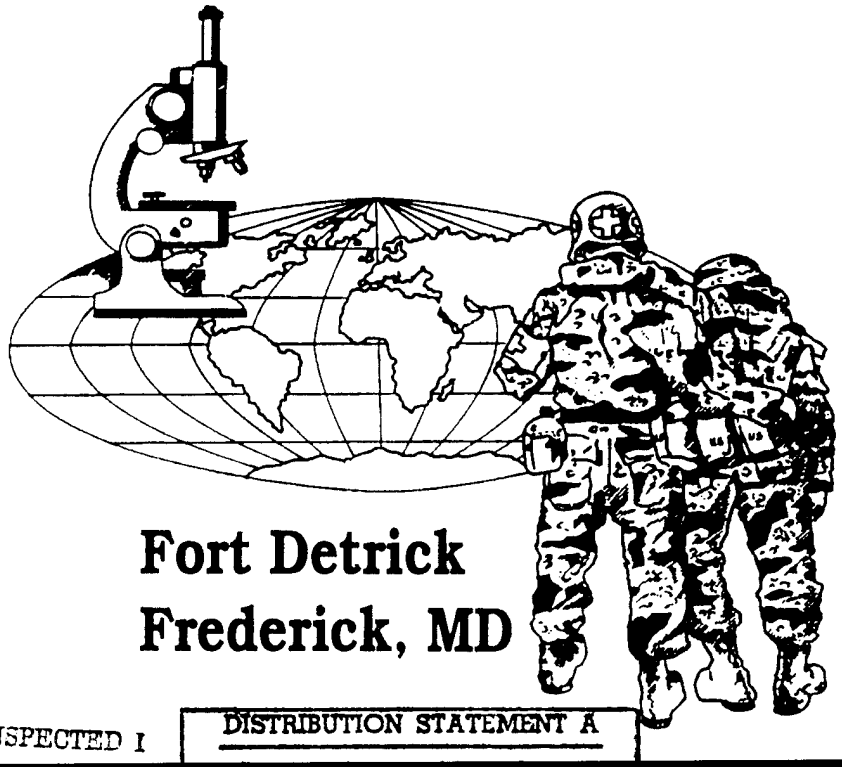
United States Army Medical Materiel Development Activity

1995 ANNUAL REPORT



Fort Detrick
Frederick, MD

1995 ANNUAL REPORT

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FORT DETRICK
FREDERICK, MARYLAND 21702-5009

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U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
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1995 ANNUAL REPORT
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MESSAGE FROM THE COMMANDER

In 1995, the United States Army Medical Materiel Development Activity (USAMMDA) moved with renewed vigor into its second decade of developing quality products for the Soldier, Sailor, Airman, and Marine. USAMMDA continues to accomplish the necessary changes in business practices and personnel initiatives started several years ago, reengineered to a lean and productive activity.

USAMMDA was appointed the role of pivotal DOD agency in providing a proactive response to the Presidential Advisory Commission (PAC) on Persian Gulf War Veterans' Illnesses. A host of misconceptions and misperceptions, particularly that U.S. Forces in Operation Desert Storm (ODS) were used as experimental subjects, were finally laid to rest. Many staff hours were dedicated to assembling data from widely diverse sources to demonstrate DOD involvement in the use of licensed and Investigational New Drugs (IND) to protect troops from Iraq's expected use of chemical and biological warfare agents. The draft report for the PAC produced in CY95 clearly shows how much concern and effort the Command expends in carefully weighing the risks and benefits before using any investigational product.

We support the deployment of our forces in Operation Joint Endeavor by ensuring that developmental products can be used to protect the health of our service members, if necessary. We have assumed the responsibility to ensure that if any of these developmental products are used, we meet every Food and Drug Administration (FDA) and DOD human use requirement to ensure their safe use and accountability. Staff involvement ranges from interacting with Institutional Review Boards for design and approval of protocols through acquiring drugs and vaccines to be used.

Unprogrammed resource requirements continued to significantly impact our programs throughout the year. Even our successes caused greater reprogramming of resources than ever before. We received rave reviews at this year's annual meeting of the Association of the United States Army in Washington, D.C., for our full-sized mock up of the Armored Treatment and Transport Vehicle (ATTV) concept model. Interest was so great that the ATTV was selected to participate in Force XXI in February 1997, requiring us to rapidly produce a fully-functional prototype of a product that is still in the concept stage. The accelerated program will cause significant realignment of programmed resources to accommodate building, equipping and testing a prototype production medical suite for the vehicle. Resourcing the program has extended across the entire organization, and we face extremely short deadlines for production of the prototype vehicle. It is a challenge which we relish; we are committed to success!

External requirements, such as the Command's Telemedicine effort, again required decrements to other USAMMDA-funded programs, creating maximum levels of risk in product development. USAMMDA's resourcing of the Telemedicine program resulted in several instances of postponement or cancellation of lower priority programs; most proposed new products remained unfunded. Examples of the real affects of reduced availability of resources: funding for the continued development of Chikungunya Live Vaccine, Rift Valley Fever, Live, and Recombinant HFRS Vaccine (Puumala) were delayed until CY98; the Microencapsulated Antibiotic, Ampicillin, was cancelled; the Field Medical Oxygen Generating and Distribution System (FMOGDS) passed user testing, and was transitioned at Milestone III to full-scale production. Funding reductions make it unlikely that this system will be procured.

As our taskings changed due to the continued downsizing of the government, and reductions in both personnel and resources impacted, our physical structure was adjusted accordingly and we were forced to make some painful personnel reductions. Our Biological Systems Division was reconfigured to two teams - one which handles only infectious disease vaccines and one which handles only biological defense vaccines. This restructuring enabled more effective interaction with the Joint Program Office - Biological Defense, which now is centrally managing the bio-defense program. Additionally, we have significantly reduced both our in-house test capability and our capacity for in-house prototyping.

CY 1995 was a year of significant personnel turnover in our organization, as we said goodbye to, and welcomed, several new key personnel. The Project Manager of our Biological Systems Division, Dr. Walter Brandt, retired after a distinguished career with the Federal Government. He had been with USAMMDA since the creation of the agency and we have sorely missed his expertise and his quiet, gentle presence. Our Deputy Commander, LTC Jim Stewart, departed for an exciting one-year fellowship (Army War College) in environmental policy. He was succeeded as Deputy Commander by LTC Jeff Gere, who has been with USAMMDA for several years in our Pharmaceutical Systems Division. We welcomed two new key players as MAJ Neil Ahle arrived from the U.S. Army Medical Research Institute of Chemical Defense (USAMRICD) and was rapidly promoted to Deputy Project Manager in Pharmaceutical Systems Division replacing LTC Gere, and MAJ Tracey Syvertson arrived at USAMMDA to become the Deputy Project Manager of our Applied Medical Systems Division.

USAMMDA continues to expand the envelope of execution in advanced medical materiel development and acquisition under the DOD 5000 series of directives. There were seven Milestones (MS) at various levels conducted in the past year. Products that did not meet the necessary transition requirements were terminated, an example being the Nerve Agent Antidote system which failed to show increased efficacy over fielded treatments. USAMMDA staff were active participants in conferences and review

groups to reduce impediments to efficient and effective development by removing unnecessary review steps and documents. We find this to be a responsible and logical extension of USAMMDA's recent initiatives to expand the responsibility, authority and accountability of the product managers.

During the past year, USAMMDA was successful in expanding our partnerships with industry. The antimalarial causal prophylactic (WR238,605) and the antileishmanial treatment (WR 6026) drugs moved into accelerated development with the signing of Cooperative Research and Development Agreements (CRDA) for both products with SmithKline Beecham Pharmaceuticals, Inc. Based on collaborative work from a similar agreement, the FDA granted licensure to SmithKline Beecham for a vaccine against hepatitis A this year. This is a shining example of how industry can share military laboratories and resources to accelerate the development of a product that not only serves the military but also the private sector.

Formal business plans and incremental funding continue to be the mainmasts for product development at USAMMDA. Under the control of the Project Management Support Division, a Project Management Division Database (PMDD) and Product Management Database System (PMDS) continued to mature. The system provides a validated and consolidated database for the direct acquisition of information for the Financial Management System (FMS) and the General Analysis/Priority System (GAPS) to support Product/Project Manager decision making. The USAMMDA Project and Product Managers used this system to achieve some impressive successes during the past year in controlling cost of development by having ready access to financial planning and execution information.

Several new antiparasitic products continued to progress through the predevelopment cycle this year. Leishmania Skin Test, the Topical Antileishmanial Drug Paromomycin, the Antimalarial Drug Arteether and Azithromycin for Scrub Typhus all had MS 0 In-Process Reviews (IPR). Two products being developed to protect U.S. Forces against the lethal effects of chemical agents moved one step closer to completion: MS I reviews were conducted for both the Cyanide Pretreatment, as well as the Topical Skin Protectant, and both were transitioned into the demonstration and validation stage.

A form, fit, and function test was completed to finalize details of a Basis of Issue Plan for the Liquid Oxygen Production, Storage, and Distribution System. The Portable Rugged Laser Optometer Phase 2 Small Business Innovation Research (SBIR) was successfully completed showing the use of non-Federal capital to develop the technology for the commercial market. Also, the X-ray System, Dental Miniature, was transitioned to the U.S. Army Medical Material Agency (USAMMA) for procurement.

Quality of the programs and products under our responsibility is always foremost in our minds. The Quality Assurance Office (QAO) supported a variety of programs in an ever-expanding role to produce the best possible product by doing it right the first time. The QAO was the single area that expanded this past year, but with a payback that was many-fold. The QAO completed 18 study site visits in CY95. There were 13 pre-study, 6 study initiations, 17 mid-study and 7 closeout study visits. QAO also was involved in several Establishment License Application/Product License Application (ELA/PLA) submissions and participation in Good Laboratory Practices (GLP) inspections.

This annual report clearly displays that quality, performance, and productivity were the hallmarks of CY95. Either a product or program meets the standard or we stop work on it. Our first year in a new decade for medical product development indeed illustrates that we live up to our motto of "Developing Quality Medical Products for U.S. Forces" and, in doing so, we provide the Soldier, Sailor, Airman and Marine with the competitive edge.

GEORGE E. LEWIS, JR.
Colonel, VC
Commanding

U.S. ARMY MEDICAL MATERIEL DEVELOPMENT ACTIVITY

"Developing Quality Medical Products for U.S. Forces," the motto of the U.S. Army Medical Materiel Development Activity (USAMMDA)[1], truly represents operations as the proponent for all medical materiel advanced development for the Department of Defense (DOD). The USAMMDA is a subordinate unit of the U.S. Army Medical Research and Materiel Command located at Fort Detrick, Frederick, Maryland. This unique organization manages and directs medical materiel advanced development, achieving U.S. Army and Joint Service materiel system schedule and cost objectives performance.

1. MISSION STATEMENT

USAMMDA's specific mission is to manage the execution of the development component of the Army Medical Department (AMEDD) medical materiel acquisition program to achieve Department of the Army and Joint Service materiel system performance, schedule, cost and logistic objectives. This includes responsibility for centralized planning, direction, control, management, and focus for the Medical Materiel Developer's Program; achieving the Army's unique and Joint Service operational performance, schedule, cost and logistics objectives for each system and subsystem; developing acquisition strategies and resource allocations; and coordinating Combat Developer (CBTDEV) and Trainer plans to ensure combat readiness and initial production capability.

2. GOAL

Execute a world class medical materiel development program that will deliver the most effective, affordable and supportable products to the field.

3. OBJECTIVES

- Foster continuous improvement.

- Accelerate, streamline and economize product development.

- Maintain management authority, responsibility and credit at the most effective echelon.

- Measure and evaluate product development progress and outcome.

- Increase timeliness, reliability and coverage of Business Plans.

- Increase interoperability of staff.

- Consistently maintain an attitude of positive change to meet challenges of today. . .tomorrow. . .and the 21st century.

QUALITY - INTEGRITY - ACCOUNTABILITY

4. ORGANIZATION[2]

The Commander directs program execution through three Project Management Divisions (PMD), and assures adequate support for the programs through the Project Management Support Division (PMSD). The Project Management Divisions focus on three separate and distinct development technology areas: the Biological Systems Project Management Division (BSPMD), the Pharmaceutical Systems Project Management Division (PSPMD), and the Applied Medical Systems Project Management Division (AMSPMD). While the specific Project Management Divisions address issues related to product development, the PMSD provides centralized program-wide administrative, financial, contractual, and logistical support.

The Quality Assurance Office reports directly to the Commander. This office provides direct support to the Project Management Divisions by being responsible to the Product Managers for ensuring quality and acceptability of test data, control processes, manufacturing data, and regulatory documentation for submission to the FDA in support of product safety and effectiveness for licensure and approval. Quality Assurance personnel conduct protocol review and monitoring for Good Clinical Practices, provide oversight of a regulatory affairs documents contract, ensure regulatory compliance in the conduct of clinical trials, and monitor adherence to current Good Manufacturing Practices (cGMP) in the operation of manufacturing facilities associated with advanced development projects.

A brief description of Division/Office highlights their principal focus, military relevance and objectives:

a. <u>The Biological Systems Project Management Division (BSPMD)</u> manages the development and initial production of biological products. These products are developed to prevent casualties or loss of soldier effectiveness due to natural disease and biological warfare agents. The diseases may be naturally acquired as a result of close contact conditions, contaminated environment, or biting insects, or acquired by deliberate enemy exposure of troops to aerosols of biological agents, including toxins. Product Managers utilize domestic and foreign medical technology to remedy deficiencies identified by the CBTDEV and assess research project outcomes for their application to disease protective measures.

(1) Reducing the impact of disease on operations will contribute significantly to soldier effectiveness. Casualties from disease have been a major cause of hospital admissions and ineffectiveness on the battlefield. For example, the figures for admission for soldiers during a year in Vietnam were as follows: disease - 70.6 percent; battle casualty - 15.6 percent; nonbattle injury - 13.8 percent.

(2) The BSPMD addresses requirements for effective preventive measures against diarrheal diseases, malaria, hepatitis, meningitis, insect transmitted viruses, toxins, hemorrhagic fevers, and other diseases of concern to the military. Methods to address these deficiencies include vaccines, immune globulins and insect repellents.

b. The Pharmaceutical Systems Project Management Division (PSPMD) manages the development and the initial production of drugs, related drug delivery systems such as autoinjectors, resuscitative fluids, skin protectants and skin decontaminating products.

(1) PSPMD develops products for fielding as preventive, protective, and therapeutic modalities for use against chemical warfare threats, certain endemic diseases and the treatment of combat casualties. The development of products against these threats will sustain the fighting force, save lives, and enhance a casualty's recovery and return to duty.

(2) The PSPMD's objective is to develop pharmaceuticals to be used for prophylaxis, immediate treatment and definitive treatment against a wide variety of naturally occurring diseases, or of chemical agents and combat injuries. These pharmaceuticals include those for pretreatment and for use following exposure to organophosphorus compounds (nerve agent), vesicants (mustard) and cyanide, and those to protect or treat soldiers suffering from malaria, schistosomiasis and leishmaniasis. In addition, a topical skin protectant is being developed to protect the skin against the toxic effects of exposure to mustard and other percutaneous chemical threat agents. The PSPMD also develops more conventional products such as blood replacement fluids.

c. The Applied Medical Systems Project Management Division (AMSPMD) plans, directs, and controls the materiel development of all assigned applied medical systems (medical devices and equipment). A testing laboratory, fabrication shop, and drafting/design section provide the AMSPMD with an in-house capability to modify commercial items for military medical applications as well as the ability to design and fabricate concept prototypes. These assets, along with a skilled force of engineers, health care specialists, and acquisition professionals, comprise the most comprehensive program for the development and testing of field medical materiel within DOD.

(1) The development of compact, lightweight, lifesaving diagnostic and therapeutic devices provides military health care personnel with the best equipment for the treatment of combat casualties while simultaneously reducing the medical logistics burden. The development of devices for medical protection against chemical warfare agents and other military hazards offers clear benefit to U.S. Forces on the modern battlefield.

(2) The AMSPMD's objective is to develop and support the acquisition of compact, lightweight, rugged medical and medical support equipment in response to the needs of the AMEDD and the Joint Services. The AMSPMD strives to ensure the timely fielding of new hardware and software by evaluating and exploiting new technologies in the areas of patient care and medical support. A listing of the activities accomplished by the testing laboratory, fabrication shop, and drafting/design section can be found in Appendix C.

d. **The Project Management Support Division (PMSD)** provides financial, contractual, logistical, and administrative support to the three Project Management Divisions. The successful accomplishment of the PMD programs is inextricably linked to PMSD's performance in the following areas: a centralized program-wide administrative, Planning, Programming, Budgeting and Execution System (PPBES); operation of a business planning and execution information management system (Project Management Division Database (PMDD) and Product Management Database System (PMDS)); oversight and operation of major support contracts; preparation of product development and production contracts; coordination of the medical Research, Development, and Acquisition (RDA) Mission Area Materiel Plan (MAMP); program development and defense through the Concept Based Requirements System (CBRS) cycle; integrated logistical support planning, MANPRINT and user test coordination support planning for products; personnel and property resource management actions; and management of Defense Acquisition Workforce training requirements for the USAMMDA staff. These responsibilities and capabilities enhance in-house and program wide fiscal performance and improve resource accountability for materiel development throughout the AMEDD.

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[1] Appendix A provides a list of commonly used acronyms
[2] Appendix B provides an organization chart

PRODUCT DESCRIPTION, MAJOR ACCOMPLISHMENTS AND PROJECTIONS

Advanced development products are presented in this section according to their 1995 Medical RDA Mission Area Materiel Plan (MAMP) prioritization. The MAMP is a concerted effort to determine the relative value to a field commander of the various products for reducing morbidity and mortality. Predevelopment products anticipated to transition to advanced development in CY96 and for which project management documentation activities were conducted, are listed in this report in MAMP-rank order. Biological Defense program products were not considered in the Medical MAMP this year due to management by the Joint Program Office - Biological Defense (JPO-BD); products are presented at the end of the MAMP-ranked products. A list of supporting contracts, special products, and non-MAMP prioritized products follows the MAMP Prioritized Products List. A listing of all products, by technical divisions, can be found in Appendix E.

1. **MAMP Prioritized Products**:

a. **Advanced Development Products**:

(1) **Antimalarial Drug WR 238,605 (WR)** is an 8-aminoquinoline derivative which has demonstrated antimalarial potential in preclinical studies. It is being developed as a replacement for primaquine for the prophylaxis and treatment of malaria.

- The in-life phase of a study entitled "Multiple Dose Safety, Tolerance and Pharmacokinetic Study of WR 238,605 When Given to Healthy Male and Female Subjects" was completed.

- A Phase 2 study entitled, "Evaluation of WR 238,605 as a Prophylactic Agent Against Induced *Plasmodium falciparum* Malaria Infection in Healthy Non-Immune Subjects II: A Multiple-Dose Causal versus Suppressive Study" was initiated.

- A Collaborative Research and Development Agreement (CRDA) was established between this Command and SmithKline Beecham Pharmaceuticals, Inc. This CRDA will help to accelerate the development of WR 238,605 and reduce resource requirements on the Government.

(2) **Antimalarial Drug, Azithromycin (WR)** is an azalide, a subclass of macrolide antibiotics, similar to erythromycin. It is an FDA approved oral medication manufactured and marketed by Pfizer, Inc., for the treatment of respiratory tract infections. It has antimalarial activity in both in vitro and in vivo drug evaluation systems. The product is being developed as an alternative to doxycycline for the prophylaxis of malaria.

- The in-life portion of a Phase 2b field study was successfully completed in Kenya to determine efficacy of the drug.

- An end-of-Phase 2 meeting was held with the FDA to discuss plans for pivotal Phase 3 studies to gain approval for the product.

(3) **Antimalarial Drug, Halofantrine, Prophylactic (WR)** is a 9-phenanthrenemethanol compound being developed as an alternative to chloroquine and mefloquine for the prophylaxis of multi-drug resistant *P . falciparum* malaria.

- A study entitled, "Halofantrine as Prophylaxis Against Malaria: Multiple Dose Safety, Tolerance and Pharmacokinetic Study" was initiated at Georgetown University.

- A study to examine the cardiotoxicity of halofantrine and its metabolites was completed in collaboration with Georgetown University Medical School.

- Metabolism and drug interaction studies were initiated at Georgetown University Medical School.

(4) **Nerve Agent Pretreatment Pyridostigmine (IC/WR)** is a cholinesterase-inhibiting drug that is a pretreatment for nerve-agent lethality when used in conjunction with antidotal atropine and 2-pralidoxime chloride.

- A clinical study was completed 2QCY95 evaluating the tolerance of females and low-weight individuals to the doctrinal dose (30 mg every 8 hours) of pyridostigmine given for 21 days. Quarterly followup of the volunteers will continue for one year.

- A rodent preclinical study to investigate whether there is interaction between the insect repellents DEET and permethrin and the nerve-agent pretreatment, pyridostigmine, was completed and incorporated into the New Drug Application (NDA).

- A contract was signed between the Defense Personnel Support Center (DPSC) and Roche Products, Ltd., which provides, in part, for the delivery of a Drug Master File (DMF) to the FDA. The DMF is necessary for the submission of the NDA.

(5) Clinical testing of a **Tick-Borne Encephalitis Virus Vaccine (TBE) (RD)** to compare the standard immunization schedule with an accelerated schedule has been completed with the result that acceptable vaccination can be completed in approximately 1 month using three doses. However, the manufacturer of the vaccine

made a corporate decision not to submit a PLA to the FDA. A CRDA with a new manufacturer is now being negotiated. Phase 1 testing should begin in 2-3QCY96.

(6) **Hantaan M-S (Vaccinia Vectored) Vaccine (RD/SL)** is a live vaccine for military personnel being deployed to regions in which this agent is endemic. The vaccine was engineered at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) by inserting the genes which code for Hantaan antigens into the live vaccinia virus carrier (smallpox vaccine). The resulting recombinant vaccine was manufactured by the Salk Institute and was shown to elicit antibodies against both vaccinia and Hantaan viruses.

- Studies performed in volunteers at USAMRIID determined that a two-dose subcutaneous route of immunization will be used in future studies. A Phase 2 trial in vaccinia naive and in vaccinia immune individuals is scheduled to begin in U.S. military volunteers in Korea in 1QFY96.

(7) **Detoxified LPS-OMP Meningococcal Group B Vaccine (WR)** consists of noncovalent complexes of purified meningococcal outer membrane proteins (OMP) and alkaline detoxified meningococcal lipopolysaccharide (LPS). One lot of this vaccine was manufactured at Walter Reeed Army Institute of Research (WRAIR). This lot was bottled into 5,000 doses. Preclinical studies are underway. A new IND will be submitted in CY97.

(8) **Argentine Hemorrhagic Fever Live Vaccine (AHF) (RD/SL)** is an attenuated vaccine for military personnel being deployed to areas where AHF is endemic. The vaccine was prepared by growing the virus in fetal rhesus monkey lung cells in a collaborative effort between USAMRIID and the Salk Institute.

- Laboratory and field studies with this vaccine have been completed.

- A PLA and an ELA for AHF will be submitted to the FDA in CY96.

(9) **Malaria SPf66 Blood Stage Vaccine (WR/SL)** is a product based on a Columbian vaccine that consists of three peptides derived from two merozoite proteins and one circumsporozoite protein of *Plasmodium falciparum*. In preparation for clinical studies, the vaccine was synthesized by a rapid solid phase procedure in accordance with cGMP.

- A Phase 2b double-blind placebo controlled clinical study initiated in FY93 at Shoklo Camp in Thailand was completed in CY95. This study gave three vaccinations of either the SPf66 vaccine or Hepatitis B recombinant vaccine as the placebo. A total of 1,188 children finished the study with 593 receiving the placebo and 595 receiving the

Spf66. In this study, the SPf66 provided no protection from the first incidence of falciparum malaria.

(10) **Topical Skin Protectant (TSP) (IC)** is a perfluorinated formulation, which, when spread on the skin, forms a thin and breathable film surface capable of significant protection against percutaneous penetration of chemical and a limited number of biological warfare agents. Doctrinally, TSP is to be used as an adjunct to mission-oriented protective posture gear, not as a replacement. Use of the TSP enhances the effectiveness of fielded skin decontaminating systems.

- Dermal toxicity studies in human volunteers were completed in 2QCY95.

- A Quantitative Fit Factor study was completed in 3QCY95 and showed that TSP applied on the face did not affect the seal between the skin and the M40A1 gas mask.

- Animal efficacy testing, completed in 3QCY95, showed that the insect repellent (DEET), when used in conjunction with the TSP, reduced its effectiveness against the percutaneous hazard of the sulfur mustard, HD.

(11) **Cholera Whole Cell Plus B Subunit Vaccine (Cholera Indication) (WR/SW/NV)** is a combination killed, whole bacterial cell and B cholera toxin subunit oral vaccine for prevention of diarrheal and systemic illness caused by *Vibrio cholera* infections. Field studies suggest that the B subunit also affords some protection against enterotoxigenic *Escherichia coli* (ETEC), a common cause of diarrheal disease. The vaccine is being tested against both indications in collaboration with the Naval Medical Research Institute (NMRI).

- A large placebo-controlled efficacy field trial in 20,782 volunteers began in Pampas de San Juan in Lima, Peru, in November 1993. There was active and passive surveillance for diarrheal disease throughout the following year. A booster dose was administered in the fall of 1994. Surveillance continued in the second year for diarrheal disease. Antibody titers rebounded to levels at least as great as those after the primary series. For both cholera seasons monitored, there were 3-5 confirmed cholera cases per week in the study area.

- An analytical plan has been prepared, and the code for the trial will be broken in 1QCY96. This will determine the efficacy of the vaccine against cholera and against ETEC diarrhea.

(12) **Cholera Whole Cell Plus B Subunit Vaccine (ETEC Indication) (WR/SW/NV)** is the same vaccine used to protect against cholera. There is cross protection against enterotoxigenic *Escherichia coli* (ETEC) by the B subunit of the cholera

toxin. The vaccine is being tested against both cholera and ETEC in collaboration with the NMRI.

- In the same field trial in which the cholera vaccine is being tested, the volunteers are screened for ETEC diarrhea. This is a secondary indication for the cholera vaccine. Results will be available 1QCY96.

(13) **Chikungunya Live Vaccine (RD/SL)** is an attenuated product produced by growing the virus in cultured human lung cells at USAMRIID. The Salk Institute produced the investigational lots of virus vaccine.

- Clinical trials involving approximately 145 individuals through CY95 continue to demonstrate that the live vaccine is safe and immunogenic.

- Due to funding decrements, work on this vaccine in CY96 will be limited to completion of serology on volunteers who received the vaccine in 1995.

(14) **E. coli Vectored S. flexneri Shigella Vaccine (WR/SL/IS)** is an oral vaccine produced by inserting genes for *Shigella flexneri* antigens into an *Escherichia coli* vector. This bioengineered vaccine was developed at WRAIR, produced at the Salk Institute - Government Services Division, and tested at the University of Maryland Vaccine Testing Facility, and in Israel. Funds were not spent on this product in CY95, and present plans are to detransition this product in 1QCY96.

(15) **Campylobacter Vaccine (NV)** is a killed, whole cell, adjuvanted oral vaccine for prevention of diarrheal and systemic illness caused by gram-negative bacteria of the genus *Campylobacter*.

- Manufacture of a pilot lot of vaccine was completed, an IND submitted, and Phase 1 studies completed at USAMRIID. The vaccine was safe and immunogenic in volunteers. A mutant form of the adjuvant to be mixed with the vaccine has been purchased, and an IND was submitted for its Phase 1 testing, scheduled for 4QCY95.

(16) **Cyanide Pretreatment (CP), WR 242511 (WR/IC)** is an oral formulation of an 8-aminoquinoline that induces the formation of methemoglobin, which will provide pre-exposure protection against cyanide poisoning. Animal data suggest that this regimen will protect against the lethal effects of one to two times the dose that results in the death of 50 percent (LD_{50}) of the people exposed to cyanide. At the present time, there is no FDA approved pretreatment for cyanide exposure. A Milestone I decision advanced the CP to the Demonstration and Validation phase in 1QCY95.

- Developmental toxicity (Segment II) studies in rats and rabbits were completed.

- Work initiated included serial probe recognition in non-human primates and in vitro rat and human liver metabolism.

(17) **Hypertonic Saline Dextran (LR/TP)** is a safe and effective small-volume resuscitative fluid suitable for rapid field administration that can be used to stabilize hypovolemic shock casualties.

- A CRDA was executed with Trauma Products, Inc. (TPI). Currently, a package of data is being submitted to the FDA. This package contains the results of a retrospective meta-analysis of clinical data, as well as TPI's cGMP data. HSD awaits FDA approval.

(18) **Schistosome Topical Antipenetrant (WR/NV/MI)** is a niclosamide-based lotion that is designed to prevent the skin penetration of free-swimming *Schistosoma* cercariae.

- A critical meeting of the Schistosomiasis Scientific Steering Committee occurred in 3QCY95. The committee provided recommendations for the clinical trials necessary to obtain FDA approval.

(19) **Rift Valley Fever, Live Vaccine (RD/SL)** is an improved vaccine that will provide immunity with a single dose rather than the three doses required for the current inactivated vaccine. The vaccine will provide greater protection in a shorter amount of time to service members operating in geographic areas where there is high risk of infection with Rift Valley Fever.

- Studies of varying vaccine doses were completed in CY95.

- Due to funding decrements, work on this vaccine will be limited to evaluation of doses of 25,000 and 50,000 plaque forming units (PRU) in FY96.

(20) The **Medical/Dental Filmless Imaging System (ID)** is a system for the filmless capture and display of diagnostic images. The system is aimed at the elimination of film, film processors, and chemicals from the field by obtaining the radiographic information in a digital format.

- A prototype medical system, based on amorphous crystal technology, is being prepared for field evaluation. This system and the dental version are currently under development by commercial companies and will be available for procurement by July 1997.

(21) The **Intraosseous Infusion Device (LR)** is a product that will allow access to the intraosseous space for the infusion of resuscitative fluids when peripheral vascular access is unobtainable. It is intended to be used on the battlefield for the severely traumatized casualty in profound shock.

- The design has been finalized and the contractor, Pyng Medical Corporation, has produced prototypes at their own expense for Technical Testing (TT) and User Testing (UT) at the U.S. Army Medical Department Test Board.

(22) **Nerve Agent Antidote, Multichambered Autoinjector (MA)** is a single-barreled, dual-chambered autoinjector that injects the nerve agent antidotes, atropine and 2-pralidoxime chloride, through a single needle. It is being developed as a replacement for the Mark I Nerve Agent Antidote Kit, which requires two separate injections.

- In a critical clinical study conducted during 2QCY95, the developmental MA was found to be not bioequivalent to the Mark I .

- The contractor submitted alternative concepts to correct the deficiencies in the design. This will result in an impact on cost and schedule.

(23) The **Field Triage Light (BL)** is a portable light, powered by rechargeable batteries, for illumination at triage sites and for emergency lighting. Batteries will provide power to a 15 watt fluorescent light in excess of eight hours, or to an incandescent light for a lesser time.

-Two FTL candidates were developed. Testing will be conducted in 1996 to compare the two units. Comparisons will be based on light color and intensity, battery duration, human factors, battery life, weight, and volume.

(24) The **Self-Contained Ventilator (AL/IC/HS)** is a battery-powered ventilator designed to pump filtered ambient air or bottled gas and sustain casualty respiration even in a chemical environment. This ventilator will be used at levels I/II.

- The U.S. Army Aeromedical Research Laboratory (USAARL) performed TT on candidate ventilators. A Joint Working Group (JWG) was held to review the results. None of the candidates met the requirement. An Acquisition Strategy was formulated to pursue a Modified Nondevelopment item (NDI) strategy.

(25) The **Low Temperature Sterilizing System (SI)** effects rapid sterilization of surgical instruments by the use of a packaged dry-powdered chemical sterilant that is added to potable water, which forms a peracetic acid solution. This chemical sterilant

may be used up to eight hours and is suited to sterile processing of immersible instruments and accessories.

- The contractor for this Phase 2 SBIR contract is in the final stages of development and is preparing documentation for submission to the FDA and the Environmental Protection Agency (EPA) for approval to market. This new product will be more effective and more environmentally-friendly than the currently fielded glutaraldehyde-based chemical sterilant. A MS I/III IPR is scheduled for mid-1996.

(26) **Antileishmanial Drug WR 6026 (WR)** is an 8-aminoquinoline derivative developed as an oral treatment for visceral leishmaniasis.

- A Phase 2 efficacy trial was initiated in Brazil in 2QCY95.

- Mutagenicity studies of WR 6026 were completed. A Segment II teratology study also was conducted during CY95.

- A CRDA was negotiated with SmithKline Beecham Pharmaceuticals, Ltd. The CRDA will enable acceleration of the development of this drug while minimizing the financial investment by the government.

(27) The **Armored Treatment and Transport Vehicle (ATTV)** (formerly Armored Ambulance) is a collaborative effort to design a medical interior for an existing armored vehicle, which will replace the M113 armored ambulance. Emphasis is placed on new medical technologies for improved patient treatment and care during ground evacuation.

- A full size wooden concept model of a medical enclosure was constructed and outfitted with a full complement of medical equipment. Telemedicine and Life Support for Trauma and Transport capabilities were included with state-of-the-art equipment for ventilation, suction, and vital signs monitoring. The enclosure was mounted to a Multiple Launch Rocket System (MLRS) chassis to create a full size model ATTV that was displayed at the 1995 annual meeting of the Association of the United States Army in Washington, D.C., 16-18 October 1995. Response to the concept model was overwhelmingly positive.

(28) The **Liquid Oxygen Production, Storage, and Distribution System (LOPSDS)** is a transportable, centralized generating and storage system that produces liquid oxygen (LOX) in a Theater of Operations. Bulk tanks (100 to 400 gallons) are used to transport LOX product to hospitals where it is vaporized into gaseous oxygen for distribution to operating rooms and patient wards or to fill pressurized oxygen cylinders.

- Commercial systems are available that produce LOX from ambient air and may satisfy battlefield requirements for medical oxygen. The Life Cycle Cost Assessment for LOPSDS was finalized and incorporated into the Operational Requirements Document (ORD). A detailed system requirements plan was staffed and a JWG convened to discuss issues associated with system operation, maintenance, training and support. The LOPSDS Mission Needs Statement (MNS) was approved by Headquarters, Department of the Army, and the ORD was approved by the U.S. Army Training and Doctrine Command in May 1995. A System Safety Working Group was held to update the Safety Assessment Report and finalize a decision to conduct an Oxygen Hazard Analysis. A Form, Fit and Function test was completed in November 1995, to finalize details of a Basis of Issue Plan (BOIP) for the LOX equipment.

(29) The **Field Anesthesia Machine (FAM)** is a compact, rugged anesthesia system for the delivery of the volatile anesthetic agent forane. The FAM will be an FDA approved upgrade to, or replacement for, the Ohmeda Model 885A FAM, which is not approved by the FDA for use in CONUS hospitals.

- The development contract to upgrade and obtain FDA approval of the Ohmeda Model 885A FAM was delayed until at least CY98, while tech-base studies are being conducted to determine the optimum FAM technology.

(30) The **Lightweight Motor Blower (LWMB)** is a small, battery-operated optional blower that will provide filtered, ambient air to a patient being transported inside the Wrap, Patient, Chemical Protective (WPCP) (NSN 6530-01-383-6260) in hot climatic conditions.

- The Edgewood Research, Development and Engineering Center (ERDEC) conducted initial technical testing of blowers submitted by five companies and selected two for possible procurement. Final selection will be based on ability of the blower to serve both the WPCP application and to interface with aviators' masks. Production of either or both can begin as soon as this decision is made. Both candidate blowers will be demonstrated to the Medical CBTDEV for selection of one to use with the Chemical Protective Patient Wrap.

Nerve Agent Antidote System (NAAS), HI-6 (IC/WR/DC) was conceived as a replacement for the fielded Nerve Agent Antidote Kit or the Multichambered Autoinjector. A service-member carried item for self-aid and buddy-aid, it would contain atropine and an improved acetylcholinesterase reactivator, HI-6. This system was terminated at the MS I IPR held on 25 April 1995. In a comparative animal efficacy study, NAAS failed to demonstrate increased efficacy over current 2-pralidoxime and atropine therapy in rhesus monkeys challenged with lethal doses

of GA, GB, GD, GF, and VX nerve agents. This test failure justified the termination of the program.

Microencapsulated Antibiotic, Ampicillin, Dental (MEAA)(ID/SR) is an antibiotic delivery system designed for single dose, direct wound site application by medical personnel at the time of debridement of maxillofacial injuries. It is capable of maintaining antibiotic concentrations at high levels at the wound site while producing systemic concentrations that are much lower than with conventional treatments.

- Based on the affordability and risk/benefit assessment, a Special IPR recommended in 3QCY95 that the MEAA advanced development program be terminated. The Milestone Decision Authority (MDA) approved the IPR recommendation and encouraged the tech-base laboratory to explore opportunities to transfer the technology, which has significant commercial potential, to industry.

Dengue Fever Virus Multivalent Vaccine - No advanced development effort was expended on initiating a project for Dengue because no suitable candidate was proposed.

Biological Defense Program Products:

(a) Tularemia Live Vaccine (RD/SL) is an attenuated vaccine for military personnel being deployed to an area where there is a potential threat use of *Francisella tularensis*. Several lots of vaccine were prepared at the Salk Institute. Clinical trials to establish lot consistency (for licensure) were completed at Johns Hopkins University and USAMRIID.

- A PLA/ELA was filed with the FDA in CY95.

(b) Cell Culture derived Vaccinia - Live Vaccine (RD/SL) is a new, cell culture produced animal poxvirus (vaccinia) that is free of bacteria presently found in the calf lymph (Wyeth) vaccine to be used for protection against smallpox.

-A Phase 2 study showed that the candidate vaccine was immunogenic in those volunteers that developed a pox lesion. Two of the three volunteers given the vaccine by scarification had titers equal to the Wyeth vaccine.

- A Phase 2 expanded study is scheduled at Brooke Army Medical Center, Fort Sam Houston, 1QCY96 to compare titers in volunteers administered the candidate vaccine to those given the licensed Wyeth Vaccine via scarification.

- A draft Request for Proposals (RFP) seeking a contractor to perform vaccinia neutralization assays was released in CY95.

(c) C. botulinum Toxoid, Pentavalent (Types A,B,C,D,E) (SL/PC/MD) is a toxoid used to prevent botulism. The Michigan Department of Public Health (MDPH) completed blending and bottling of 91,770 doses of pentavalent toxoid, which included the high purity Type E toxoid produced at the Center for Applied Microbiology and Research (CAMR), Porton Products, Ltd., U.K. Additional lots of high purity type E toxoid produced at the CAMR also have been sent to the USAMRIID for shipment to MDPH.

- Two protocols were submitted to the FDA under the IND BB-IND 3723 for the immunization of DOD personnel. One is "Administration of Pentavalent Botulinum Toxoid to Individuals Preparing for Contingency Combat Operations" (without informed consent) and the other is "Administration of Pentavalent Botulinum Toxoid to DOD Personnel" (with informed consent).

(d) Clostridium botulinum Type F Toxoid (PC/RD) is a toxoid used to prevent botulism due to the F serotype. Phase 2 clinical studies were begun at the Center for Vaccine Development (CVD), University of Maryland, for *C. botulinum* type F botulinum toxoid. The study began on 15 May 1995, and there are presently 59 volunteers enrolled in the study.

(e) C. botulinum Type G (PC) is a toxoid used to prevent botulism due to the G serotype. Development of production and purification methodology has continued to progress. A cGMP fermentation methodology was completed. Unresolved issues are related to the purification methodology that remain to be developed.

(f) Q Fever CMR Extract Vaccine (RD/SL) is a purified formalin and gamma irradiation inactivated vaccine prepared at the Salk Institute. The intracellular bacteria, *Coxiella burnetii*, are harvested from the infected yolk sacs of embryonated chicken eggs. Extraction with chloroform-methanol (devised at the USAMRIID) is believed to lessen the reactogenicity of the vaccine.

- Expanded clinical trials for a 100 µg dose in 59 volunteers at the CVD showed the vaccine is safe. A Phase 2 study is underway (CY95) to determine the reactogenicity of the vaccine in known skin test positive individuals.

- In CY95, monkeys were immunized with the vaccine and challenged by an aerosol route at 6 months. We plan to use these data in our PLA to the FDA.

(g) Botulism Immune Globulin $F(ab')_2$ Heptavalent Equine (RD/OT) is an equine immunoglobulin prepared by fractionation of horse plasma from hyperimmune animals to treat personnel exhibiting symptoms of botulism. The plasma is treated with pepsin to cleave the Fc portion of the antibody molecule. The F(ab')2 fragments are

isolated by affinity chromatography. PerImmune, Inc., is the contractor which maintains, harvests and processes the horse plasma to produce the final product. The horses have been immunized, and plasma is being collected. Validation of the manufacturing facility is underway. Phase 1 animal studies will be conducted in CY96.

(h) **Botulism Immune Globulin (Human) (RD)** is a human immunoglobulin used in the treatment of botulism. It is prepared by fractionation of plasma from volunteers hyperimmunized with pentavalent botulinum toxoid.

- Lot 1A will be transitioned for use by intravenous administration under a treatment protocol with informed consent. Lots 1B, 2A and 2B will be used for *in vitro* and preclinical studies only. Lot 1B was found to be pyrogenic and contained less than 90% monomers and dimers.

- Lot 2A, which was positive for endotoxin, was pyrogenic and contained less than 90% monomers and dimers.

- Lot 2B was positive for Human Immunodeficiency Virus (HIV) by Enzyme Linked Immunosorbent Assay (ELISA), but negative by Western Blot analyses. This lot will be used in passive transfer challenge studies in animals to produce a surrogate efficacy study for licensure of the pentavalent botulinum toxoid.

(i) The **Diagnostic Kit for Biological Warfare Agents (NL/NM/RD)** is a rapid system for use in a field medical laboratory to initially identify exposure to biological warfare agents from clinical samples. The kit is a screening method to provide rapid information to the medical care provider that can be later confirmed using more sensitive technologies.

- Several JWGs were held to bring together Army and Navy laboratory scientists, the Logistician, and the CBTDEV. A Milestone 0 IPR was conducted 1QCY95. This program is expected to transition into Phase 1 - Demonstration and Validation by 3QCY96. Collaboration is ongoing with ERDEC to provide insight on related DOD technology.

(j) **Ricin Toxoid Vaccine (RD/SL)** is a formalin inactivated toxin, adsorbed to alhydrogel under cGMP by the Salk Institute. An IND application was filed with the FDA 3QCY95.

(k) **Improved Anthrax Vaccine (RD/SL)** was produced in pilot lots by the USAMRIID. Product definition and scale-up production procedures are in progress.

- A Drug Master file was submitted to the FDA CY95 seeking advice and approval of the nonspore-bearing nature of the new vaccine strain.

- A draft RFP for production of cGMP pilot lots of vaccine was prepared in CY95.

- An abbreviated cost analysis comparing the Improved Anthrax vaccine to a reduced schedule for the licensed product was prepared in CY95.

(l) **Staphylococcal Enterotoxin B (SEB)Toxoid (WR/RI)** produced by formaldehyde inactivation of SEB. The cGMP toxin is being produced by Battelle, Inc., and will be toxoided, combined with the proteosome adjuvant, and bottled at the WRAIR vaccine production facility at Forest Glen. Projected product availability for preclinical testing is 1QCY97.

(m) **Recombinant Venezuelan Equine Encephilitis Vaccine** was produced in pilot lots by the USAMRIID.

- A sources sought seeking a development manufacturer of cGMP pilot lots was prepared in CY95.

(n) **Recombinant Staphylococcal Enterotoxin Vaccine,** a pre-transition product, is a bivalent product produced by site directed mutagenesis of the complimentary DNA (cDNA) for the parent toxin in three specific positions. The resultant peptide is rendered nontoxic but retains the ability to induce production of neutralizing antibodies. The addition of the A serotype to the B serotype potentiates the immune response to the B serotype and induces protective immunity to multiple toxin serotypes. A Milestone 0 IPR was held 4QCY95.

(o) **Ricin A Chain Vaccine**, a pretransition product, is a nontoxic subunit of the native toxin that induces protective immunity. The product is in clinical trials as a chemotherapy for several forms of cancer. Actions to conduct a Milestone 0/I have been initiated. Production and bottling of cGMP product for use in preclinical and clinical trials was initiated in CY95.

b. Predevelopment Products:

(1) **Topical Antileishmanial Drug, Paromomycin (WR279396),** a predevelopment product, is a topically applied cream for the treatment of cutaneous leishmaniasis consisting of 15% paromomycin sulfate and 0.5% gentamicin sulfate. Currently, there is no FDA approved treatment for cutaneous leishmaniasis in the USA. The present treatment, pentostam, is administered intravenously and requires extensive treatment in a hospital setting. A topical treatment could be used in the field and would reduce lost duty days and the very high cost of hospital treatment.

- Milestone 0 IPR was held in April 1995. The product is in development in the Tech Base, and an Investigational New Drug Application is expected to be filed in 1QCY96.

(2) **Antimalarial Drug, Arteether (WR)**, a predevelopment product, is an antimalarial drug that is a derivative of the Chinese herbal remedy Qinghaosu. It has been shown to inactivate malaria parasites in cell cultures and animal model test systems. It is intended as an expedient, intramuscularly injected treatment for severe and complicated multi-drug resistant malaria; without the availability of this drug, fatality rates among nonimmune adults could exceed ten percent.

- A Milestone 0 IPR was conducted in 2QCY95.

- A Milestone I IPR is scheduled for 1QCY96.

(3) **Leishmania Skin Test (WR)** is a formalin-killed promastigote antigen used to test for exposure to *Leishmania spp.* A Phase 1 clinical trial using Good Manufacturing Practices (GMP) produced antigen is scheduled for completion 2QCY96, and the product will be transitioned to advanced development 4QCY96 for Phase 2 trials.

(4) The **Azithromycin (Scrub Typhus)** program goal is to determine the effectiveness of azithromycin in the treatment of scrub typhus. Azithromycin is licensed by the Food and Drug Administration for the treatment of skin and soft tissue infection, respiratory infections, and non-gonococcal urethritis. This drug could also be used as a substitute for doxycycline and chloramphenicol to treat women during pregnancy. This disease is a military threat because patients are generally prostrate during fever and may suffer a prolonged convalescence which would remove them from combat duties.

- Milestone 0 IPR was held in April 1995. The Investigational New Drug Application has been drafted but has not been filed pending identification of a funding source for clinical studies.

2. **Production and Deployment Support:**

a. The **Aerosol, Generator, Ultra Low Volume, Electric (AGULVE) (BL)** is a lightweight aerosol dispersal unit for pesticide application operations. The unit is comprised of a spray head and pump, which is powered from a vehicle's electric power supply.

- Twenty-four AGULVEs are being procured by USAMMA through the U.S. Army Aviation and Troop Command (ATCOM). Assistance will be provided to ATCOM as needed during procurement and fielding.

b. **M40 Chemical-Biological (CB) Protective Mask Vision Correction (Materiel Change)** is a vision-correction device using the Ballistic Laser Protective Spectacle prescription lens carrier (PLC) and is internally mounted on the M40 CB protective mask. The prescription lens carrier is mounted in the frame component of this eyewear.

- The initial production of 75,000 units was completed, and the project was transitioned to the OTSG.

c. The **Sprayer, Pesticide, Electric, Liquid (SPEL) (BL)** is a lightweight, electric sprayer for the application of pesticides to insect breeding areas. This unit is comprised of a hand-held spray nozzle, a 20-gallon storage tank, and a pump that operates from the electric power supply of the transporting vehicle.

- Eight SPELs are being procured by USAMMA through ATCOM. Assistance will be provided to ATCOM as needed during procurement and fielding.

d. The **X-ray System, Dental; Miniature (ID)** is a small, lightweight, hand-held dental x-ray system for field use. It is battery operated and suitable for use with self-developing film or digital imager.

- This product has been transitioned to USAMMA and is in the procurement cycle; a request for bids will be advertised. A user evaluation of the miniature x-ray and a special collimator for medical radiographs is being conducted at WRAIR.

e. **The Antimicrobial Dermal Dressing (ADD) (ID)** is a wound dressing capable of providing sustained release of antimicrobial agents at the site of superficial dermal injury to prevent infection, enhance healing, and protect against the external environment.

- The ADD is an NDI for which the AMEDD has withdrawn the requirement. The Special Operations Force (SOF) has a current requirement for the ADD, and USAMMDA has been providing technical support on a reimbursable basis. However, SOF has not funded the project since FY93. A Special IPR in 4QCY95 recommended that the ADD be terminated as an AMEDD developmental project.

f. **Hepatitis Vaccine, Inactivated (HAV) (WR/SK)** vaccine, produced by SmithKline Beecham, was tested and determined to be safe and immunogenic.

- A PLA filed in CY93 for the HAV vaccine produced by SmithKline Beecham and advanced development supported by USAMMDA was approved in CY95. The vaccine was added to the supply system.

g. The **Field Medical Oxygen Generating and Distribution System (FMOGDS)** is an on-site, lightweight medical oxygen generating and distribution system that provides both bedside and cylinder-refill oxygen capabilities within Table of Organization and Equipment (TOE) hospitals and medical logistics organizations. The system is designed to provide greater mobility and operational flexibility and to reduce the logistics burden of medical grade oxygen resupply.

- A user test was conducted at Fort Sam Houston by the AMEDD Test Board in March 1995. The test included 1600 hours of operation during which there were only three unscheduled minor maintenance actions.

- A Milestone IIIa IPR was held in June 1995, with an affirmative decision for full-scale production.

- Phase 2 of the contract (full scale production) may not be exercised due to funding reprioritization.

3. **Contract Projects**:

a. **University of Maryland Vaccine Testing Facility** conducts Phase 1 safety tests and Phase 2 safety and efficacy tests of vaccines. Phase 2 clinical studies were begun at the Center for Vaccine Development, University of Maryland, for *C. botulinum* type F botulinum toxoid. The study began on 15 May, and there are presently 59 volunteers enrolled in the study. Recruitment of third cohort is underway with first vaccination to occur 1QCY96. Phase 2 clinical studies are underway for Chikungunya Live Vaccine. Due to funding decrements, work on this vaccine in CY95 was limited to the 25 volunteers on study. Funding issues have been resolved and recruitment will begin for additional volunteers 1QCY96.

b. **South Florida Drug Research Corporation** conducts Phase 1 clinical studies on candidate pharmaceutical products. These studies evaluate the pharmacokinetics, pharmacodynamics, tolerated dose levels and associated side effects of each tested product. These studies are done in a 60 bed clinical facility or on outpatients. Each study is performed under a specific task order and detailed protocol. During CY95, the contract with South Florida expired; following a competitive solicitation, they were awarded a follow-on contract. Also occurring in CY95:

- A study was completed evaluating the tolerance of females and low-weight individuals to the doctrinal dose of pyridostigmine (30 mg every eight hours) for 21 days. Quarterly followup of each subject will continue for one year. A draft report was delivered.

- A draft report of the single-dose study of the antimalarial drug WR 238,605 was delivered.

- A dermal (toxicity and photosensitivity) study of the Topical Skin Protectant was completed and a final report delivered.

- A sensitization study of the Topical Skin Protectant was completed.

c. The **University of Illinois at Chicago, Toxicology Research Laboratory** conducted non-clinical toxicology studies on candidate pharmaceutical products. These GLP-compliant animal studies are required by the FDA to support INDs and NDAs for pharmaceutical products. Each study was performed under a specific task order and in accordance with a detailed protocol. During CY95:

- One, two and four-week Segment II teratology range finding and in vitro mutagenicity studies on the anticyanide drugs WR 242,511 and WR 269,410 were completed. Segment II teratology work on WR 242,511 was completed.

- Segment II teratology and in vitro mutagenicity work on the Antimalarial Drug WR 238,605 was completed. A 6-month study of WR 238,605 in the rat was initiated.

- A four-week and a 13-week toxicity study of Antimalarial Drug Halofantrine, Prophylactic were completed.

- A four-week dermal study of the Topical Antileishmanial Drug, WR 279,396 was completed.

- Segment II teratology and in vitro mutagenicity studies of the Antileishmanial Drug WR 6026 were completed.

- A protocol was developed for a toxicity study on *Campylobacter* vaccine in mice.

- An RFP for the successor non-clinical toxicology contract (to begin 4QCY96) was prepared and competed.

d. **Salk Vaccine Production Facility** is a manufacturing facility dedicated exclusively to the development and production of investigational vaccines for clinical trials and diagnostic reagents under federal regulatory guidelines. The facility is managed by a delivery order contract for scheduling production of vaccines and reagents.

- The Salk Facility continued to perform tests to extend the shelf life of Vaccinia Immune Globulin (VIG) as a result of tasking from the Assistant Secretary of Defense for Health Affairs. A new production lot of VIG was approved in CY95. The Salk is responsible for receiving, inventorying, storing, potency testing, and shipping VIG as directed.

- Management responsibility for the contract passed to the Director, Research Area IV, HQ, USAMRMC, in CY95 in anticipation of USAMMA management.

4. **Special Projects**:

a. The **Convulsant Antidote Nerve Agent (CANA)** is a diazepam 10 mg autoinjector intended to prevent or abate convulsions and the resulting seizure-associated brain injury caused by nerve agent poisoning. The CANA is a soldier-carried item to be used by buddy-aid in conjunction with the Mark I Nerve Agent Antidote Kit. Survival Technology, Inc. (STI) has been qualified as a source for the manufacture of the CANA under an Industrial Base Maintenance Contract. Although the product has been transitioned to the DPSC, USAMMDA continues to provide technical support to DPSC and STI in the CONUS production of CANA.

b. The **Medical Aerosolized Nerve Agent Antidote (MANAA)** is an aerosol inhalant drug delivery system which packages an anticholinergic agent, antropine sulfae, in a pressurized cannister for administration by medical personnel as followup therapy to the atropine autoinjector for nerve agent poisoning. 3M Pharmaceuticals is currently manufacturing production lots of these devices for delivery to the DPSC.

c. **Vaccinia Immune Globulin (VIG)** is used to treat vaccinia complications resulting from immunization with investigational vaccinia vectored vaccines, use of standard vaccinia as a smallpox vaccine, or to treat cases following offensive use of smallpox virus by adversaries. The VIG manufacturer uses plasma from immunized volunteers to ensure a product that exhibits potency criteria required for a licensed product.

- The Alpha Therapeutic Corporation collected vaccinia immune plasma for two production runs of VIG. This plasma was sent to the Hyland Division, Baxter Healthcare Corporation, for manufacture of VIG. Two additional collection and production runs of VIG are scheduled for CY96.

- Approximately 6,000 vials of VIG were obtained from the first production run by Hyland. The Product License for VIG was approved by the FDA in CY95.

d. Monitoring of **predevelopment products requiring human use studies** continued. INDs and Phase 1 studies for several dengue vaccines and *P. falciparum* malaria sporozoite vaccines are on-going. A microencapsulated ETEC Vaccine was tested at the University of

Maryland. An IND was assembled for a *Leishmania* Skin Test, which will be an immunological technique for screening of individuals suspected to be infected with *Leishmania tropica.*

e. The Greer Laboratories **Plague Vaccine** licensure, submitted 4QCY93, was approved by the FDA 3QCY94. A postmarketing surveillance protocol is in preparation for implementation in CY96.

f. The **Aircrew Protective Mask, XM45, Vision Correction** supports some of the development aspects of new vision corrective eyewear for the XM45, such as optical fabrication support for eyewear lenses.

- This project was transitioned to the OTSG.

g. The **Electrochemical Ozone Generating Module (LT)** generates high concentrations of ozone from water and oxygen in air. Ozone is a very effective gaseous sterilant. When dissolved in water, it oxidizes organic molecules. The module could be retrofitted on an ethylene oxide sterilizer or used to sterilize and treat waste water.

- The prototype ozone sterilizer has been delivered by the contractor. Tests will be conducted to verify the sterilizer's effectiveness and to establish the effects of ozone on medical equipment.

h. The **Expert System for Trauma Management** is a technology watch for new developments in artificial intelligence and expert systems (AI/ES), which can be applied to military medicine.

- A system based on fuzzy logic is being investigated for potential application to vital signs monitoring. The objective is to identify trends in the data so intervention can be initiated early.

i. The **Far Forward Suction Apparatus** is a compact, line or battery-operated suction pump and collection vessel that allows the user to select a vacuum level in either an intermittent or continuous suction mode. This unit will support requirements for oropharyngeal, nasogastric, and peritoneal suction.

- A market investigation was completed and only one experimental prototype was identified that may meet the CBTDEV's requirements. This prototype was demonstrated to the CBTDEV and was well received. As a result, final development and FDA licensing of the new unit are being closely monitored. The design of the device is now complete, and it is currently undergoing environmental tests. Once FDA licensing is complete, then product information, including essential characteristics, will be forwarded to the USAMMA for type classification and procurement.

j. The **Field OB/GYN Examination Table** is a lightweight portable patient treatment platform for OB/GYN examination in field medical facilities. Initial efforts focused on modifying an existing patient examination platform, such as the Field Examination Chair or the Far Forward Surgical Table.

- The Technical Data Package (TDP) was delivered to the Defense Medical Standardization Board (DMSB) for procurement. Assistance will be provided to the procuring activity as needed.

k. A **Portable Rugged Laser Optometer (RP/BL)** is the objective of an SBIR contract to build a compact device capable of measuring the refractive error in the vision of a soldier in an austere field environment. Unlike current devices that use lenses and must be operated by a trained practitioner, the laser optometer will be automated and require seconds for an accurate measurement.

- A Phase 2 SBIR contract was successfully completed. The contractor is using non-Federal capital to develop the technology for the commercial market.

l. The **Field X-ray Table** is a lightweight platform for medical imaging of patients in the field. It weighs less than 125 pounds and has a "buckey system" that allows patient imaging in either the horizontal or vertical position. A table identified from an extensive market investigation was procured and modified to meet CBTDEV requirements.

- The CBTDEV has accepted our product specifications and recommendations for standardizing the table. The package has been forwarded to the USAMMA for procurement.

m. The **Thawed Blood Processing System (LR)** is a fully integrated system that will remove the glycerol solution (used to preserve blood cells) prior to administration to patients. The system will be automated to allow rapid blood-cell processing with minimal manpower requirements. The system will be closed to prevent contamination of the blood during processing and will support increased shelf-life of the processed blood.

- The contract for Phase 2 of the SBIR program was awarded in March 1995. The objectives for Phase 2 are to develop a first-generation prototype in the first year and an advanced, second-generation prototype in the second year. The primary requirements for the advanced prototype are to be fully automated, to deglycerolize thawed blood in less than 30 minutes, and to attain a three-week shelf life of the output blood.

QUALITY ASSURANCE OFFICE

The Quality Assurance Office (QAO) directly supports the Project Management Divisions by being responsible to the Product Managers for ensuring quality and acceptability of test data, control processes, manufacturing data and regulatory documentation for submission to the FDA in support of product safety and effectiveness. During 1995, the Quality Assurance Team was actively involved in the entire product development process by pursuing 18 early protocol reviews; 13 pre-study, 6 study initiation, 17 mid-study and 7 close-out study visits; involvement in ELA/PLA submissions; and participation in GLP inspections. With the emphasis on quality at all levels in the development process and the expanding role of quality assurance in supporting product development came a growth in the team size, with the addition of one military and one civilian authorization. Flexibility, creativity, and resilience were the attributes that supported the Quality Assurance Team during the year long Regulatory Affairs Specialist vacancy, the prolonged period of time to award the Regulatory Affairs Contract and the charge to serve as point of contact when the Commander, USAMMDA was designated as Sponsors Representative for technology base INDs.

Despite the decreased manpower, the QAO maintained an active travel schedule which included CONUS study site visits to USAMRIID; WRAIR; the CVD, a Phase 1/2 Biological Systems contractor; the South Florida Drug Research Corporation, a Phase 1 Pharmaceutical Systems contractor; Pharmakinetics, a subcontracted Pharmaceutical Contract Research Organization; Georgetown University; ERDEC; U.S. Army Research Institute of Environmental Medicine (USARIEM); and the National Naval Medical Center. Additionally, overseas monitoring visits were conducted in Kenya for Azithromycin and SPf66, Israel for ETEC, Egypt for ETEC, and Argentina to retrospectively evaluate the Argentine Hemorrhagic Fever data in preparation for PLA/ELA submission. Pre-study evaluation of new sites for clinical trials were conducted in Egypt and at Harris, a contract research organization in Lincoln, NE. Quality Assurance team members equipped four Product Managers with study site monitoring tools to do Quality Assurance assessments during their study initiation site visits. The team effort of the Product Managers and Quality Assurance personnel increased the efficiency and quality of product development.

Quality Assurance team members participated in the review of a Tularemia ELA/PLA submitted in September 1995, a draft Argentine Hemorrhagic Fever Vaccine ELA/PLA for submission in CY96 and a Pyridostigmine Bromide NDA for resubmission in 1QCY96. A GLP review of a contract toxicology facility was conducted with assistance from the Regulatory Affairs contractor.

The previous Regulatory Affairs contract, scheduled to expire 3QCY94, was extended through 15 September 1995. The new Regulatory Affairs contract went into effect 1 July 1995, with contract award to EER Systems, Inc. In October, the Project Manager for EER Systems Inc., who had interfaced closely with USAMMDA staff, resigned. A replacement Project Manager is currently being sought. Contractor involvement was sought in updating Investigator Brochures and conducting close out monitoring visits for products which will potentially have either NDAs or ELA/PLAs submitted.

As the designated Sponsors Representative for technology base INDs, the Commander, USAMMDA appointed the Chief, Quality Assurance Office as his point of contact. Follow-up was conducted on the status of the draft regulation for Human Use Studies Program (HUSP) which was submitted to HQ, USAMRMC in early March 1994 to no avail. The QA team implemented its own standardized formats for protocol review and monitoring visits during 1995 and will strive to implement its own SOPs to facilitate consistency in QA activities.

RESOURCES MANAGEMENT

1. **Project Management Division Database (PMDD) and Product Management Database System (PMDS)**: The enhancement of two database systems that assist the Project and Product Managers in planning and programming product development costs continues as new methods for utilizing the data become evident. The PMDD system enables the Project Managers to designate the Product Manager-product pairing and to allocate funds to specific products. The PMDS system enables the Product Managers to identify planned activities through integrated commercial project management software with funding requirements associated with each of their products and to generate Business Plans and Information Papers. Information on planned, committed and obligated funds will be displayed on the PMDD and PMDS reports. In addition, the planned activities from PMDS become the baseline data for the Financial Management System (FMS) and the General Analysis/Priority System (GAPS) through a transfer procedure. FMS also has undergone further enhancements to improve the system's responsiveness and performance, including making FMS a multiuser system. Automated linking of the four systems provides tremendous productivity gains for USAMMDA as Project Managers can react faster to changes in project plans and execution requirements and share the updated plan with development partners in the laboratories and contract sites.

2. **Project Management Documentation Support Contract**: The Project Management Support Division continued to provide the Contracting Officer's Representative for the USAMMDA support contract. This contract provides the Project Managers with additional resources in developing necessary project management documentation, cost estimates and analytical services in a timely and efficient manner. This year a new contract for these services was awarded to Cambridge Consulting Corporation, McLean, Virginia. Some minor turbulence has occurred in making the adjustment from the previous support contractor's staff to the new Cambridge staff, however, these have not impeded the quality or timeliness of deliverables from the contractor. Cost estimating tasks, cost and operational effectiveness analyses, and abbreviated analyses tasks to support Milestone In-Process Reviews continued to stay at a high level during the year. Other significant work included preparing documentation read ahead packages for In-Process Reviews. A major effort during the year was the conversion of the majority of the USAMMDA Business Plan program schedules from the Project Scheduler$_{TM}$5 Project Management software to Project Scheduler$_{TM}$6. Work has also continued throughout the year on the USAMMDA automated financial management and program analysis software support effort and several modifications and upgrades were implemented.

3. **Medical Research, Development, and Acquisition (RDA) Mission Area Materiel Plan (MAMP):** In 1994, the AMEDD Center and School (AMEDDC&S) took the lead in organizing and executing the AMEDD's MAMP. The 1995 Medical RDA MAMP Meeting (9 August 1995) performed product assessments for evaluating USAMRMC Research and Development (R&D) program with respect to medical-related combat requirements. Representatives from USAMMDA, AMEDDC&S, and USAMMA evaluated and formally assessed 35 products against 11 operational capability requirements (OCRs). The OCRs, based on AMEDD deficiencies, enhancements, and obsolescences, are weighed in terms of relative importance. A paired comparison technique is used to determine the relative weight of AMEDD OCRs used in the ranking process. A medical materiel "fix" is integrated to pinpoint the highest payoff for advanced development efforts. Prevention is valued relatively more important than either treatment or evacuation. The value-added concept, which measures regional applicability and level of care/intervention, determined the relative value to a field commander of keeping troops on line by factoring in prevention efforts, return to duty actions, or treatment in fixed facilities, against the probability of a product's use in one of the six Unified Command geographical regions. The evaluation process is further enhanced with the addition of morbidity and mortality concepts. A logistical confidence component is added to the scoring process to assess the logistical supportability (provisioning, shelf-life, size, transportability, environmental requirements, durability, maintainability, and power requirements).

Results of the MAMP, Appendix D, meeting were distributed to all interested parties. The MAMP results are used as a tool to determine program planning and execution.

INFORMATION MANAGEMENT

Automated Data Processing Support: Installation was completed on the local area network (LAN) manager-based Pathworks network which provides increased capabilities for the users. Management of the network is more efficient due to Windows-based network software, increased security features and centralized printer controls. A new mail system (cc:Mail) was installed on the network providing users with an easier interface to the world-wide electronic mail system. Bulletin boards and in-house mailing lists have decreased the need for hardcopy distribution and have put more tools on the user's desktop by electronic means. The increasing use of network-based applications has provided for a centralized database system for the Product Managers, Project Managers and PMSD staff. A network was established in the Visual Information Section to allow for connectivity of all graphics stations and printers. The illustrators created a new layout for the conference room as well as a new backdrop for the televideo room. A brochure was produced which describes the services that are provided by the Visual Information Section.

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HUMAN RESOURCES

Actions continued during the year to effect military reductions based on the TAA-01 Study and civilian reductions imposed by HQDA Affordability Analysis. The divisions implemented plans to reduce manpower over the next five years by assessing mission requirements and redistribution of workload. Military authorizations were reduced by 10 (a 50% reduction) and civilian authorizations by 11 (a reduction of 21%).

There were no civilian accessions, one employee transferred, four employees were promoted, five individuals retired, and two employees were lost due to a reduction in force.

Military personnel actions included two promotions, five accessions, four retirements, and three transfers.

Civilian Awards:

28 exceptional performance evaluations
34 performance awards
1 Meritorious Civilian Service Award
1 Achievement Medal for Civilian Service
1 Time-Off Award
3 Invention Awards
3 On-the-Spot Awards

Military Awards:

3 Meritorious Service Medals
4 Legion of Merit
1 "A" Prefix Designator

A list of USAMMDA's key personnel and unit strength is presented in Appendix F.

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FISCAL PERFORMANCE

1. **In-House**: In FY95, USAMMDA's In-House fiscal execution exceeded the USAMRMC disbursement target by 26 percent. Obligations were less than two percent below the established target.

	Allotment	Obligations	Disbursements
FY 1995 Dollars ($000)	5,040	4,946	3,873
Target (%)		100	51
Actual (%)		98	77

2. **Program Wide**: The laboratory disbursement target for FY95 was exceeded in Program Element 654807 (6.5). Performance in the command-wide development program fell below levels reached in FY94 in both obligation and disbursement execution percentage, attributable to a drop in extramural and laboratory activity. Fiscal execution performance at the project level is provided in Appendix G.

	Allotment	Obligations	Disbursements
FY 1995 Dollars ($000)	25,431	23,097	10,654
Target (%)		100	51
Actual (%)		91	42

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LOGISTICS MANAGEMENT

1. **Integrated Logistics Support and MANPRINT Documentation**: The following Integrated Logistic Support Plans (ILSP) were prepared in support of Milestone IPRs for USAMMDA products.

TYPE	PRODUCT
MS I	Cyanide Pretreatment
MS O/I	Ricin Toxoid Vaccine
MS I	Campylobacter Vaccine
MS I	Nerve Agent Antidote System
Special IPR	Microencapsulated Antibiotic Ampicillin, Dental
MS IIIa	Field Medical Oxygen Generating and Distribution System
MS II	Q Fever CMR Extract Vaccine

2. **Other Product Specific Documents:**

Division	Product	Document
AMSPMD	Field Medical Oxygen Generating and Distribution System	Updated System Safety Report
		Hazard Analysis
		System Safety Risks Assessment
		Updated ILSP
	Liquid Oxygen System	System MANPRINT Management Plan
BSPMD	Botulinum Toxoid, Types A-E	ILSP
PSPMD	Topical Skin Protectant	ILSP
	Antimalarial Drug, Azithromycin	ILSP

3. **General Logistics, Test and Documentation Support:**

- Reviewed and updated Medical Annex to the Army Materiel Plan.

- Prepared Logistic Assessment for USAMMDA for the 1995 MAMP and MARP Conferences.

- Review and analysis of Advanced Development of Medical Materiel under RDA 21 concept paper.

- Reviewed Revision "C" to MIL-STD-962B, DOD Standard Practice for Defense Standards, Handbooks, Acquisition Guides, and Bulletins.

PRESENTATIONS

Ahle, Neil W., Advanced Development Status of Cyanide Pretreatment (WR242511), U.S. Army Medical Research Institute of Chemical Defense Commander and Staff STO Briefing, Aberdeen Proving Ground, MD, August 1995

Bavari, S., R. D. LeClaire, M. L. Jones, and R. G. Ulrich. Immunizations that produce cross-reactive antibody prevent the lethal effects of several *Staphylococcus aureus* superantigens. American Society for Microbiology, Washington D.C., May 1995

Braitman, David J., Briefing on the Antimalarial Drug Azithromycin to the Food and Drug Administration, Rockville, MD, October 1995

Clawson, Ronald E., Briefing on DOD Use of Challenge IND's to the National Institute of Allergy and Infectious Diseases, October 1995.

Langford, Michael J., USAMMDA overview at the 1995 Short Course on Military Veterinary Medicine, September 1995

Langford, Michael J., Briefing on Administration of Pentavalent Botulinum Toxoid to DOD Personnel presented to the Assistant Secretary of Defense (Health Affairs), Honarable Stephen C. Joseph, MD, MPH, August 1995

LeClaire, Ross D., W. M. Kell, S. Bavari, T. Smith, and R. E. Hunt, Briefing on Protective Effects of Niacinamide in Staphylococcal Enterotoxin-B-induced Toxicity to International Congress of Toxicology-VII, Seattle, WA, July 1995

Liu, Dai-Kee, Briefing on the Topical Skin Protectant (IC) to the Food and Drug Administration, Rockville, MD, April 1995

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MAJOR TRAINING EVENTS ATTENDED

Ahle, Neil W., MAJ, Personnel Management for Executives (I), Lancaster, PA, June 1995

Ahle, Neil W., MAJ, Fundamentals of Systems Acquisition Management, Fort Belvoir, VA, July 1995

Ahle, Neil W., MAJ, Good Clinical Practices and the Regulatory Process, Fort Detrick, MD, August 1995

Ahle, Neil W., MAJ, Current Good Manufacturing Practice for Quality Control Laboratory Personnel, East Brunswick, NJ, August 1995

Ahle, Neil W., MAJ, Preparing Clinical Protocols and Managing Clinical Investigations, East Brunswick, NJ, September 1995

Ahle, Neil W., MAJ, Practical Considerations in Preparing Investigational New Drug and New Drug Applications (IND/NDAs), East Brunswick, NJ, September 1995

Ahle, Neil W., MAJ, Good Laboratory Practices, East Brunswick, NJ, September 1995

Ahle, Neil W., MAJ, Strategic Use of the Internet for Drug Development, Alexandria, VA, October 1995

Ahle, Neil W., MAJ, Board Certification, the American Board of Toxicology, Raleigh, NC, October 1995

Ahle, Neil W., MAJ, Interagency Operations Security Fundamentals Course, Fort Detrick, MD, November 1995

Albright, Deanna W., High Performance Management Dynamics, Fort Detrick, MD, March 1995

Albright, Deanna W., Intermediate WordPerfect 6.0 for Windows, Fort Detrick, MD, September 1995

Arnold Mark F., Introduction to Acquisition Workforce Test and Evaluation (TST-101), Huntsville, AL, April 1995

Bowers, Elizabeth A., Advanced WordPerfect 6.0 for Windows, Fort Detrick, MD, May 1995

Bowers, Elizabeth A., Introduction to Lotus 4.0 for Windows, Fort Detrick, MD, August 1995

Braitman, David J., LTC, International Harmonization of Toxicology Requirements for Pharmaceuticals, Seattle, WA, July 1995

Braitman, David J., LTC, Regulatory Affairs Professional Society Meeting, Washington, DC, September 1995

Braitman, David J., LTC, Strategic Use of the Internet for Drug Development, Alexandria, VA, October 1995

Brown, Mark W., Introductory Physics II, Frederick Community College, Frederick, MD, May 1995

Brown, Mark W., General Chemistry, Frederick Community College, Frederick, MD, December 1995

Burman, Mary C., LTC, Introduction to Windows 3.1, Fort Detrick, MD, January 1995

Burman, Mary C., LTC, Disk Operating System 6.0 - Introduction, Fort Detrick, MD, February 1995

Burman, Mary C., LTC, Introduction to WordPerfect 6.0 for Windows, Fort Detrick, MD, February 1995

Burman, Mary C., LTC, Advanced Lotus 4.0, Frederick, MD, April 1995

Caldwell, Donald W., Advanced DOS 6.0, Frederick, MD, February 1995

Caldwell, Donald W., Introduction to Acquisition Workforce Test & Evaluation, DSMC, Boston, MA, August 1995

Clawson, Ronald E., Seventh International Symposium on Recent Advances in Drug Delivery Systems, Salt Lake City, UT, February-March 1995.

Clawson, Ronald E., FDA Pre-Approval Inspection, Malvern, PA, October 1995

Clawson, Ronald E., Strategic Use of the Internet for Drug Development, Alexandria, VA, October 1995

Clawson, Ronald E., Current Progress in Military Neuroscience Research, Baton Rouge, LA, November 1995

Cole, Janice M., Intermediate Systems Acquisition Course, DSMC, Fort Belvoir, VA, May 1995

Cutsail, Cindy E., Advanced WordPerfect 6.0 for Windows, Fort Detrick, MD, August 1995

Dickens, Annette D., lLt, Good Laboratory Practices, East Brunswick, NJ, September 1995

Dickens, Annette D., 1Lt, Good Clinical Practices, East Brunswick, NJ, November 1995

Doughty, D. Scott, In Vitro Diagnostics Conference, Arlington, VA, January 1995

Ferguson, Warren R., Intermediate Contractor Performance Measurement, DSMC, Fort Belvoir, VA, January 1995

Gere, Jeffrey A., LTC, Intermediate Systems Acquisition Course, Fort Belvoir, VA, April 1995

Gere, Jeffrey A., LTC, Strategic Use of the Internet for Drug Development, Alexandria, VA, October 1995

Hathaway, Cecil C., Logistics Executive Development Course, Fort Eustis, VA, March 1995

Hathaway, Cecil C., Configuration Management, St. Louis, MO, June 1995

Hathaway, Mary A., Advanced WordPerfect 6.0 for Windows, Fort Detrick, MD, February 1995

Hathaway, Mary A., Intermediate WordPerfect 6.0 for Windows, Fort Detrick, MD, August 1995

Higgins, Yvonne K., Production/Quality Management Fundamentals, AFIT, Wright-Patterson AFB, OH, August 1995

Higgins, Yvonne K., Lessons from the Past: Challenges for the Future, Bethesda, MD, October 1995

Langford, Michael J., COL, Good Laboratory Practices, East Brunswick, NJ, March 1995

Langford, Michael J., COL, Intermediate Systems Acquisition Course, DSMC, Fort Belvoir, VA, February 1995

Langford, Michael J., COL, Preparing Clinical Protocols and Managing Clinical Investigations, East Brunswick, NJ, March 1995

Langford, Michael J., COL, Practical Considerations in Preparing Investigational New Drug and New Drug Applications (IND/NDAs), East Brunswick, NJ, March 1995

LeClaire, Ross D., LTC, Good Clinical Practices and the Regulatory Process, Fort Detrick, MD, January 1995

LeClaire, Ross D., LTC, Fundamentals of Systems Acquisition Management, DSMC, Hanscom AFB, MA, February 1995

LeClaire, Ross D., LTC, Biologics Compliance, Regulatory Affairs Professionals Society Workshop, Washington, DC, May 1995

LeClaire, Ross D., LTC, Board Certification, the American Board of Toxicology, Raleigh, NC, October 1995

Lee, Terry J., Intermediate Test and Evaluation Course, Fort Belvoir, VA, April 1995

Lee, Terry J., Intermediate Acquisition Logistics Course, ALMC, Fort Lee, VA, May 1995

Lee, Terry J., Configuration Management, AMEC, Rock Island, IL, May 1995

Lee, Terry J., Reliability and Maintainability Overview, AFIT, Wright-Patterson AFB, OH, June 1995

Liu, Dai-Kee, Regulatory Affairs Professional Society Drug Approval and Drug Compliance Workshops, Washington, DC, May 1995

Liu, Dai-Kee, Pharmaceutical Process Development, East Brunswick, NJ, September 1995

Liu, Dai-Kee, Regulatory Affairs Professional Society Meeting, Washington, DC, September 1995

Liu, Dai-Kee, Strategic Use of the Internet for Drug Development, Alexandria, VA, November 1995

Miller, Robert E., MAJ, Combat Casualty Care Course, Fort Sam Houston, TX, September 1995

Miller, Robert E., MAJ, Preparing Clinical Protocols and Managing Clinical Investigations, East Brunswick, NJ, September 1995

Miller, Robert E., MAJ, Practical Considerations in Preparing Investigational New Drug and New Drug Applications (IND/NDAs), East Brunswick, NJ, September 1995

Morgan, Sharon L., Stress Management for Administrative Personnel, Fort Detrick, MD, July 1995

Nelson, James H., Command and General Staff Officer Course (correspondence), January 1995-1997

Nelson, James H., Current Good Manufacturing Practice (cGMP) for the Medical Device Industry, East Brunswick, NJ, March 1995

Nelson, James H., Army Management Staff College, Fort Belvoir, VA, December 1995

Pace, Judith G., 3rd International Symposium on Productivity and Quality Improvement with a Focus on Government, Institute of Industrial Engineers, Norcross, GA, February 1995.

Pace, Judith G., *In vitro* Methods for Product Development and Safety Assessment (SOT), Baltimore, MD, March 1995.

Pace, Judith G., Biologics Approval Workshop, RAPS, Washington, DC, May 1995.

Pace, Judith G., Biologics Compliance Workshop, RAPS, Washington, DC, May 1995.

Pace, Judith G., International Society on Toxinology (PanAmerican), Frederick, MD, August 1995.

Pace, Judith G., Board Recertification, The American Board of Toxicology, Raleigh, NC, October 1995

Paschal, Charles R., Current Good Manufacturing Practice (cGMP) for the Medical Device Industry, East Brunswick, NJ, March 1995

Poole, Anna M., Intermediate Systems Acquisition Course, Wright-Patterson Air Force Base, OH, August 1995

Poole, Anne M., Supervisor Development Course, Fort Eustis, VA, August 1995

Poole, Anna M., EEO Counselor Training, Fort Detrick, MD, October 1995

Reams, William H., Current Good Manufacturing Practice (cGMP) for the Medical Device Industry, East Brunswick, NJ, March 1995

Reams, William H., Introduction to Windows 3.1, Fort Detrick, MD, August 1995

Salisbury, Lloyd L., Principles and Techniques for User Interface Design, University of Michigan, Ann Arbor, MI, May 1995

Schieferstein, George J., Current Good Manufacturing Practices for the Pharmaceutical and Allied Industries, East Brunswick, NJ, February 1995

Sheffer, Linda J., Systems Acquisition Funds Management, DSMC, Fort Belvoir, VA, January 1995

Sheffer, Linda J., Total Army Quality Process Action Team Training, Fort Detrick, MD, May 1995

Sheffer Linda J., Intermediate Systems Acquisition Course, Fort Belvoir, VA, June 1995

Wivell, Stephanie V., Intermediate WordPerfect 6.0 for Windows, Fort Detrick, MD, June 1995

Wivell, Stephanie V., Process Action Team Training, Fort Detrick, MD, August 1995

Zittle, Virginia L., Intermediate WordPerfect 6.0 for Windows, Fort Detrick, MD, February 1995

DISTINGUISHED VISITORS

Drs. Erik Helgstrand, Ulf Bjare, and Per Askelof, SBL Vaccin, AB, Stockholm, Sweden. Review progress on clinical trials and discuss potency assays of the cholera and ETEC vaccines, 24 March 1995.

Dr. Richard John Horton, Ms. Hilary Christoudoulou, SmithKline Beecham Pharmaceuticals, Hertfordshire, United Kingdom. Negotiate Antimalarial Drug WR 238,605/Antileishmanial Drug WR 6026 CRDA, April 1995.

Drs. Yohanna Holldack and Helmut Müller, Behringwerke, Aktiengesellschaft, Marburg, Germany. Review production and funding requirements for collaboration on application for Food and Drug Administration licensure of a TBE vaccine, 4 April 1995.

Mr. Carl Hamilton and Mr. Melvin Moss, Ministry of Defence, Colchester, Essex, England, Preview the Decontaminable Litter, 8 May 1995.

Drs. Peter Hambleton, Howard Trantor, Christopher Wiblin, Barry Thornton, Clifford Shone, Jack Melling, and Stephen Prior; Centre for Applied Microbiology and Research, Porton Products, Porton Down, United Kingdom. Review the Botulism Immune Globulin Program, 26 May 1995.

Mr. David Johnson, Mr. Michael Jacobs, Pyng Medical Corporation. Conduct meeting for the Intraosseous Device at the request of the Combat Developer, 7 July 1995.

LTC Dani Cohen, Israeli Defence Force. Review progress on Phase 2 ETEC clinical trial in Israel, and to confer on planned Phase 3 trial, 13 September 1995.

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APPENDIX A

COMMONLY USED ACRONYMS

AMEDD	Army Medical Department
AMSPMD	Applied Medical Systems Project Management Division
BOIP	Basis of Issue Plan
BSPMD	Biological Systems Project Management Division
CAMR	Centre for Applied Microbiology and Research
CBTDEV	Combat Developer
cDNA	complimentary DNA
cGMP	Current Good Manufacturing Practices
CRDA	Collaborative Research and Development Agreement
CVD	Center for Vaccine Development
CY	Calendar Year
DEET	Diethyltoluamide
DOD	Department of Defense
DMF	Drug Master File
DMSB	Defense Medical Standardization Board
DNA	Deoxyribonucleic Acid
DPSC	Defense Personnel Support Center
ELA	Establishment License Application
EPA	Environmental Protection Agency
ERDEC	Edgewood Research, Development and Engineering Center
FDA	Food and Drug Administration
FMOGDS	Field Medical Oxygen Generating and Distribution System
FMS	Financial Management System
FY	Fiscal Year
GAPS	General Analysis/Priority System
GCP	Good Clinical Practices
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
HIV	Human Immunodeficiency Virus
ILSP	Integrated Logistic Support Plans
IND	Investigational New Drug Application
IPR	In-Process Review
JWG	Joint Working Group
LOX	Liquid Oxygen
MAMP	Mission Area Materiel Plan
MC	Materiel Change
MDPH	Michigan Department of Public Health
MNS	Mission Needs Statement
MS	Milestone

MS	Milestone
NDA	New Drug Application
NDI	Nondevelopment Item
NMRI	Naval Medical Research Institute
ORD	Operational Requirements Document
OTSG	Office of The Surgeon General
PLA	Product License Application
PLC	Prescription Lens Carrier
PMD	Project Management Division
PMDD	Project Management Division Database
PMDS	Project Management Database System
PMSD	Project Management Support Division
PPBES	Planning, Programming, Budgeting and Execution System
PSPMD	Pharmaceutical Systems Project Management Division
QA	Quality Assurance
RDA	Research, Development, and Acquisition
RFP	Request for Proposals
SBIR	Small Business Innovation Research
SOF	Special Operations Force
TDP	Technical Data Package
TEMP	Test and Evaluation Master Plan
TT	Technical Testing
TWG	Technical Working Group
TWIG	Test Integration Working Group
RDA	Research, Development and Acquisition
USAARL	U.S. Army Aeromedical Research Laboratory
USAMMA	U.S. Army Medical Materiel Agency
USAMMDA	U.S. Army Medical Materiel Development Activity
USAMRIID	U.S. Army Medical Research Institute of Infectious Diseases
USAMRMC	U.S. Army Medical Research and Materiel Command
USARIEM	U.S. Army Research Institute of Environmental Medicine
UT	User Testing
WRAIR	Walter Reed Army Institute of Research

PAID (PRODUCT ASSOCIATION IDENTIFICATION) CODES

A system to identify significantly contributing Labs/ Contractors/CRDA Partners, etc., with products.

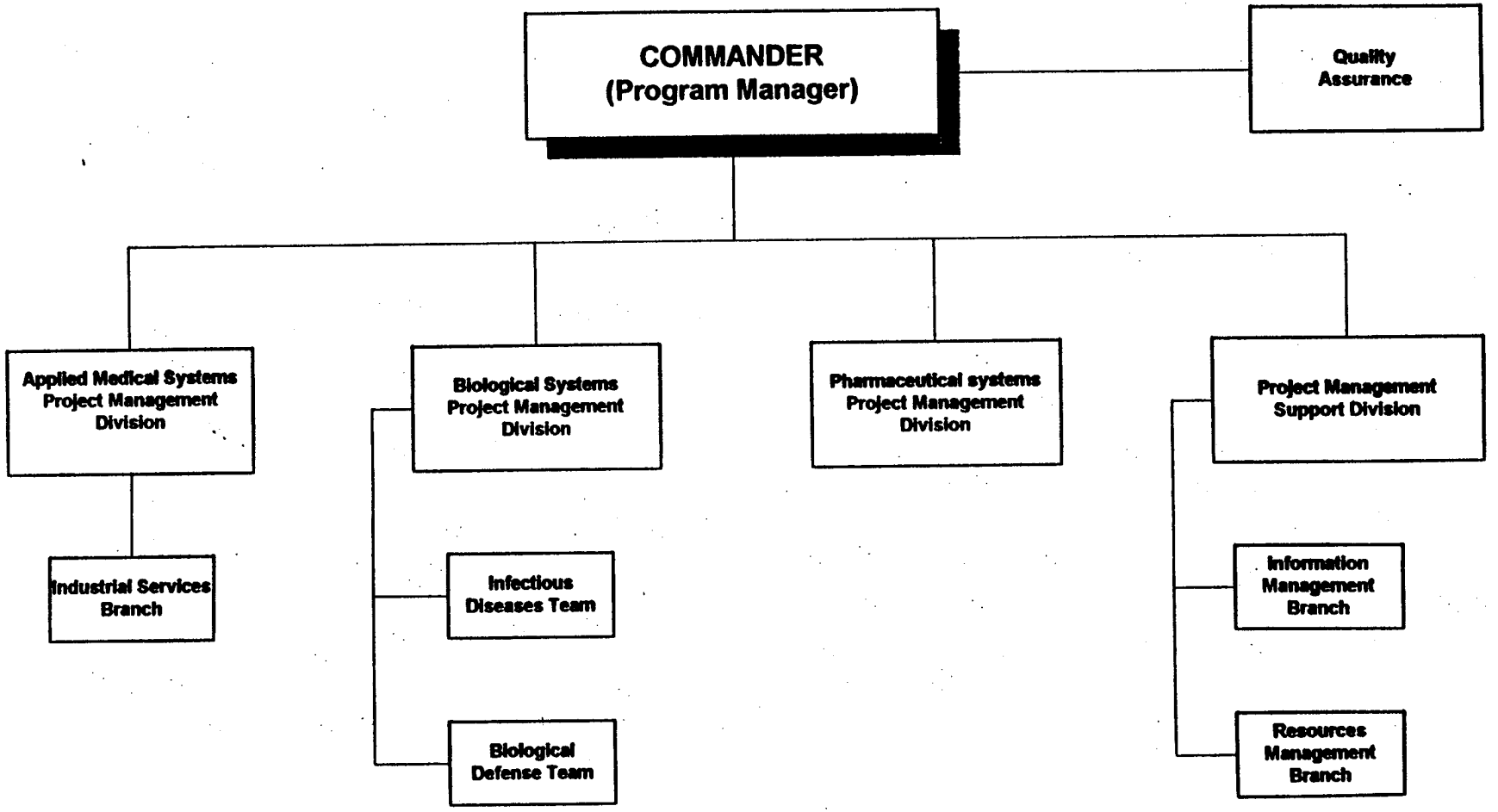
CODE LABS	ORGANIZATION
AL	U.S. Army Aeromedical Research Laboratory
BL	U.S. Army Biomedical Research and Development Laboratory
BR	U.S. Army Institute of Surgical Research
IC	U.S. Army Research Institute of Chemical Defense
ID	U.S. Army Institute of Dental Research
LR	Letterman Army Institute of Research
MR	U.S. Army Medical Research and Materiel Command
NV	Naval Medical Research and Development Command
RD	U.S. Army Medical Research Institute of Infectious Diseases
RM	U.S. Army Institute of Environmental Medicine
WR	Walter Reed Army Institute of Research

OTHER (Contractors, CRDA Partners, etc.)

3M	3M Corporation
AH	Advanced Haemotechnologies
AR	Army Research Laboratory
AV	Program Manager, Aviation Life Support Equipment
BC	Biken/Connaught
BE	Becomist
BT	Battelle
CB	U.S. Army Chemical and Biological Defense Agency
CI	Coulston, Inc.
CR	Charles River Analytics, Inc.
CV	University of Maryland at Baltimore (UMAB), Center for Vaccine Development
DC	DOD-Canada
EH	U.S. Army Environmental Hygiene Agency
EP	EPA
GT	GENENTECH
IA	University of Iowa
IM	IMMUNO-AG
IS	Israeli Defence Force
JX	Disease Vector Ecology and Control Center, Jacksonville (Navy)
LT	Lynntech, Inc.

CODE LABS	ORGANIZATION
MD	MDPH
MG	MICROGENESYS
MI	MILES
MT	Model Tech, Inc.
NH	NIH
NL	Naval Research Laboratory
NM	Naval Medical Research Institute
NR	Noise Removal System
NT	Natick Research, Development and Engineering Center
OT	PerImmune, Inc. (formerly Organon Teknika)
PC	Porton-CAMR
PF	Pfizer, Inc.
RA	Rasor Associates, Inc.
RC	Rayex Corp
RP	Rochester Photonics
SE	Sepracor, Inc.
SI	Steris, Inc.
SK	SmithKline, Beecham, Inc.
SL	SALK
SO	Program Manager for the Soldier
SR	Southern Research Institute
ST	Sterimatics
SW	Swedish Bact. Lab
TA	U.S. Army Tank-Automotive and Armaments Command
TP	Trauma Products Inc.
TR	Technical Research Associates

U.S. ARMY MEDICAL MATERIEL DEVELOPMENT ACTIVITY



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APPENDIX C

INDUSTRIAL SERVICES

The Industrial Services Branch (ISB) supports the design and fabrication of prototypes and modification of medical equipment and medical support equipment for field use. Tradesmen skilled in working with metal, wood, and fabric produce unique items for testing and evaluation, and limited quantities for military emergencies.

In FY95, 99 service requests were completed by ISB. About 80% of the tasks were support for the design and fabrication of prototypes for field medical materiel, such as the DEPMEDS Orthopedic Traction Device, modified Lightweight X-ray Table, Medical Envelope, Dental Aid Bag, ATTV model program, and support to the Ballistic-Laser Protective Spectacles program. Other organizations supported by ISB and the number of specific projects from each are listed below:

Organization	Projects
USAMRMC	23
USABRDL	8
WRAIR	3
USAMRICD	5
USAMRIID	3
USAMRAA	1
USAMMA	4
MATMO	4
USAG	4
OTHER	17

Product Test and Evaluation

During 1995, testing and engineering services were provided for two different projects:

a. Low Temperature Storage Testing was conducted on the Digital Thermometer.

b. Vibration Testing was conducted on the Space Tissue Loss Bio Module constructed by Walter Reed Army Institute of Research in preparation for the Space Shuttle Mission.

c. In addition, tests and evaluations were performed by the AMEDDBD for two USAMMDA projects. An IOT&E was conducted on the FMOGDS and an evaluation was performed on the Decontaminable Litter.

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APPENDIX D

PROGRAM PRIORITIZATION MAMP LIST

PRODUCT	1995 AMEDD PRIORITY
Antimalarial Drug, WR238605	1
Antimalarial Drug, Azithromycin	2
Antimalarial Drug, Halofantrine Prophalactic	3
Nerve Agent Pre-Treatment Pyridostigmine	4
Tick-borne Encephalitis Vaccine	5
Hantaan M-S (Vaccinia Vectored) Vaccine	6
Detoxified LPS-OMP Meningococcal Group B Vaccine	7
Argentine Hemorrhagic Fever Live Vaccine	8
Malaria SPf6 Blood Stage Vaccine	9
Topical Skin Protectant	10
Cholera Whole Cell Plus B Subunit Vaccine	11
ETEC Whole Cell, Recombinant B Subunit Vaccine	12
Chikungunya Live Vaccine	13
Shigella Vaccine, E. Coli Vectored S. Flexneri	14
Campylobacter Vaccine	15
Cyanide Pre-Treatment	16
Hypertonic Saline Dextran	17
Schistosome Topical Antipenetrant	18
Rift Valley Fever Live Vaccine	19
Dengue Fever Virus Multivalent Vaccine	20
Medical/Dental Filmless Imaging System (MDFIS)	21
Intraosseous Infusion Device	22
Nerve Agent Antidote, Multichambered Autoinjector (MA)	23
Field Triage Light	24
Self-Contained Ventilator	25
Low Temperature Sterilizing System	26
Antileishmanial Drug, WR6026	27
Antimalarial Drug, Arteether	28
Armored Ambulance	29
Azithromycin (Scrub Thyphus)	30
Topical Antileishmanial Drug, Paromomycin	31
Leishmania Skin Test	32
Liquid Oxygen Production, Storage, and Distribution System	33
Field Anesthesia Machine	34
Blower, Lightweight Ancillary Chemical Protective Patient Wrap	35

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APPENDIX E

PRODUCT LIST BY PROJECT MANAGEMENT DIVISIONS

BIOLOGICAL SYSTEMS

BD Team

- Botulism Immune Globulin (Human)
- Botulism Immune Globulin F(ab')2 Heptavalent , Equine
- C. botulinum Toxoid Types A-E
- C. botulinum Toxoid Type F
- C. botulinum Toxoid Type G
- Cell Culture Derived Vaccinia - Live Vaccine (RD/SL)
- Diagnostic Kit for Biological Warfare Agents
- Improved Anthrax Vaccine
- Q Fever CMR Extract Vaccine
- Ricin Toxoid
- Staph enterotoxin B (SEB) Toxoid
- Tularemia Live Vaccine
- Vaccinia Immune Globulin (VIG)

ID Team

- Argentine Hemorrhagic Fever Live Vaccine (AHF)
- Campylobacter Vaccine
- Chikungunya Live Vaccine
- Cholera Whole Cell +B Subunit Vaccine
- Detoxified LPS-OMP Meningococcal Group B Vaccine (WR)
- E. coli vectored S. flexneri Shigella Vaccine
- Enterotoxigenic E. coli Whole Cell +B Subunit Vaccine
- Hantaan M-S (Vaccinia-Vectored) Vaccine
- Hepatitis A Vaccine, Inactivated
- Insect/Arthropod Repellent Lotion (Materiel Change)
- Malaria SPf66 Blood Stage Vaccine
- Recombinant Vaccine for Hemmorrhagic Fever Renal Syndrome (PUUMALA) (RD)
- Rift Valley Fever Live Vaccine
- Tick-borne Encephalitis Vaccine

PHARMACEUTICAL SYSTEMS

- Antimicrobial Dermal Dressing (ADD)
- Antileishmanial Drug, WR 6026
- Antimalarial Drug, WR 238605- Hypertonic Saline Dextran (HSD)
- Antimalarial Drug, Azithromycin
- Antimalarial Drug, Arteether (WR)
- Antimalarial Drug, Halofantrine, Prophylactic
- Convulsant Antidote for Nerve Agents (CANA)
- Cyanide Pretreatment (CP) WR242511 (WR/IC)
- Microencapsulated Antibiotic, Ampicillin, Dental (MEAA)
- Nerve Agent Antidote, Multichambered Autoinjector (MA)
- Nerve Agent Antidote System (NAAS)
- Nerve Agent Pretreatment, Pyridostigmine (NAPP)
- Schistosome Topical Antipenetrant (TAP)
- Topical Antileishmanial Drug, Paromomycin (WR279396)
- Topical Skin Protectant (TSP)

APPLIED MEDICAL SYSTEMS

- XM45, Aircrew Protective Mask, Vision Correction (XM45)
- Aerosol, Generator, Ultra Low Volume, Electric (AGULVE) (BL)
- Armored Treatment and Transport Vehicle (ATTV)
- Electrochemical Sterilizing System
- Expert System for Trauma Management (ESTM)
- Far Forward Suction Apparatus (FFSA)
- Field Anesthesia Machine (FAM)
- Field Medical Oxygen Generating and Distribution System (FMOGDS)
- Field OB/GYN Examination Table
- Field Triage Light (FTL) (BL)
- Field X-ray Table
- Intraosseous Infusion Device (IID)
- Lens Surfacing Generator
- Lightweight Motor Blower (LWMB)
- Lightweight X-ray Film Development Kit (BL)
- Liquid Oxygen Production, Storage and Distribution System (LOPSDS)
- Low Temperature Sterilizing System (LTSS)
- M40 Chemical Biological (CB) Protective Mask Vision Correction (Materiel Change)
- M43A1 Chemical Biological (CB) Protective Mask Vision Correction
- Medical/Dental Filmless Imaging System (MDFIS) (ID)
- Portable Rugged Laser Optometer (PRLO)
- Self-Contained Ventilator (SCV)

- Sprayer, Pesticide, Electric, Liquid (SPEL) (BL)
- Thawed Blood Processing System (TBPS)
- Vision Corrective Eyewear (VCE)
- X-ray System, Dental, Miniature (ID)

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APPENDIX F

KEY PERSONNEL AND UNIT STRENGTH

Key Personnel:

Position	Name	Date
Commander	COL G.E. Lewis, Jr.	01 Jan 95 to 31 Dec 95
Deputy Commander	LTC J. R. Stewart	01 Jan 95 to 14 Jul 95
Acting Deputy Program Manager, Combat Medical Systems	Dr. J.H. Nelson	17 Jul 95 to 29 Aug 95
Acting Deputy Program Manager Combat Medical Systems	Dr. R.E. Clawson	30 Aug 95 to 31 Oct 95
Deputy Commander	LTC J.A. Gere	01 Nov 95 to 31 Dec 95
Project Manager, BSPMD	Dr. W.E. Brandt	01 Jan 95 to 31 Mar 95
Acting Project Manager	LTC J. R. Stewart	01 Apr 95 to 14 Jul 95
	Dr. J.H. Nelson	17 Jul 95 to 29 Aug 95
	Dr. R.E. Clawson	30 Aug 95 to 31 Dec 95
Project Manager, AMSPMD	Dr. J.H. Nelson	01 Jan 95 to 08 Sep 95
Acting Project Manager	Dr. D.W. Caldwell	09 Sep 95 to 15 Dec 95
Project Manager	Dr. J.H. Nelson	16 Dec 95 to 31 Dec 95
Project Manager, PSPMD	Dr. R.E. Clawson	01 Jan 95 to 31 Dec 95
Chief, PMSD	Mr. W.R. Ferguson, Jr.	01 Jan 95 to 31 Dec 95
Chief, Quality Assurance Office	LTC M. C. Burman	03 Jan 95 to 31 Dec 95
Administrative Officer	Ms. D.W. Albright	01 Jan 95 to 31 Dec 95

Strength: As of 31 December 1995:

	Military	Civilian	Total
Required	21	58	79
Authorized	10	44	54
Actual	10	41	51

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APPENDIX G

FISCAL PROGRAM EXECUTION

DIRECT

Project	Allotment ($000)	PERCENT In-House OBL	In-House DISB	Extramural OBL	Extramural DISB	Total OBL	Total DISB
808	7,179	87	63	95	37	92	48
836	2,915	97	65	97	26	97	40
993	4,679	96	70	81	4	87	33
Total D/V (6.4)	14,773	92	66	91	24	91	42
832	1,372	99	57	58	25	65	31
848	876	92	64	99	16	98	23
849	3,991	93	74	84	44	87	56
Total EMD (6.5)	6,239	93	71	79	34	84	46
Total Program	21,012	92	67	87	28	89	43

REIMBURSABLE

Project	Allotment ($000)	PERCENT In-House OBL	In-House DISB	Extramural OBL	Extramural DISB	Total OBL	Total DISB
JPO-BD							
D/V	3,880	99	67	99	24	99	32
EMD	539	99	86	100	24	99	65
Total Reimbursable	4,419	99	73	99	24	99	36