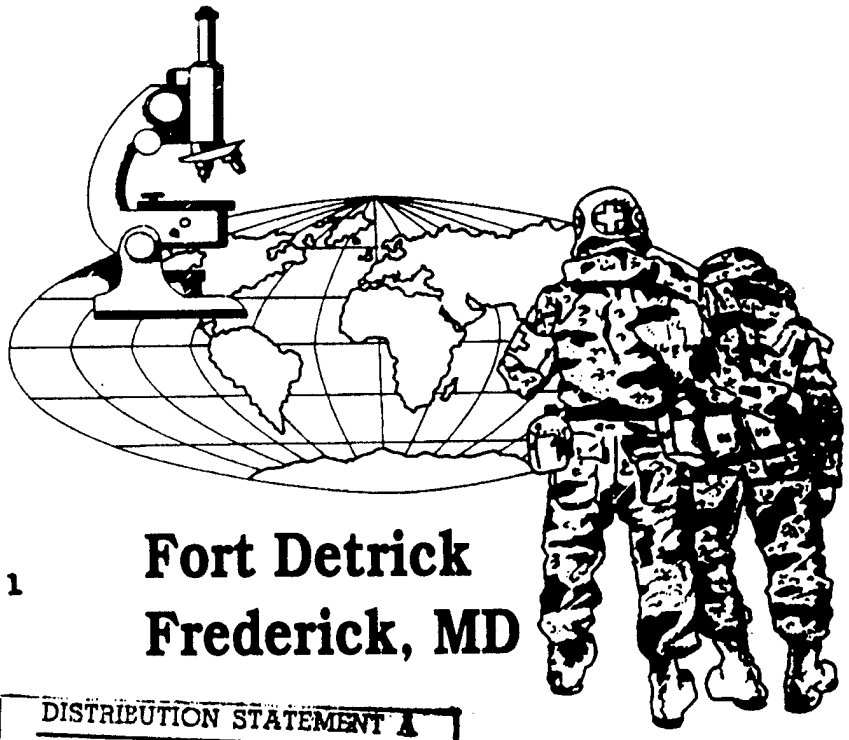
United States Army Medical Materiel Development Activity

1997 ANNUAL REPORT



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MEDICAL MATERIEL DEVELOPMENT ACTIVITY
1997 ANNUAL REPORT
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MESSAGE FROM THE DIRECTOR

Friends and Colleagues,

The U.S. Army Medical Materiel Development Activity (USAMMDA) is an organization with a fresh new outlook - one committed to new innovations in Medical Materiel Development - one that embraces new advanced technologies, streamlined management and innovative business practices. Our goal is to maintain the spirit of cooperation with our partners - the U.S. Army Medical Research and Materiel Command (USAMRMC) and its many outstanding laboratories and activities, the U.S. Navy Medical Research and Development Command and its laboratories, the U.S. Army Medical Department Center and School, and our partners in industry and academia. To this end, USAMMDA, during the past year, has created and formed a partnership with the U.S. Navy through a Memorandum of Understanding which resulted in a Naval Officer being detailed to USAMMDA as a product manager. Continuing in this spirit of multi-Service cooperation and the avoidance of unnecessary duplication of efforts, USAMMDA is working toward an agreement with the U.S. Air Force for assignment of an Air Force Officer as a product manager.

Significant among this past year's many accomplishments are the following:

Under USAMMDA's guidance, the development of the Armored Medical Treatment Vehicle (AMTV) progressed from a concept plywood model to a fully operational combat ready prototype in 9 months. The AMTV prototype joined in the Army's Task Force XXI Advanced Warfighting Experiment where it performed exceptionally well and demonstrated a high degree of survivability throughout the battlefield. Twice, it was the Brigade's most forward armored vehicle in support of counter reconnaissance missions. The successful performance of the vehicle during the rotation at the National Training Center enabled the project to be tagged as one of the U.S. Army Training and Doctrine Command "winners" and it was subsequently submitted as a candidate for the Warfighting Rapid Acquisition Program. Our leadership ability in directing an engineering effort to develop an improved medical treatment and transport capability for the Army is directly responsible for significantly and materially improving the Army's technical capability to execute the national military strategy.

The effort to license Pentavalent Botulinum, Toxoid (A-E) vaccine recently received a tremendous boost when a Food and Drug Administration Advisory Committee recommended that a serological endpoint could be used to demonstrate efficacy. USAMMDA personnel and other international botulinum toxin experts presented evidence that because of the low and unpredictable incidence of botulism worldwide and ethical considerations attendant to intentional exposure, controlled human efficacy studies were not feasible. In lieu of human efficacy studies, comprehensive animal

studies were proposed to include infusion of human antibodies into guinea pigs and challenge with all five serotypes of toxin. These studies are currently being conducted at a contract facility. In addition to these efficacy studies, human clinical studies to collect safety and immunogenicity data necessary for licensure are being planned.

At USAMMDA we recognize that technology development and its shaping are absolutely key to our future and to this end, we have marshaled a combined force of acquisition professionals and outstanding scientists. We have created an organization which is committed to our vision of "World Class Medical Materiel Solutions for U.S. Warfighters."

JAMES H. NELSON, PhD
Director

APPLIED MEDICAL SYSTEMS
PROJECT MANAGEMENT DIVISION

THE PROGRAM

INTRODUCTION

The Applied Medical Systems Project Management Division (AMSPMD) is a multidisciplinary team with broad mission capabilities for the advanced development of medical products used to sustain and support the warfighters. The team consists of product managers and model makers, who have expertise in project management, engineering, fabrication, and technical testing. Product Managers (PdM) conduct analyses of functional requirements, development and/or execution of technical execution plans, and development of program strategies for any program component from pre-Milestone I through Milestone III. The PdMs also direct program resources and defend program content and structure in science and acquisition forums. The focus for the Division has been on early involvement of products that are within the technology base resulting in streamlined development efforts by combining Milestones and transitioning medical products rapidly to the logistician for procurement and fielding. As a result of this emphasis, the Division has brought in the Drinking Water Microbiological Assay System (DWMAS), Warrior Medic (WM), Fibrin Bandage (FB), Medical Situational Awareness and Control (MSAC), and the Armored Medical Evacuation Vehicle (AMEV).

MILITARY RELEVANCE

The AMSPMD designs, develops, and tests field medical equipment in support of battlefield combat casualties. The AMSPMD specializes in adapting and hardening commercial off-the-shelf technology for joint military applications. For example, USAMMDA personnel were intimately involved in the development of a far forward resuscitative surgery capability in support of the U.S. Marine Corps and Navy's Operational Maneuver from the Sea.

OBJECTIVES

- Partner with users and their representatives, both internally and externally, to identify and define requirements.

- Provide technical expertise within all phases of the materiel development process.

- Seek partnerships with industry and government organizations to evaluate, test, and field medical solutions to soldiers, sailors, airmen, and marines.

- Fortify professional development through education and training.

- Modernize infrastructures to improve efficiency and effectiveness.

- Assist in standing up a Division to support telemedicine initiatives.

NEW PRODUCT DESCRIPTION(S)

• The **Warrior Medic (WM)** is a the medic variant of the Soldier Systems Command's Land Warrior System. It is the Land Warrior Leader configuration, excluding the Weapons Subsystem and Hand-Held Display, which enhances the combat medic's modular rucksack, implements an electronic Field Medical Card, and improves medical situational awareness and casualty reporting.

• The **Fibrin Bandage (FB)** uses lyophilized fibrinogen and thrombin on an absorbable substrate which results in a strong clot and has been successful in controlling massive hemorrhage in animal models. A thin layer of human fibrin, thrombin, and fibrin is sprayed onto a gauze-like dressing at low temperatures. The dressing remains inactive in a vacuum packed plastic wrapper until applied to the wound site using direct pressure.

• The **Drinking Water Microbiological Assay System (DWMAS)** is a lightweight, one-man potable device that provides rapid detection of total coliform, fecal coliform, *e-coli*, and other enteric organisms associated with field drinking water.

• The **Medical Situational Awareness and Control (MSAC)** workstation provides an automated deployable medical command post link to other battlefield Command and Control (C2) systems. The MSAC provides situational awareness and serves as an invaluable C2 tool for tactical medical operations. The system uses the underlying functionalities and capabilities of MCS/PHOENIX Beta, the Battle Command Decision Support System, developed for the Battle Command Battle Lab at Fort Leavenworth, Kansas. Medical Commanders and their battle staffs will be able to obtain accurate information on the status of their medical resources.

• The **Armored Medical Evacuation Vehicle (AMEV)** uses an M2 Bradley as a replacement for the M113 ambulance. The platform provides uninterrupted lifesaving combat medical support for casualties from Mechanized Infantry and Armor Battalions, and Armored Cavalry Squadrons. The vehicle provides ample work space and medical equipment required for essential treatment en route. The Bradley variant also

significantly improves the mobility, survivability, situational awareness, and communications commensurate with the supported force.

EXISTING PRODUCT DESCRIPTIONS

- The **Armored Medical Treatment Vehicle (AMTV)** is under development to correct identified shortcomings of M577A2 Battalion Aid Station (mobility, survivability, and capability to rapidly treat combat casualties). The AMTV is a derivative of the Command and Control Vehicle (C2V) on a Bradley-based chassis. The AMTV enclosure provides collective protection from chemical/biological agents, an environmental control system, and a separate power source for medical systems not currently found in the M113 family of vehicles.

- The **Critical Care System for Trauma and Transport (CSTAT)** is a mini-intensive care unit consisting of a self-contained evacuation platform for life support incorporating an on-board ventilator, suction unit, oxygen source, patient vital signs monitoring, and closed-loop therapeutic capabilities. The CSTAT interfaces with current military and civilian medical evacuation vehicles and leverages commercial off-the-shelf technology to the maximum extent possible.

- The **Thawed Blood Processing System (TBPS)** is an automated, pump driven deglycerolization filtration device that replaces the existing labor intensive unit currently in use. The new device will reduce size and weight of the existing system by 75% and is expected to reduce disposable costs from approximately $135 to $60. The device employs a simple "pop-in cassette" and an automated microprocessor control system that simplifies the operator control to a single start button. Blood in the new system is totally isolated and closed by the peristaltic pump and solenoid pinch valves to achieve sterility and attain a 2-week extendable shelf life with the automatic addition of a blood additive.

- The **Field Triage Light (FTL)** is powered by a rechargeable battery for use in the triage area of field treatment operations. The light is a man-portable package containing a battery that will provide 8 hours of uninterrupted power, a 110/220 volt recharging circuit, and cables that can provide alternative power to the light; e.g., vehicle battery power.

- The **Far Forward Suction Apparatus (FFSA)** is a portable dual mode aspirator capable of both a high-volume continuous mode for clearing the airway, and a low-volume intermittent mode for maintenance aspiration during transport. The device weighs less than 10 pounds and has dimensions of 12" x 9" x 5". It is capable of operating from multiple power sources including 110/220 volts AC, 10-30 volts DC, or a battery pack capable of at least one hour of continuous operation. Performance

specifications include a vacuum range of 0 to 500 mm Hg; and volume flow of 0 to 4 liters per minute. The design for the collection container is universal enabling the device to be used with any commercial collection containers, both disposable and reusable.

- The **Advanced Surgical Suite for Trauma Casualties (ASSTC)** is a self-contained, rapidly deployable structure capable of providing an area for trauma management, resuscitative surgery, ancillary services, and temporary patient holding. This surgical suite is a compact, modular structure that quickly expands to a shelter space that facilitates patient flow from post-operative care to evacuation for Echelon II Level deployment.

Technology Watch:

- The **Low Temperature Sterilizing System (LTSS)** is a prepackaged dry-powdered chemical sterilant that is added to potable water to effect rapid sterilization of surgical instruments. This product will replace glutaraldehyde which requires over 8 hours immersion time, is toxic, environmentally unacceptable, and is less than optimally effective.

- The **Self-Contained Ventilator (SCV)** is a powered, individually operated ventilatory assistance device for use on casualties in forward areas (Echelon I and II) and during evacuation.

- The **Portable Field Oxygen Concentrator (PFOC)** is a lightweight, man-portable oxygen concentrator ruggedized for field use, which will produce high purity oxygen at a minimum flow of three standard liters per minute. The unit replaces "D" cylinders during patient transport and treatment. The concentrator will be powered by battery or line power and will require Food and Drug Administration (FDA) approval prior to adapting technology for military applications.

- The **Intraosseous Infusion Device (IID)** is a medical device for rapid administration of IV fluids in the bone marrow as an alternative to vascular access for severe shock treatment. The intraosseous infusion device allows placement of a rigid needle into non-collapsible bone for the infusion of fluids and medications directly into bone marrow.

MAJOR ACCOMPLISHMENTS

- A prototype **AMTV** was manufactured by United Defense Limited Partnership (UDLP) under contract from Tank-Automotive and Armament Command, and performed well in Task Force XXI conducted in March 1997. It was then retrofitted for use as a treatment vehicle and evaluated in a Concept Experimentation Program Test in June 1997. A Milestone I/II Acquisition Decision Memorandum was signed 2 July 1997. A common configuration of the AMTV and the C2V has been identified to provide production cost savings.

- Development of a companion vehicle, **AMEV**, was initiated and an Analysis of Alternatives (AOA) was completed. The AOA indicated a modified A2 version of the Bradley Fighting Vehicle is the vehicle of choice for the AMEV. One Bradley A2 was modified by UDLP for use as a concept model AMEV. The turret was removed, the power train upgraded, and the roof raised to an inside height of 63 inches to provide space for four litter patients, four ambulatory patients, and a crew of three. Litter racks and mock-ups of vehicular and medical subsystems were made and installed by USAMMDA. The AMEV concept model will be displayed at the Army Medical Evacuation Conference in San Antonio, Texas, in February 1998.

- A Milestone 0 was approved for the **CSTAT** by the Milestone Decision Authority in June 1997. An Operational Requirements Document was drafted by the U.S. Army Medical Department Center and School (USAMEDDC&S), and an AOA was drafted by USAMMDA. Electromagnetic Interference (EMI) Technical testing of four "Test and Evaluation" prototype units was conducted.

- Design of a 24-hour post wash **TBPS** prototype device to replace the existing labor intensive unit currently in use system was accomplished in 1997. Successful testing of the prototype system was conducted at the Naval Blood Research Laboratory (NBRL) in Bethesda, Maryland. The test data indicated that the prototype is capable of satisfying all FDA requirements for blood chemistry including removal of both the cryoprotectant glycerol and free plasma hemoglobin. The device is fully automated and a 75% reduction in size and weight compared to the currently used device. It will also reduce the cost of the disposable from the current $135 to approximately $60.

- The **Infantry Cart** was made of wood when received from U.S. Army Research Institute of Environmental Medicine (USARIEM). An aluminum container was fabricated, which reduced the weight by 20 pounds. To improve the stability, the suspension design was changed to a pair of lightweight trailing arms hinged by a rubber torsion element that also served as both springs and shock absorbers. Two towing tongues replaced the original single tongue. Using two tongues improved the ergonomics and user safety, and made it possible to use the standard Load Bearing

Equipment belt and suspenders in place of a special belt. The design goals were met and the prototype carts were sent to USARIEM for further evaluation.

- The **FTL** was fabricated and tested for technical performance. It is currently undergoing User Tests at Fort Sam Houston, Texas.

- The Impact Model 326 **FFSA** has been identified by both the Army and Air Force as the best commercial device to satisfy all military requirements because of its dual mode capability. The high volume continuous mode with 500 mm Hg will be used in emergency trauma care primarily to clear airways; whereas, the intermittent mode will be used for maintenance aspiration during transport. The device has been approved by the FDA and put into initial production. A Commercial Item Description has been written; and a National Stock Number, 6515-01-435-0050L, has been issued by the Defense Medical Standardization Board. Aeromedical testing including EMI, Radio Frequency Interference, vibration shock, high temperature, low temperature, and medical evacuation user tests have been successfully completed at Brooks Air Force Base. The final test report is now being prepared for publication. In addition, clinical testing on six emergency patients was conducted by the Hancock County (Tennessee) Emergency Rescue Squad. Results of the tests were favorable and documented in a test report.

- The Marine Corps will organize and chair future meetings of the Test Integration Working Group (TIWG) for the **ASSTC**. The TIWG will culminate in the development of a Test and Evaluation Master Plan (TEMP). The **ASSTC** is currently assigned to the Marines Corps Warfighting Lab for the next 12 months where it will undergo the operational testing identified in the TEMP. The Directorate of Combat and Doctrine Development determined that the AMEDD has no requirement for the ASSTC. Therefore, the USAMMDA has reallocated its personnel and funds to developing other products with requirements. The Joint Special Operations Command (JSOC) is interested in modifying the ASSTC to meet its unique mission requirements. The JSOC and the USAMMDA currently cannot afford the cost of developing a JSOC variant of ASSTC, but have agreed to reevaluate the funding issue next fiscal year.

- Members of USAMMDA were part of the USAMRMC **Oxygen** IPT that was formed to examine the requirements for oxygen systems and innovative methods of oxygen production. In support of the Oxygen IPT, a market investigation of portable oxygen systems was conducted. This market investigation established an information data base for U.S. and foreign manufacturers of oxygen equipment and systems. This organization provided facilities and technical support to Pacific Northwest Laboratories during two demonstrations of ceramic oxygen generators being developed under USAMRMC contracts. In addition, continuing contacts were made with industry and other government agencies to keep current with advances in oxygen generation technologies.

- The JSOC **Resuscitation Station** first prototype engineering design was completed in December 1997.

PROJECTIONS

- A common configuration of the **AMTV** and the C2V will be examined for potential production cost savings.

- A fully operational prototype **AMEV** will be produced for field evaluation. A Milestone I/II IPR will be conducted. Representatives from USAMMDA, the Materiel Developer, will serve on the Deputy Chief of Staff, Operations IPT to provide input on the Bradley Pure Fleet initiative.

- The manufacturer of **TBPS**, Rasor Associates, and the NBRL will begin collecting data for an FDA 510(k) device approval in 2Q98. The initial FDA submittal will be for the "Model A" which is limited t 24-hour post wash shelf life. The "Model B" for 2-week post wash shelf life will be an upgrade to the "Model A."

- Evaluate results of **FTL** User Testing. Obtain a requirements document or commitment from the combat developer or initiate technology watch for a commercial item. Publish technical paper to incentivize industry to develop a similar capability which will increase demand and drive down unit cost.

- Oak Ridge Centers for Manufacturing Technology will complete modifications and improvements to the **ASSTC** and the Marine Corps will conduct Limited User's Assessment.

- The JSOC **Resuscitation Station** will be fabricated and delivered to Fort Bragg for user's assessment in March 1998. Changes to the table will be made based on user feedback and 6 more stations in the final configuration will be fabricated and delivered in 1998.

- After evaluation of the USAMMDA version of the **Infantry Cart** by USARIEM, USAMMDA will work to reduce the weight of the cart by fabricating a composite variant using the new composite laboratory capability.

- If the **Warrior Medic** is successful in obtaining advanced development funding in FY98, a Milestone 0/II will be conducted. This streamlined developmental effort that leverages the Land Warrior system, projects an initial operational test and evaluation for first quarter FY99 and first unit equipped by the fourth quarter FY99.

- The formation of an Integrated Product and Process Team for development of a sound acquisition strategy for the **FB** is crucial for transition of the product to advanced development. A Milestone 0/I is projected for 4th quarter 98. The Integrated Product and Process Team (IPPT) will consist of the Red Cross, Institute of Surgical Research, Walter Reed Blood Research Program Office, Office of the Surgeon General, Joint Staff, and the Army Medical Department Center and School.

APPLIED MEDICAL SYSTEMS
PROJECT MANAGEMENT DIVISION

INDUSTRIAL SERVICES BRANCH

INTRODUCTION

The Industrial Services Branch (ISB), Applied Medical Systems Project Management Division, is a small team of craftsmen model makers possessing at least two trade skills who design, develop drawing packages, and rapidly prototype medical equipment in support of USAMRMC. The ISB is capable of rapidly prototyping medical devices in a range of scales and variety of materials and can also harden commercial off-the-shelf equipment for use in a field environment.

Several initiatives were undertaken in 1997 to modernize ISB capabilities. These include upgrade of existing computers, training and installation of "Pro-E," a three-dimensional CAD/CAM program used commonly in industry, and the purchase and installation of a new computer numeric controlled machine that significantly improves machining capability. Several shop personnel and product managers attended training courses on composite materials. A composite laboratory was set up.

The Joint Special Operations Command Surgeon's office asked the ISB to fabricate a new **Resuscitation Station** to replace their "LeMark" table currently in their medical set. The new table was designed to be a rapidly deployable, man portable surgical table equipped with lights and electrical outlets, and a system to collect liquids used during surgery. Medical supplies are conveniently placed on a frame for easy access during surgical procedures.

An **Infantry Cart** designed and constructed by USARIEM was re-designed by the ISB to make it easier to transport the equipment used by small units. The design goals for the improvement were: weight reduction (weighed 75 lbs upon receipt as USAMMDA), improve stability over rough terrain, and improve the man-machine interface.

In FY97, 70 service requests were completed by the ISB. Approximately 89% of the tasks were in support of the design and fabrication of prototypes for the AMTV. Other organizations supported by ISB are listed below:

Organization	Projects	Hours
USAMRMC	18	194
TATRC	11	193
6th TMMMC	8	30
USACEHR	6	173
USAMRIID	5	156
WRAIR	5	97
USAMMA	5	20
USARIEM	1	473
USAMRICD	1	16
USAG	1	8

PHARMACEUTICAL SYSTEMS
PROJECT MANAGEMENT DIVISION

INTRODUCTION

The Pharmaceutical Systems Project Management Division centrally manages the development and acquisition of pharmaceutical and biological products (drugs, vaccines, toxoids), related drug delivery systems (e.g., autoinjectors), resuscitative fluids, and skin protectants. These products are fielded as preventive, protective and therapeutic modalities for use against infectious diseases, chemical and biological warfare threats, and for the treatment of combat casualties. Product managers leverage domestic and foreign medical technology to remedy deficiencies identified by the Combat Developer and monitor military, industrial, and university research projects for potential solutions to identified problems.

MILITARY RELEVANCE

U.S. Military forces must be prepared to serve anywhere in the world against any threat. This could result not only in conventional injuries sustained during combat operations but exposure to chemical and biological warfare agents as well as exposure to endemic diseases not commonly found in the United States. The development of products against these threats will help save lives, sustain the fighting force and enhance return to duty.

OBJECTIVES

This Division's objective is to develop safe, effective products to be used for prophylaxis, immediate treatment, or definitive treatment of a wide variety of naturally occurring diseases, exposure to chemical and biological agents, and combat injuries. These products include those used for prophylaxis and treatment of botulism exposure, pretreatment and treatment of nerve agent exposure, topical skin protection against percutaneous chemical threat agents, a new multichambered autoinjector which will improve the delivery of nerve agent antidotes, and rapid methods to identify biological threat agents in clinical samples. Additionally, drugs and vaccines are under development to protect against or treat malaria, cholera, shigellosis, meningitis, hemorrhagic fevers, and leishmaniasis.

PRODUCT DESCRIPTIONS

- **Antimalarial Drug WR 238,605** is an 8-aminoquinoline derivative that has demonstrated antimalarial potential in Phase 1 clinical studies. It is being developed as a replacement for primaquine for the prophylaxis and treatment of malaria. A Cooperative Research and Development Agreement (CRDA) has been established with SmithKline Beecham for the development of this product

- **Antimalarial Drug, Azithromycin** is an azalide, a subclass of macrolide antibiotics, similar to erythromycin. It is a U.S. 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.

- **Antimalarial Drug, Halofantrine, Prophylactic** is a 9-phenanthrene-methanol compound. It is a U.S. FDA approved drug for the treatment of malaria. It is being developed as an alternative to chloroquine and mefloquine for the prophylaxis of malaria.

- **Tick-Borne Encephalitis Virus (GERMAN-BPL# 366) Vaccine (TBE)** is an inactivated viral vaccine for prevention of Central European Encephalitis (CEE), which occurs in several European countries, as well as Russia and China.

- **Topical Skin Protectant (TSP)** 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 some chemical and the biological warfare agent, T-2 Mycotoxin. Doctrinally, TSP is to be used as an adjunct to mission-oriented protective posture gear, not as a replacement.

- **Hantaan M-S (Vaccinia Vectored) Vaccine,** a live vaccine engineered at the U. S. Army Medical Research Institute of Infectious Diseases (USAMRIID), was prepared by inserting the genes which code for Hantaan antigens into the live vaccinia virus carrier (smallpox vaccine). The resulting recombinant vaccine elicits antibodies against both vaccinia and Hantaan viruses.

- **Cholera Whole Cell Plus B Subunit Vaccine** 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 testing against both indications has been completed in collaboration with the Naval Medical Research Institute (NMRI).

- **Enterotoxigenic *E. coli* (ETEC) Vaccine** is an oral vaccine prepared from several strains of inactivated whole bacterial cells plus the B subunit of the cholera toxin. This vaccine is manufactured by the SBL Vaccin AB (Sweden) and is being tested in collaboration with the NMRI and the manufacturer.

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

- **Nerve Agent Pretreatment, Pyridostigmine (NAPP)** is a cholinesterase-inhibiting drug which is used prophylactically to mitigate the risk of mortality from the use of nerve agents. Studies show that prophylactic use of NAPP considerably enhances the efficacy of the standard nerve agent antidotes (atropine + 2-pralidoxime).

- **Hypertonic Saline Dextran (HSD)** is a safe and effective small-volume resuscitative fluid, suitable for rapid field administration to stabilize hypovolemic shock casualties. A CRDA has been established with Medisan Pharmaceuticals (Sweden) for the development of this product.

- **Cyanide Pretreatment (CP), WR242511** is an 8-aminoquinoline methemoglobin-forming compound being developed as an oral prophylaxis for cyanide poisoning. Data suggest that this regimen will protect against the lethal effects of two times the LD_{50} (the dose which results in 50 percent of the deaths in the exposed group) of cyanide.

- **Campylobacter Vaccine** is a killed, whole cell oral vaccine adjuvanted with heat labile toxin from *Escherichia coli*. The vaccine is designed to protect against diarrhea and systemic illness caused by gram-negative bacteria of the genus *Campylobacter*.

- **Chikungunya Live Vaccine** is an attenuated vaccine which prevents fever, headache, and severe joint pain caused by the Chikungunya virus. It is designed for administration to military personnel prior to deployment to endemic areas worldwide.

- **Schistosome Topical Antipenetrant (TAP)** is a niclosamide-based skin lotion that is designed to prevent schistosome infection. The lotion applied on the skin will prevent the penetration of free swimming infectious schistosome larvae.

- **Rift Valley Fever Live Vaccine** 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.

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

- **Leishmania Skin Test Antigen** is a formalin-killed promastigote-derived antigen used for screening of Service members who may have been infected with *Leishmania spp.* The antigen was produced under current Good Manufacturing Practices (cGMP) by the Biologics Research Department at the Walter Reed Army Institute of Research (WRAIR).

- **Antileishmanial Drug WR 6026** is an 8-aminoquinoline drug developed as an oral treatment for visceral leishmaniasis. A CRDA has been established with SmithKline Beecham for the development of this product.

- **Malaria Recombinant Vaccine (RTS, S) with Adjuvant Combinations** is a vaccine for the prevention of *Plasmodium falciparum* infections. The vaccine consists of recombinantly engineered immunogenic fractions of the malaria sporozoite surface coat coexpressed with protective epitopes from the hepatitis B surface antigen. The vaccine is formulated in a liquid emulsion containing potent immunostimulants. The CRDA has been established with SmithKline Beecham for the development of this product.

- ***Clostridium botulinum* Toxoid, Pentavalent (Types A,B,C,D,E)** is a toxoid vaccine produced from the specific monovalent toxins of *C. botulinum*, serotypes A,B,C,D, and E, and blended into a pentavalent product. It is produced by the Michigan Biologics Products Institute (formerly Michigan Department of Public Health). Its intended use is for prophylaxis of soldiers against botulism due to aerosol exposure of the aforementioned toxin serotypes.

- ***Clostridium botulinum* Type F Toxoid** is a toxoid vaccine produced from the toxin of *C. botulinum* serotype Type F. It is an Investigational New Drug Application (IND) product produced by the Centre for Applied Microbiology and Research, Porton Down, United Kingdom. Its intended use is for prophylaxis against botulism due to aerosol exposure of the toxin, serotype F.

- **Botulism Antitoxin, Heptavalent Equine, Types A,B,C,D,E,F & G** is an equine antitoxin under development as an intravenously administered treatment of botulism. This antitoxin is prepared by fractionation of plasma from horses hyperimmunized with a single serotype of highly purified toxin. The PerImmune Inc. manufacturing process for this product is designed to minimize the risk of serum sickness and other complications associated with other horse-protein derived products. Because it is heptavalent, this equine preparation should be a broadly effective treatment for botulinal intoxication.

- **Botulism Immune Globulin F (ab')$_2$, Heptavalent, Equine** is an equine antitoxin, manufactured by the University of Minnesota, to be administered intravenously for treatment of botulism. The most important difference between this antitoxin and the current BB-IND 7451 Botulism Antitoxin is that this product was derived from the plasma of one horse, immunized with multiple toxins.

- ***Clostridium Botulinum* Type F Toxoid Vaccine** is an alum-adsorbed, purified monovalent F toxoid manufactured by Porton Products Limited in the United Kingdom. It is intended to protect military personnel against the effects of exposure to Type F toxin when used as a biowarfare threat.

- **Botulism Immune Globulin (BIG)(Human)** is a human pentavalent (A-E) botulinal immune globulin that contains neutralizing activity against botulinal neurotoxins types A,B,C,D, & E. This product is available under an IND protocol for emergency treatment use only.

- The **Diagnostic Kit for Biological Warfare Agents** will be a rapid screening system for use in a field medical laboratory (hospital level), or for use by preventive medicine and veterinary organizations to initially identify biological warfare threats, in clinical samples or in zoonotic specimens. The kit will provide rapid information to the medical care provider and to the preventive medicine and veterinary organizations that can later be confirmed using more sensitive and quantitative technologies.

- **WR279396 Antileishmanial Drug** consists of two aminoglycosides, paramomycin and gentamicin, in an aquaphilic cream to topically treat cutaneous leishmaniasis.

DEVELOPMENT FACILITIES

- **The Vaccine Testing Facility at the University of Maryland at Baltimore's Center for Vaccine Development** conducts Phase 1 Safety and Phase 2 Safety and Efficacy Studies of vaccines. This facility is the only university vaccine center in the world engaged in the full range of vaccinology -- from basic science through vaccine development, clinical evaluation and field studies.

- The mechanism of an Interagency Agreement between the FDA and the USAMRMC was utilized for a **Contingency Vaccine Storage Facility** located at the FDA's National Center for Toxicological Research, Jefferson, Arkansas.

- **South Florida Drug Research Corporation (Miami, FL)** 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. Studies are done in a 60 bed clinical facility or on outpatients. Each study is performed under a specific task order and detailed in accordance with protocol.

- The **Southern Research Institute (SRI), (Birmingham, AL)** conducts toxicology studies on candidate pharmaceutical products. These Good Laboratory Practices (GLP)-compliant animal studies are required by the FDA to support INDs and New Drug Applications (NDA). Each study is performed under a specific task order and in accordance with a detailed protocol.

MAJOR ACCOMPLISHMENTS

- A Phase 2a treatment study of **WR 238605** has been completed. WR238605 was effective in preventing relapsing vivax malaria.

A Phase 2a prophylactic study for **WR238605** was conducted in Kenya. WR238605 was 95 percent effective in protecting against falciparum malaria in semi-immune individuals.

- Field studies for **Azithromycin** were completed in Irian Jaya, Indonesia and Thailand. Azithromycin was 95 - 98 percent effective in protecting against vivax malaria but only 70 percent effective against falciparum malaria.

- A Phase 1 safety study of **Halofantrine** was completed at Georgetown University. Daily doses of 500 mg of Halofantrine caused a prolongation of the QTc interval. The risk of this prolongation must be determined. A Phase 2 efficacy study has been postponed.

- CRDA Negotiations continued with the German manufacturer of the **Tick-Borne Encephalitis Virus (GERMAN-BPL# 366) Vaccine** to finalize pricing policy between the manufacturer and the USAMRMC.

- A clinical efficacy study demonstrated that the **Topical Skin Protectant (TSP)** protects against poison ivy contact dermatitis, a surrogate to chemical warfare agents challenge model. A concurrence on issues regarding TSP's manufacturing development was obtained from the FDA. The NDA for the TSP is under preparation.

- A new lot of the **Hantaan M-S (Vaccinia Vectored) Vaccine** has been produced and the lot release data sent to the FDA. Volunteers receiving the vaccine developed measurable titers against both Hantaan virus and against smallpox virus. However,

those volunteers who had previously received the smallpox vaccine failed to develop a titer against Hantaan virus. Therefore, this vaccine has limited military use. A Special In-Process Review was held 2QCY97 and the decision was to terminate the advanced development of the Hantaan M-S vaccine.

- The IND sponsorship for the **Cholera Whole Cell Plus B Subunit Vaccine** has been turned over to SBL Vaccin AB and consideration for licensing relinquished. No further funds for development are being expended.

- **Enterotoxigenic *E. coli* (ETEC) Vaccine** - A Phase 1/2 safety and immunogenicity trial was initiated on Egyptian infants and school-age children.

- Discussions regarding the feasibility of licensing **Argentine Hemorrhagic Fever Live Vaccine** were conducted with the FDA. Due to loss of the manufacturer, no future intent to routinely manufacture it by the Army, and the extremely low level of use, the FDA recommends that licensure of this product not be pursued.

- The revised NDA for the **Nerve Agent Pretreatment Pyridostigmine** was filed with the FDA on 24 May 1996 and a "not approvable" letter was received from the FDA on 24 May 1997. An Army-based response to that FDA-based letter was sent to the FDA in December 1997. Further action to obtain FDA-based approval of the NDA will depend upon FDA's response to the Army's letter.

- The CRDA partners have worked closely with the FDA to obtain guidance on submission of **Hypertonic Saline Dextran** covariant meta-analysis data. These data and cGMP practice data were submitted to the FDA as an addendum to the HSD NDA submission. The FDA sent a not-approvable letter to the CRDA partners. A meeting was held in August with the FDA to discuss issues and to develop a plan for addressing FDA concerns. Several responses have been submitted to the FDA.

- Segment III (chronic) reproductive studies were begun for **Cyanide Pretreatment**. Training of non-human primate test subjects was completed for the serial-probe recognition study. The final draft of the IND document was completed; and submission to the FDA is awaiting inclusion of the Institutional Review Board approved clinical study protocol.

- Clinical challenge studies of the **Campylobacter Vaccine** conducted by investigators from the Naval Medical Research Institute are being conducted at USAMRIID.

- Clinical studies were completed providing additional safety and immunogenicity data for **Chikungunya Live Vaccine**.

- It was determined, through Scientific Steering Committee and follow-up discussions, that a definitive human efficacy study using the **Schistosome Topical Antipenetrant** lotion is unfeasible. Alternate formulations recommended by the Centers for Disease Control and Prevention (CDC) are not desired for military use, and the program is currently unfunded because of budget cuts. Therefore, we are pursuing the possibility of a technology transfer before recommending the termination of the program.

- **Rift Valley Fever, Live Vaccine** development was sustained as an unfunded requirement.

- The FDA approved the regulatory filing of a 505(b)(2) for the **Multichambered Autoinjector**. That filing requires comparable bioavailability data but does not require clinical efficacy data.

- The Phase 1 clinical trial for the **Leishmania Skin Test Antigen (LSTA)** was completed at the WRAIR clinical trial section. The LSTA entered the program definition and risk reduction phase of development.

- A Phase 2 efficacy open clinical trial of the antileishmanial drug **WR 6026** continued in Vitoria, Brazil during 1997. The purpose of the trial is to determine the most efficacious dose needed to treat visceral Leishmaniasis.

- A Pre-IND submission meeting between the Department of the Army, PerImmune, Inc., and the FDA, Office of Blood Research and Review, Division of Blood Applications was held on 18 March 1997, regarding the **Botulism Antitoxin, Heptavalent, Equine, Types A,B,C,D,E,F, & G**. Per the FDA's recommendation, adventitious virus testing was conducted on the plasma pools, procine pepsin, and final products that were used to manufacture the heptavalent lot of antitoxin to be used for the planned clinical study. Based on this test data and experience with similarly derived products, it is unlikely that this product presents any unusual potential for human risk. The IND was submitted to the FDA on 11 December 1997. Planning was completed for the conduct of a Phase 1 clinical study protocol entitled "*Safety and Pharmacokinetics of Botulism Antitoxin, Heptavalent, Equine, Types A,B,C,D,E,F, and G Administered Intravenously to Human Subjects*" as the intended initial safety evaluation of this botulism antitoxin.

- All lots of **Botulism Immune Globulin (BIG) F (ab')$_2$, Heptavalent, Equine** were potency tested. This product remains available for use in emergency treatment situations.

• **Clostridium Botulinum Type F Toxoid Vaccine** -- For the clinical study "*Phase 2 Safety and Immunogenicity Study of Type F Botulinum Toxoid in Volunteers,*" the 12 month serology was drawn from the last cohort in July 1997. The booster phase of the trial is underway. Although causing more local reactions than a licensed, alum-adsorbed hepatitis B vaccine, the alum-adsorbed Bot F toxoid (10 μg dose) administered three times over 28 to 42 days was generally well tolerated and safe, whether injected by the subcutaneous or intramuscular route.

• **Botulinum Immune Globulin (BIG)(Human)** was used as the test antibody in animal studies conducted by Battelle Medical Research and Evaluation Facility to support neutralizing titer as a serological endpoint to serve as a surrogate marker for efficacy of the Botulinum Pentavalent Toxoid Vaccine. The BIG (Human) antitoxin is available under an IND clinical protocol for emergency treatment use only to individuals who may have been exposed to botulinum toxin(s).

• For the **Diagnostic Kit for Biological Warfare Agents,** Draft Analysis of Alternatives was completed which analyzed risk factors, operational effectiveness, and life cycle costs. The lack of funding delayed program initiation.

• A proof of principle trial for the **Antileishmanial Drug, WR279396,** is currently underway in Brazilian Army troops naturally infected during jungle training exercises in the Amazon Region outside Manaus, Brazil.

• Ongoing efforts at the **University of Maryland at Baltimore Vaccine Testing Facility** include:

(1) A Phase 1 clinical study of four dengue monovalent live-attenuated vaccine candidates. This year a determination of whether administration of a second dose of the dengue vaccines will improve their immunogenicity was investigated. Moreover, based on the results of the first clinical trial iteration performed in May - June 1997, the study protocol will be amended to call for simultaneous administration of all four dengue vaccines mixed in a syringe, i.e. combination vaccination. The concept is that the remaining two clinical iterations would be used to explore the optimum dose of each dengue virus type when all are mixed as quadrivalent combinations.

(2) In April 1997, the Phase 2 Chikungunya Virus Vaccine Safety Study was fully enrolled with 48 volunteers, and they will be followed for one year after immunization.

(3) For the clinical study "*Phase 2 Safety and Immunogenicity Study of Type F Botulinum Toxoid in Volunteers,*" the 12 month serology was drawn from the last cohort in July 1997. The booster phase of the trial is underway.

- The Interagency Agreement for a **Contingency Vaccine Storage Facility** at the National Center for Toxicological Research expired in CY97.

- In a double-blind, placebo controlled Phase 1/2a laboratory mosquito challenge study, the **Malaria Recombinant Vaccine (RTS,S) with Adjuvant Combination** protected 86 percent of the volunteers. All volunteers who received the vaccine, even those who were not protected from *Plasmodium falciparum,* also produced high levels of protective antibodies to the Hepatitis B Virus. In July 1996, a combination MS 0/I was conducted that moved this product into advanced development. A second Phase 2 study was completed in 1QCY97 to verify the first study. A Phase 2b study in Kenya is planned to start in 1QCY98.

- A licensing effort to submit an Establishment License Application/Product License Application (ELA/PLA) to the FDA for ***Clostridium botulinum* Toxoid, Pentavalent (Types A,B,C,D,E)** is currently underway. The animal studies for development of serological endpoints of protection were completed in CY97 and the data are currently being analyzed. As a consequence of the FDA Advisory Committee meeting, further animal studies were suggested by the FDA staff. Those animal protocols were drafted and submitted to the FDA. The first of these new studies has been initiated. The "pivotal" human immunogenicity study was delayed due to indemnification issues. Various regulatory issues have been discussed with the FDA staff during CY97. Also, data for the submission of the ELA and PLA have been actively accumulated and analyzed.

- **South Florida Drug Research Corporation** A final report was received for the study titled "An Assessment of the Contact Sensitization and Contact Photo Allergic Potentials of a Topical Skin Protectant." A draft report for the study titled, "A Multiple Dose Safety, Tolerance and Pharmacokinetic Study of WR 238605 When Given to Male and Female Subjects" was delivered. A new task order has been initiated to conduct a single dose rising study for WR 242511, a potential cyanide prophylaxis.

PROJECTIONS

- A Phase 2 prophylactic study for **WR 238,605** will be conducted in Kenya in semi-immune and nonimmune individuals. A full dose-ranging study is planned in a holoendemic area. A Phase 2b vivax treatment study for **WR238605** will be conducted in Thailand.

- A Special In-Process Review will be held in CY98 to determine the future development of **Azithromycin.**

- A Special In-Process Review will be held in CY98 to determine the future development of **Halofantrine.**

- It is anticipated that CRDA negotiations for **Tick-Borne Encephalitis Virus (GERMAN-BPL # 366) Vaccine** will be completed in 2QCY98, and an IND application will be prepared and submitted to the FDA. Initial clinical trials are planned for 4QCY98.

- The Chemistry, Manufacturing, and Controls section of the NDA for the **Topical Skin Protectant** will be completed in 2QCY98. The NDA will be completed and submitted in 3QCY98.

- The advanced development on **Hantaan M-S (Vaccinia Vectored) Vaccine**) was terminated in 2QCY97 based on the recommendation of the Special In-Process Review. There are no future plans for this vaccine.

- The IND sponsorship of the **Cholera Whole Cell Plus B Subunit Vaccine** has been turned over to the manufacturer, SBL Vaccin AB.

- A CRDA with SBL Vaccin AB for further development of the **Enterotoxigenic *E. coli* (ETEC) Vaccine** will be finalized. A new lot of the vaccine, suitable for performing pivotal efficacy trials, was manufactured. A pivotal (Phase 3) efficacy trial will be initiated in collaboration with the Israeli Defence Force after a CRDA is approved.

- A correspondence In-Process Review will be prepared to terminate further development of **Argentine Hemorrhagic Fever Live Vaccine (AHF).**

- The FDA-provided decision on the NDA for **Pyridostigmine** will be evaluated. Follow-up action, based on the decision of the FDA, will be undertaken, and the Acquisition Strategy for the Nerve Agent Pretreatment Pyridostigmine will be modified as necessary.

- **Hypertonic Saline Dextran** - The CRDA partner will submit final responses to issues raised by the FDA on HSD in their not-approvable letter. If all questions are satisfactorily addressed, an approvable letter can be expected.

- An IND for **Cyanide Pretreatment** will be filed with the FDA 1QCY98. Single-dose human safety and tolerance testing will begin 2QCY98. Non-human primate serial probe recognition studies will be completed 2QCY98.

- A new lot of the **Campylobacter Vaccine** will be prepared by Autex Biologics, Inc., Gaithersburg, Maryland. Epidemiological data from several potential field sites will be evaluated to determine the optimal site to test the adjuvanted **Campylobacter Vaccine** in CY98.

- The Combat Developer will review the requirement for **Chikungunya Live Vaccine** in view of funding shortfalls for 1998 and beyond.

- Tech transfer actions will be completed and a Special In-Process Review of **Schistosome Topical Antipenetrant** will be conducted in 3QCY98.

- The Combat Developer will review the requirement for **Rift Valley Fever, Live Vaccine** in view of funding shortfalls in 1998 and beyond.

- The **Multichambered Autoinjector** will undergo the critical Clinical Bioequivalence Study. The Study Report will be evaluated and then a decision on subsequent Acquisition Strategy will be made.

- A Phase 2b efficacy study for **Malaria Recombinant Vaccine (RTS,S) with Adjuvant Combinations** will be initiated in Kenya. A lyophilized RTS,S reformulated product should be completed by 4QCY98.

- A Phase 2 efficacy study for the **Leishmania Skin Test Antigen (LSTA)** will be initiated in Peru. A non-lyophilized LSTA will be manufactured under cGMP.

- The Phase 2 clinical trial in Brazil for the antileishmanial drug **WR6026** will be completed by February 1998.

- The **Botulism Antitoxin, Heptavalent, Equine, Types A,B,C,D,E,F, and G** will undergo a Phase 1 clinical study protocol to evaluate the safety of this product. After conclusion of the Phase 1 study, an emergency treatment use protocol will be filed to the IND for use of this botulism antitoxin for therapy of suspected botulism intoxication. This manufactured heptavalent antitoxin product will undergo semi-annual stability testing.

- **The Botulism Immune Globulin F $(ab')_2$ Heptavalent, Equine** will be potency tested. This product will remain available for use in emergency treatment situations.

- Twelve month post-booster serology will be drawn from the final **Clostridium Botulinum Type F Toxoid Vaccine** cohort in June 1998. The study will end in CY98.

- **Botulinum Immune Globulin (BIG)(Human)** will continue to be used as the test antibody in animal studies conducted by Battelle Medical Research and Evaluation Facility to support neutralizing titer as a serological endpoint to serve as a surrogate marker for efficacy of the Botulinum Pentavalent Toxoid Vaccine. The BIG (Human) antitoxin will remain available under an IND clinical protocol for emergency treatment use only to individuals who may have been exposed to botulinum toxins (s).

- The **Diagnostic Kit for Biological Warfare Agents** program will be transferred to the Joint Vaccine Acquisition Program - Project Management Office. An Integrated Product Team must be formed to assist in determining projected outyear funding requirements per FDA guidance for *in vitro* and *in vivo* Pharmacokinetic and Pharmacodynamic Studies to develop surrogate animal models.

- The **University of Maryland of Baltimore Vaccine Testing Facility** is conducting three clinical trials for the USAMMDA. One trial is the continuation of the Phase 1 clinical study of four dengue monovalent live attenuated vaccine candidates. In CY98, the protocol will be modified, and then reenter the queue for a clinical slot at the testing facility. The second trial is a Phase 2 Chikungunya Virus Vaccine Safety Study which will perform the one year serological follow-up of the final cohort in April 1998. This study will end in CY98. The third trial is a Phase 2 Safety and Immunogenicity Study of Type F Botulin Toxoid which will conduct 12 month post-booster serology from the final cohort in June 1998. The study will end in CY98.

- The **Contingency Vaccine Storage Facility** agreement at the National Center for Toxicological Research expired in CY97. The Joint Program Office for Biological Defense will determine if this agreement should be renewed.

- Tasks will be initiated on the **Toxicology Contract.** Two anticipated tasks are a 2-year Carcinogenicity Study of WR 238605, a potential antimalarial drug in the rat and a 6-month Carcinogenicity Study of WR 238605 in the transgenic mouse.

- It is anticipated that the ELA/PLA for ***Clostridium botulinum*** **Toxoid, Pentavalent (Types A,B,C,D,E)** will be submitted in CY00. The clinical study should be initiated in CY98 pending resolution of the indemnification issues. Also, the new animal studies should be completed in CY99. The management responsibility for this product will transition from USAMMDA to the Joint Vaccine Acquisition Program Office in CY98.

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QUALITY ASSURANCE OFFICE (QAO)
QUALITY ASSURANCE AND REGULATORY AFFAIRS

INTRODUCTION

The Quality Assurance Office (QAO) supports the Advanced Development Project Management Divisions and early clinical research activities. The Office ensures quality and acceptability of safety and efficacy study data, control processes, manufacturing data and regulatory documentation for submission to the Food and Drug Administration (FDA) in support of product approval. Although teamwork and close coordination with product development groups are essential, the Quality Assurance (QA) team provides this support function independently, reporting directly to the United States Army Medical Materiel Development Activity (USAMMDA) Director.

MILITARY RELEVANCE

The DOD, through The Surgeon General, has determined that certain pharmaceutical, biological and device products are essential for protection of the war-fighter and is committed to obtaining FDA approval documenting safety and efficacy of the products. The QA and Regulatory Affairs programs provide essential monitoring of clinical studies and regulatory advice leading to generation of data with the necessary integrity to support product approval.

OBJECTIVES

Continue to foster an environment receptive to the needs and requirements of the product development process; streamline and standardize the product development process by provision of quality assurance and regulatory affairs guidance; serve as a learning resource for regulatory requirements; forge cooperation with allied government organizations and industry.

MAJOR ACCOMPLISHMENTS

- The QAO role was expanded with the addition of responsibility for monitoring early (technology base) clinical studies and the Special Immunization Program (SIP) studies. Two additional quality assurance positions have been assigned to fulfill personnel requirements of this broadened monitoring role. A full complement will be in place with the filling of these positions and the military position vacancy which occurred in August 97.

- The change in QAO leadership underwent smooth transition in May.

- Our staff augmented QA and regulatory knowledge through attendance at Good Clinical Practices (GCP), Good Laboratory Practices (GLP), and Good Manufacturing Practices (GMP) courses. One staff member successfully completed requirements for Level III certification in the Army Acquisition Workforce.

- The Office strengthened relationships among Federal regulatory and military organizations, project and product managers, laboratories, and industry. We collaborated in the planning and development of study protocols and monitoring of priority product studies. Our monitoring and related activities have improved study performance and documentation which should enhance and accelerate the approval process. Examples include the Reduced Schedule Anthrax Vaccine, Botulism Immune Globulin f(ab')2 Heptavalent (Equine), *Botulinum* Pentavalent (ABCDE) Toxoid, *Botulinum* Type F Toxoid, Malaria Vaccine, *Shigella flexneri* Vaccine, *Escherichia coli* Vaccine, Campylobacter Vaccine, Etaquine Anti-malarial, Anti-leishmanial WR 239,396 and Topical Skin Protectant.

- Quality Assurance and Regulatory Affairs staff briefed principal investigators and product managers regarding monitoring findings from 30 specific monitoring visits and activities both in the United States and abroad. (See the Visit and Activity Schedule following this section.) Out-briefings following in-life monitoring were specifically tailored to serve as learning experiences regarding regulatory requirements for field investigators.

- The Principal Investigators Clinical Studies Handbook was developed as a regulatory learning and reference guide. This resource has also been provided on the USAMMDA internet home page and includes an annotated interactive regulation reference to FDA and international GCP requirements.

- Our office contributed to the smooth transition of the technical based antileishmanial product, WR 279,396 to Advanced Development status.

- The QAO has been responsible for managing the review, completion and timely submission to the FDA of all required documents and reports generated by technical based research conducted on human subjects.

- A QAO staff member has also become an active member of the Human Subjects Research Review Board (HSRRB) Subcommittee for Review of Materiel List Plans and Protocols.

- A QAO member has served as Contracting Officer's Representative for the Engineering and Economical Research (EER) Regulatory Affairs Contract supporting numerous product development activities. Technical knowledge of quality assurance and regulatory affairs is provided to assure that contract tasks are planned and carried

out according to needs and specifications. This activity also serves as a vital link integrating the QAO to specific current and prospective product development activity in the USAMMDA Project Management Divisions.

PROJECTIONS

- Increased involvement of the QAO as a vital support element for USAMMDA product development is anticipated. Continental United States and outside continental United States monitoring visits are planned for early 1998, and increased emphasis will be placed upon cooperation and training within the QA monitoring function for all human use studies.

- The QAO is assuming responsibility for technology base IND and SIP studies involving human subjects.

- We intend to expand internet information and education links to all study sites and to collaborate with all DOD laboratories to develop GCP training.

- The QAO will develop standard operating procedures to provide internal standards.

The QAO will collaborate with HQ, USAMRMC Regulatory Compliance and Quality Division (RCQ) in the development of command-wide policies for conducting clinical trails.

Visit and Activity Schedule, to Quality Assurance Office Annual Report for CY 97.

DATE	PRODUCT	SITE	ACTIVITY
JAN	WR 238605 (Etaquine)	Kenya	Pre-study Visit
	Halofantrine	Ghana	Pre-study Visit
	ETEC	Egypt	Pre-study Visit
	ETEC	Egypt	Close-out
FEB	Leishmaniasis Skin Test Antigen	WRAIR	Monitoring Visit
	Halofantrine	Georgetown U.	Safety Study
	Anthrax; Bot Toxoid A-E	E. Lansing, MI	Monitoring Visit
	Botulism Toxoid Type F	U. of Maryland	Mid-study Visit
	Anthrax	USAMRIID	Mid-study Visit
MAR	Leishmaniasis Skin Test	WRAIR	Monitoring Visit
MAY	Botulism Toxoid A-E	Columbus, OH	Monitoring Visit
	ETEC	Israel	Initiation/Mid-study Visit
JUN	Halofantrine	Georgetown U.	Monitoring Visit
	Topical Skin Protectant	NNMC	Mid-study Visit
	WR 238605 (Etaquine)	Kenya	Mid-study Visit
	TBE	USAMRIID	Mid-study Visit
JUL	Topical Skin Protectant	NNMC	Mid-study Visit
	Campylobacter	USAMRIID	Initiation Visit
SEP	WR 279396 (Paromomycin/Gentocin)	Brazil	Pre-study Visit
	WR 279396 (Paromomycin/Gentocin)	WRAIR	Monitoring Visit
	RTS,S, A-7492	WRAIR	Vaccine Challenge
	RTS,S, A-7492	WRAIR	Mid-study Visit
	Campylobacter	USAMRIID	Mid-study Visit
NOV	Botulism Toxoid A-E	Columbus, OH	Monitoring Visit
	Shigella Flexneri	USAMRIID	Vaccine Prep and Admin
	Q-Fever	USAMRIID	Mid-study Visit
DEC	Botulism Toxoid Type F	Baltimore, MD	Mid-study Visit
	Chikungunya Fever	U. of Maryland	Mid-study Visit
	Shigella Flexneri	USAMRIID	Mid-study Visit
	Campylobacter	USAMRIID	Mid-study Visit

PROJECT MANAGEMENT SUPPORT DIVISION

INTRODUCTION

The Project Management Support Division (PMSD) provides financial, contractual, logistical, and administrative support to the two Project Management Divisions. The successful accomplishment of project management division 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 future operational capabilities; 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.

RESOURCES MANAGEMENT

- **Project Management Division Database (PMDD), Product Management Database System (PMDS), and Special Users Database System**:The existing systems were maintained through telephone and on-site support of the Budget Analysts, Project Managers, and Product Managers. Monthly backups were maintained offsite. Minor enhancements to address problems and potential problems were incorporated, and updated versions of the programs were installed into the system. The import routines for the existing financial systems, and relationship with PMDS concerning reports for the Financial Management System (FMS), were investigated. New Product Managers and Project Managers were added into PMDS and PMDD. A separate division, Support, was established and integrated into the various systems, and a new report was created for the FMS database system.

- **Project Management Support Contract:** The Project Management Support Division provided the Contracting Officer's Representative for the USAMMDA support contract with Cambridge Consulting Corporation (CCC). The contract provides Project and Product Managers with additional resources for the development of required documentation, cost estimates and analytical services in an efficient and timely manner.

During this year, tasks given to the contractor included analyses of alternatives, preparation of Milestone In-Process Review read-ahead packages, and market investigations. The work performed this year also included providing full-time support personnel for Information Management services, project management support for the AMTV and biological warfare defense vaccine developments.

• **Medical Research, Development, and Acquisition (RDA) Mission Area Materiel Plan (MAMP): Medical Research, Development, and Acquisition (RDA) Mission Area Materiel Plan (MAMP):** In 1994, the USAMEDDC&S took the lead in organizing and executing the AMEDD's MAMP. The 1997 Medical RDA MAMP was conducted at the USAMEDDC&S on 9 June 1997. The MAMP performed product assessments for evaluating the USAMRMC Research and Development program with respect to medical-related combat requirements. Representatives from USAMMDA, USAMEDDC&S and USAMMA evaluated 37 products and formally assessed 38 products against 12 Future Operational Capabilities (FOCs). The FOCs, based on AMEDD deficiencies, enhancements, and obsolescences, are weighted in terms of relative importance. A paired comparison technique was used to determine the relative weight of AMEDD FOCs used in the ranking process. This component integrated medical materiel with an FOC "fix" to pinpoint the highest payoff for advanced development efforts. Prevention was shown to be relatively more important than either treatment or evacuation. A value-added component, 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 preventive 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 was 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). The MAMP priority list is a fully integrated effort to develop a systematic, prioritized, long-range Research, Development, and Acquisition strategy for medical materiel acquisition. Results of the MAMP, Appendix C, were distributed to all interested parties. The MAMP results are used as a tool to guide program planning and execution.

INFORMATION MANAGEMENT

• **Automated Data Processing Support:** The current local area network (LAN) was upgraded to a Windows NT-based network. New wiring for the building was installed for a 10baseT LAN interface from the old 10base2 configuration. Desktop computer workstations were all upgraded to at least 16 Mbytes of RAM and Windows 95 operating system was installed at each workstation. Additionally, all users were

provided with Microsoft Office 97 suite of applications software. The majority of the Intel 486 desktop computers were replaced with Pentium II machines.

UNIT SUPPORT

FACILITY

- **Buildings:** 622 - 12,762 sq. ft.
  1054 -16,831 sq. ft.
  1056 - 1,603 sq. ft.

- **Changes to buildings during FY97:**

Building 622 - No significant changes.

Building 1054 - Repaired plumbing and drains in the men's room. Replaced large exterior paint room to ensure energy efficiency. Replaced and widened the overhead exterior door to allow AMTV access into the building.

Building 1056 - USAMMDA has temporarily loaned floor space to the Project Manager, Medical Digital Imaging System.

- **Supply Requisitions:**

422 Total Requisitions
- 379 IMPAC Credit Card Purchases
- 33 Purchase Requests
- 20 Stocked Items through the Warehouse

$661,000 Committed to Requisitions

- **Property Book Values:**

Oct 96 - 587 line items = $4,087.156 value
Sep 97 - 430 line items = $4,119,717 value
- 157 +$ 32,561 value

HUMAN RESOURCES

- **Manpower**:

a. Planning was initiated in October 1997 to effect civilian reductions of the Research, Development, Testing and Engineering (RDT&E) manpower structure based on the Defense Planning Guidance FY 99-03. The divisions implemented plans to reduce manpower over the next four years by assessing mission requirements and redistribution of workload. Civilian authorizations were reduced by 18 (a reduction of 39%).

b. A Matrix Support Plan agreement between the Joint Program Office for Biological Defense and the USAMRMC was signed 21 July 1997. Under this agreement, USAMMDA will dedicate two full-time and two four-year term microbiologist positions to the Joint Vaccine Acquisition Program (JVAP) Project Management Office. These positions were recruited and one individual was hired in September.

c. A Supervisory Program Analyst, GS-14, was recruited under the Comptroller Career Program.

- **Personnel**:

a. There were four civilian accessions, three employees transferred, and one employee was promoted.

b. Military personnel actions included six accessions, one retirement, one resignation, and three transfers.

c. Civilian Awards:

24 exceptional performance evaluations
24 performance awards
1 Commander's Award for Civilian Service
4 Time-Off Awards
1 On-the-Spot Cash Award

d. Military Awards:

4 Meritorious Service Medals
2 Army Commendation Medals

e. David E. Steele, DVM, and Mr. D. Scott Doughty were certified at Level III in the Army Acquisition Workforce (AAW).

- **Key Personnel**:

Position	Name	Date
Director	Dr. J.H. Nelson	01 Jan 97 to 31 Dec 97
Deputy Commander	LTC T.J. Burke	01 Jan 97 to 31 Dec 97
Acting Project Manager, AMSPMD	MAJ T.L. Syvertson	01 Jan 97 to 31 Dec 97
Project Manager, PSPMD	Dr. R.E. Clawson	01 Jan 97 to 31 Dec 97
Chief, PMSD	Mr. W.R. Ferguson, Jr.	01 Jan 97 to 02 Aug 97
Chief, QAO	LTC D.K. Feil MAJ E.D. Fleming	01 Jan 97 to 05 May 97 06 May 97 to 31 Dec 97
Administrative Officer	Ms. D.W. Albright	01 Jan 97 to 31 Dec 97

- **Strength**: As of 31 December 1997:

	Military	Civilian	Contractors	Total
Required	17	51	14	82
Authorized	10	41	0	51
Actual	9	39	4	52

FISCAL PERFORMANCE

- **In-House**: In FY97, USAMMDA's In-House fiscal execution exceeded the USAMRMC disbursement target by 21 percent. Obligations were less than one percent below the established target.

	In-House		
	Allotment	Obligations	Disbursements
Fiscal 1997 Dollars ($000)	3,148	3,109	2,271
Target (%)		100	51
Actual (%)		99	72

• **Program Wide:** Disbursements exceeded the target established for the FY97 total laboratory program, and laboratory obligations were within 7% of target. Performance in the command-wide development program fell below the target levels, attributable to a drop in extramural and laboratory activity. However, total program execution was within .7% of the percentage levels reached in FY96 in both obligations and disbursements. Fiscal execution performance at the project level is provided in Appendix G.

	Program-Wide		
	Allotment	Obligations	Disbursements
Fiscal 1997 Dollars ($000)	18,170	16,974	7,827
Target (%)		100	51
Actual (%)		93	43

INTEGRATED LOGISTICS PLANNING

• **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 II	Hantaan M-S (Vaccinia-Vectored) Vaccine
MS I/II	Armored Medical Treatment Vehicle (AMTV)

• **Integrated Product Team (IPT) and Working Group Support:**

- Medical Communications for Combat Casualty Care (MC4) Integrated Product Team
- Advanced Surgical Suite for Trauma Casualties (ASSTC) Integrated Product Team
- Field Oxygen Integrated Product Team
- AMTV Integrated Product Team
- AMTV System Safety Working Group
- AMTV Test Integration Working Group

- **General Logistics/Acquisition:**

  - Updated and maintained USAMMDA World-Wide Website at http://www.armymedicine.army.mil/usammda/.

  - Provided contracting officer representatives for three contracts (Pathology Associates International; Cambridge Consulting Corporation; Guild Associates, Inc.).

  - Provided support for Joint Vaccine Acquisition Program (JVAP) Source Selection Board.

  - Updated USAMMDA Standard Operating Procedure (SOP) on Market Investigations, Transition Planning, and Integrated Logistic Support.

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APPENDIX A

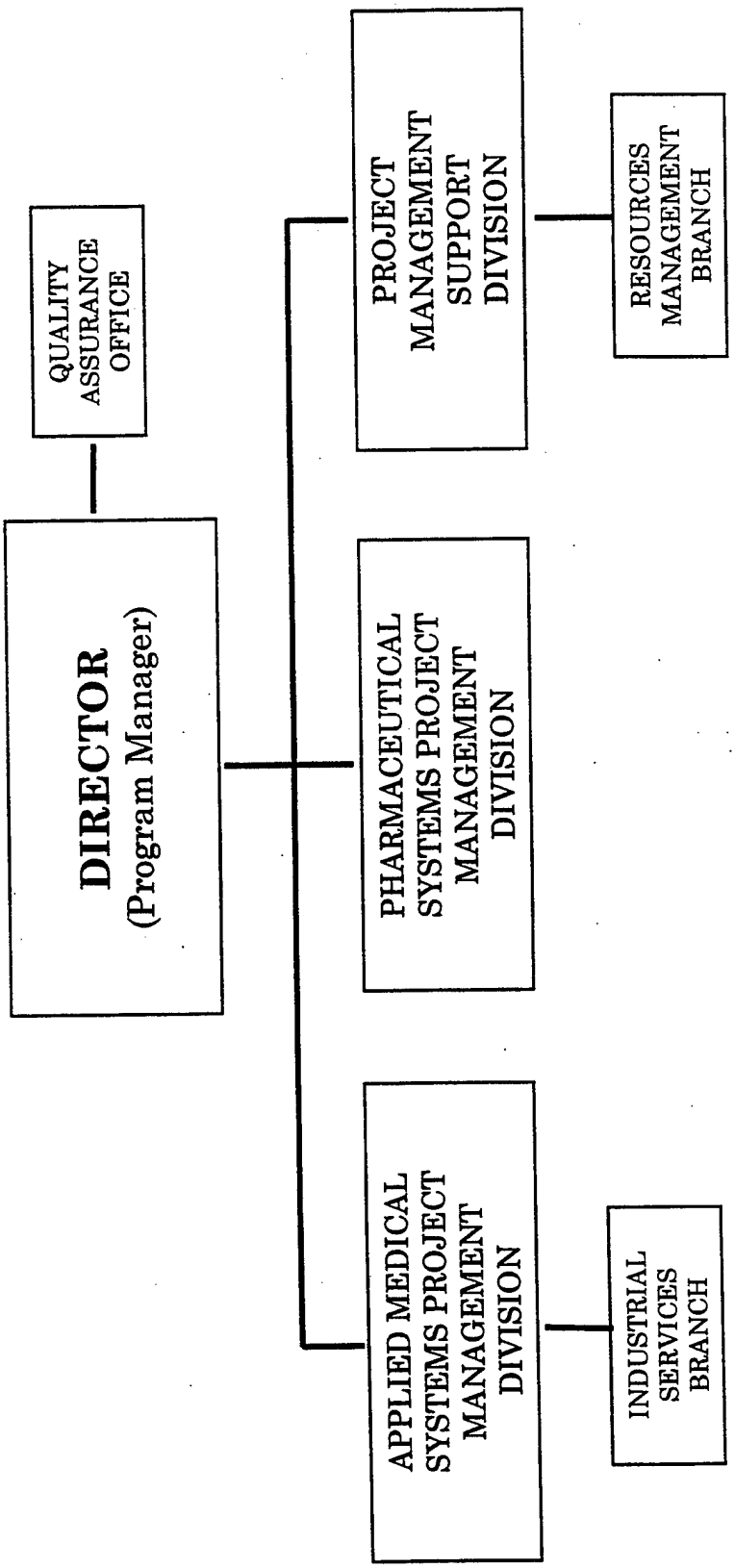
ACRONYMS

AMEDD	Army Medical Department
AMSPMD	Applied Medical Systems Project Management Division
AOA	Analysis of Alternatives
CDC	Center for Disease Control and Prevention
cGMP	Current Good Manufacturing Practices
CRDA	Collaborative Research and Development Agreement
CY	Calendar Year
C2	Command and Control
C2V	Command and Control Vehicle
DOD	Department of Defense
ELA	Establishment License Application
EMI	Electromagnetic Interference
FDA	Food and Drug Administration
FMS	Financial Management System
FOC	Future Operational Capabilities
FY	Fiscal Year
GCP	Good Clinical Practices
GLP	Good Laboratory Practices
HSRRB	Human Subjects Research Review Board
ILSP	Integrated Logistic Support Plans
IND	Investigational New Drug Application
IPPT	Integrated Product and Process Team
IPR	In-Process Review
IPT	Integrated Product Team
ISB	Industrial Services Branch
JVAP	Joint Vaccine Acquisition Program
JSOC	Joint Special Operations Command
LAN	Local Area Network
MAMP	Mission Area Materiel Plan
MANPRINT	Manpower and Personnel Integration
MC4	Medical Communications for Combat Casualty Care
MS	Milestone
NBRL	Naval Blood Research Laboratory
NDA	New Drug Application
NMRI	Naval Medical Research Institute
NNMC	National Naval Medical Center
PdM	Product Manager

PLA	Product License Application
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
QAO	Quality Assurance Office
RAM	Random Access Memory
RDA	Research, Development and Acquisition
SIP	Special Immunization Program
TEMP	Test and Evaluation Master Plan
TIWG	Test Integration W orking Group
UDLP	United Defense Limited Partnership
USAMEDDC&S	U.S. Army Medical Department Center and School
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
WRAIR	Walter Reed Army Institute of Research

APPENDIX B
ORGANIZATIONAL CHART

United States Army Medical Research and Materiel Command
United States Army Medical Materiel Development Activity



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APPENDIX C

PROGRAM PRIORITIZATION MAMP LIST

PRODUCT	1997 AMEDD PRIORITY
Hypertonic Saline Dextran	1
Topical Skin Protectant	2
Nerve Agent Antidote, Multichambered Autoinjector	3
Antimalarial Drug, WR238,605	4
Test Mate Cholinesterase Test Kit	5
Nerve Agent Pre-Treatment Pyridostigmine	6
Cyanide Pretreatment	7
Armored Medical Evacuation Vehicle	8
Life Support for Trauma and Transport	9
Medical/Dental Filmless Imaging System	10
Antileishmanial Drug, WR6026	11
Field Triage Light	12
Tick-Borne Encephalitis Vaccine-German	13
Argentine Hemorrhagic Fever Live Vaccine	14
Malaria Recombinant Vaccine (RTS,S)	15
ETEC Whole Cell, Recombinant B Subunit Vaccine	16
Campylobacter Vaccine	17
SC602 Shigella Flexneri Vaccine	18
Leishmania Skin Test	19
Advanced Anticonvulsant	20
Topical Antileishmanial Drug, Paromomycin	21
Personal Information Carrier	22
Antimalarial Drug, Azithromycin	23
Antimalarial Drug, Halofantrine Prophylactic	24
Antimalarial Drug, Arteether	25
Rift Valley Fever Live Vaccine	26
Chikungunya Live Vaccine	27
Nucleic Acid Vaccine for Hantavirus	28
WRSS1 Shigella Sonnei Vaccine	29
Antimalarial Drug, Artelinic Acid	30
Thawed Blood Processing System	31
Dengue Fever Vaccine	32
Schistosome topical Antipenetrant	33
Combined Hepatitis A/B Vaccine	34
Advanced Surgical Suite for Trauma Casualties	35
Diagnostic Device for Visceralizing Leishmaniasis	36
Combination Camouflage Face Paint/Insect Repellent	37
Microencapsulated Antibiotic, Cephalosporin	38

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APPENDIX D

PROJECT MANAGEMENT DIVISION PRODUCT LISTING

APPLIED MEDICAL SYSTEMS

- Advanced Surgical Suite for Trauma Casualties (ASSTC)
- Armored Medical Evacuation Vehicle (AMEV)
- Armored Medical Treatment Vehicle (AMTV)
- Critical Care System for Trauma and Transport (CSTAT)
- Drinking Water Microbiological Assay System (DWMAS)
- Fibrin Bandage (FB)
- Far Forward Suction Apparatus (FFSA)
- Field Triage Light (FTL)
- Intraosseous Infusion Device (IID)
- Low Temperature Sterilizing System (LTSS)
- Medical Situational Awareness and Control (MSAC)
- Portable Field Oxygen Concentrator (PFOC)
- Self Contained Ventilator (SCV)
- Thawed Blood Processing System (TBPS)
- Warrior Medic (WM)

PHARMACEUTICAL SYSTEMS

- Antimalarial Drug, Arteether
- Antimalarial Drug, Azithromycin
- Antimalarial Drug, Halofantrine, Prophylactic
- Antileishmanial Drug, WR 6026
- Antimalarial Drug WR 238,605
- Argentine Hemorrhagic Fever (AHF) Live Vaccine
- Botulinum Toxoid, Pentavalent (Types A,B,C,D,E)
- Botulinum Type F Toxoid
- Botulism Immune Globulin $F(ab')_2$ Heptavalent Equine
- Botulism Immune Globulin (BIG) (Human)
- Cyanide Pretreatment (CP), WR242511
- Campylobacter Vaccine
- Chikungunya Live Vaccine
- Cholera Whole Cell Plus B Subunit Vaccine
- Diagnostic Kit for Biological Warfare Agents
- Enterotoxigenic E. coli (ETEC) Vaccine
- Hantaan M-S (Vaccinia Vectored) Vaccine
- Hypertonic Saline Dextran (HSD)
- Leishmania Skin Test Antigen (LSTA)
- Malaria Recombinant Vaccine (RTS,S) with Adjuvant Combinations
- Nerve Agent Antidote, Multichambered Autoinjector (MA)

- Nerve Agent Pretreatment, Pyridostigmine (NAPP)
- Rift Valley Fever Live Vaccine
- Schistosome Topical Antipenetrant (TAP)
- Tick-Borne Encephalitis Virus (GERMAN-BPL #366) Vaccine (TBE)
- Tick-Borne Encephalitis Virus (AUSTRIAN-BPL #335) Vaccine (TBE)
- Topical Skin Protectant (TSP)

APPENDIX E

FISCAL PROGRAM EXECUTION

DIRECT

Project	Allotment ($000)	PERCENT In-House OBL	In-House DISB	Extramural OBL	Extramural DISB	Total OBL	Total DISB
808	3,650	95	60	96	29	95	44
836	2,768	99	72	100	39	100	58
837	795	100	100	98	59	98	60
MC4	3,813	88	58	83	24	93	45
Total 6.4	11,026	95	64	85	17	92	47
832	1,616	99	73	97	57	98	64
834	838	0	0	81	55	76	52
MC5	206	100	91	96	0	100	86
849	1,931	75	48	98	72	91	64
Total 6.5	4,591	87	63	93	63	91	63
Total Direct	15,617	93	64	92	42	92	50

REIMBURSABLE

Project	Allotment ($000)	PERCENT In-House OBL	In-House DISB	Extramural OBL	Extramural DISB	Total OBL	Total DISB
JPO-BD							
MB4	1,722	99		100		100	
MB5	831	100		100		100	
Total Reimbursable	2,553	100		100		100	

TOTAL PROGRAM

D/V	12,748	95	63	93	26	94	39
EMD	5,422	88	59	95	51	93	53
Total Program	18,170	93	62	94	34	93	43