxin	X	
Saxitoxin	X	
Ricin	X	
Brevetoxins	X	
Enterotoxins	X	
Hantaan virus	X	
Arenaviruses	X	
Vaccinia virus	X	
Botulism	X	

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