Exhibit R-2, RDT&E Budget Item Justification: PB 2012 Army **DATE:** February 2011

APPROPRIATION/BUDGET ACTIVITY

R-1 ITEM NOMENCLATURE

2040: Research, Development, Test & Evaluation, Army

PE 0604807A: Medical Materiel/Medical Biological Defense Equipment - Eng Dev

BA 5: Development & Demonstration (SDD)

| , | ' | | | | | | | | | | | | | | |
|--|---------|---------|-----------------|----------------|------------------|---------|---------|---------|---------|---------------------|------------|--|--|--|--|
| COST (\$ in Millions) | FY 2010 | FY 2011 | FY 2012 Base | FY 2012 OCO | FY 2012 Total | FY 2013 | FY 2014 | FY 2015 | FY 2016 | Cost To Complete | Total Cost | | | | |
| Total Program Element | 37.572 | 34.474 | 27.160 | - | 27.160 | 41.872 | 47.711 | 48.204 | 48.177 | Continuing | Continuing | | | | |
| 812: MIL HIV VAC&DRUG DEV | 4.296 | 4.456 | 3.866 | - | 3.866 | 2.949 | 4.329 | 4.490 | 4.486 | Continuing | Continuing | | | | |
| 832: Field Medical Systems Engineering Development | 15.104 | 17.791 | 14.807 | - | 14.807 | 23.719 | 27.720 | 27.835 | 28.141 | Continuing | Continuing | | | | |
| 849: INFEC DIS DRUG/VACC ED | 13.193 | 12.227 | 8.487 | - | 8.487 | 13.631 | 14.728 | 15.131 | 15.178 | Continuing | Continuing | | | | |
| A11: LSTAT MEDICAL TECHNOLOGY (CA) | 0.800 | - | - | - | - | - | - | - | - | 0.000 | 0.800 | | | | |
| CS5: MED MATERIEL/MED BIO DEFENSE INITIATIVES (CA) | 4.179 | - | - | - | - | - | - | - | - | 0.000 | 4.179 | | | | |
| VS8: MEDEVAC MISSION EQUIPMENT PACKAGE (MEP) - END DEV | - | - | - | - | - | 1.573 | 0.934 | 0.748 | 0.372 | Continuing | Continuing | | | | |

Note

to OPA Funds.

FY12 funds realigned (\$2899) to higher priority requirements.

A. Mission Description and Budget Item Justification

This program element (PE) funds advanced development of medical materiel within the System Demonstration and Low Rate Initial Production portions of the acquisition life cycle using 6.5 funding. It supports products successfully developed in the Systems Integration portion of the Systems Development and Demonstration phases through completion of the Milestone C Decision Review. Commercially-off-the-shelf (COTS) medical products are also tested and evaluated for military use, when available. This PE primarily includes pivotal (conclusive) human clinical trials necessary for licensure by the Food and Drug Administration. (PROJ 832) this project funds the engineering and manufacturing development of medical products for enhanced combat casualty care and follow-on care, including rehabilitation. Mature commercial-off-the-shelf (COTS) medical products are also evaluated for military use. Consideration will also be given to reduce the medical sustainment footprint through smaller weight and cube volume, or equipment independence from supporting materiel. Products from this project will normally transition

(PROJ 812) project funds military relevant human immunodeficiency virus (HIV) medical countermeasures. These funds provide for engineering and manufacturing development of candidate vaccines and drugs to permit large-scale field testing. Development focused on military unique needs effecting manning, mobilization, and deployment. Products from this project will normally transition to DoD Health Programs or OPA Funds.

(PROJ 849) funds development of candidate medical countermeasures for military relevant infectious diseases. These products fall between four major areas: vaccines, drugs, diagnostic kits/devices, and insect control measures to limit exposure and disease transmission. FDA approval is a mandatory obligation for all military

Page 1 of 27 R-1 Line Item #111 Army

Exhibit R-2, RDT&E Budget Item Justification: PB 2012 Army

DATE: February 2011

APPROPRIATION/BUDGET ACTIVITY

R-1 ITEM NOMENCLATURE

2040: Research, Development, Test & Evaluation, Army

PE 0604807A: Medical Materiel/Medical Biological Defense Equipment - Eng Dev

BA 5: Development & Demonstration (SDD)

products placed into the hands of medical providers or service members for human use. Products from this project will normally transition to DoD Health Programs or OPA funds.

This program is managed by U.S. Army Medical Materiel Development Activity (USAMMDA) and U.S. Army Medical Materiel Agency (USAMMA) of the US Army Medical Research and Materiel Command.

| B. Program Change Summary (\$ in Millions) | FY 2010 | FY 2011 | FY 2012 Base | FY 2012 OCO | FY 2012 Total |
|---|---------|---------|--------------|-------------|---------------|
| Previous President's Budget | 41.794 | 34.474 | 30.059 | - | 30.059 |
| Current President's Budget | 37.572 | 34.474 | 27.160 | = | 27.160 |
| Total Adjustments | -4.222 | - | -2.899 | - | -2.899 |
| Congressional General Reductions | | - | | | |
| Congressional Directed Reductions | | - | | | |
| Congressional Rescissions | - | - | | | |
| Congressional Adds | | - | | | |
| Congressional Directed Transfers | | - | | | |
| Reprogrammings | -3.099 | - | | | |
| SBIR/STTR Transfer | -1.123 | - | | | |
| Adjustments to Budget Years | - | - | -2.899 | - | -2.899 |

Army Page 2 of 27 R-1 Line Item #111

| Exhibit R-2A, RD1&E Project Jus | tification: PE | 3 2012 Army | | | | | | | DATE: February 2011 | | | | | |
|-----------------------------------|---|-------------|--------------|--------------------|-----------------|---------|---------|---------|---------------------|------------|-------------------|--|--|--|
| APPROPRIATION/BUDGET ACTIV | | IOMENCLA | | | PROJECT | | | | | | | | | |
| 2040: Research, Development, Tes | PE 060480 | 7A: Medical | Materiel/Med | 812: <i>MIL HI</i> | IV VAC&DRUG DEV | | | | | | | | | |
| BA 5: Development & Demonstration | BA 5: Development & Demonstration (SDD) | | | | | | Dev | | | | | | | |
| COST (\$ in Millions) | | | FY 2012 | FY 2012 | FY 2012 | | | | | Cost To | | | | |
| COST (\$ III WIIIIOHS) | FY 2010 | FY 2011 | Base | oco | Total | FY 2013 | FY 2014 | FY 2015 | FY 2016 | Complete | Total Cost | | | |
| 812: MIL HIV VAC&DRUG DEV | 4.296 | 4.456 | 3.866 | - | 3.866 | 2.949 | 4.329 | 4.490 | 4.486 | Continuing | Continuing | | | |
| Quantity of RDT&E Articles | | | | | | | | | | | | | | |

A. Mission Description and Budget Item Justification

This project funds militarily relevant human immunodeficiency virus (HIV) medical countermeasures. These funds provide for engineering and manufacturing development of candidate vaccines and drugs to permit large-scale field testing. Development is focused on militarily unique needs effecting manning, mobilization, and deployment.

The major contractor is The Henry M. Jackson Foundation for the Advancement of Military Medicine, Rockville, MD. Research efforts are coordinated with the National Institutes of Health.

| B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each) | FY 2010 | FY 2011 | FY 2012 |
|---|---------|---------|---------|
| Title: Military HIV Vaccine and Drug Development | 4.296 | 4.456 | 3.866 |
| Articles: | 0 | 0 | |
| Description: This project provides funds for engineering and manufacturing development of candidate vaccines and drugs to permit large-scale field testing of vaccines for medical countermeasures to HIV. | | | |
| FY 2010 Accomplishments: prepared preliminary clinical study report on the completed expanded safety/efficacy trial in Thailand and conduct a critical design review (CDR) to determine future development of the prime-boost vaccine based on trial results. Follow up clinical trial for HIV positive for viral load in order to validate viral load as a surrogate endpoint for use in HIV vaccine studies. | | | |
| FY 2011 Plans: Finalize and submit to the Food and Drug Administration (FDA) results from the expanded safety/efficacy trial in Thailand, update/revise the clinical development plan, and continue to follow up clinical trial for HIV positive for viral load. | | | |
| FY 2012 Plans: Perform three inter-related studies to enhance our understanding of precisely how the vaccine strategy used in the safety/efficacy trial completed in 2009 caused vaccine recipients to be protected from infection, including intense laboratory studies using samples from the trial, and commencement of two small clinical vaccine trials to generate data and samples to hopefully define what vaccine responses to try to generate for next increment studies. | | | |
| Accomplishments/Planned Programs Subtotals | 4.296 | 4.456 | 3.866 |

Army Page 3 of 27 R-1 Line Item #111

| Exhibit R-2A, RDT&E Project Justification: PB 2012 Army | | | DATE: February 2011 |
|---|--|-------------|----------------------------|
| APPROPRIATION/BUDGET ACTIVITY | R-1 ITEM NOMENCLATURE | PROJECT | |
| 2040: Research, Development, Test & Evaluation, Army | PE 0604807A: Medical Materiel/Medical | 812: MIL HI | V VAC&DRUG DEV |
| BA 5: Development & Demonstration (SDD) | Biological Defense Equipment - Eng Dev | | |
| | | | |

C. Other Program Funding Summary (\$ in Millions)

N/A

D. Acquisition Strategy

Test and evaluate commercially developed vaccine candidates in government-managed trials.

E. Performance Metrics

Performance metrics used in the preparation of this justification material may be found in the FY 2010 Army Performance Budget Justification Book, dated May 2010.

Army Page 4 of 27 R-1 Line Item #111

Exhibit R-3, RDT&E Project Cost Analysis: PB 2012 Army DATE: February 2011 APPROPRIATION/BUDGET ACTIVITY **R-1 ITEM NOMENCLATURE PROJECT** 2040: Research, Development, Test & Evaluation, Army PE 0604807A: Medical Materiel/Medical 812: MIL HIV VAC&DRUG DEV BA 5: Development & Demonstration (SDD) Biological Defense Equipment - Eng Dev FY 2012 FY 2012 FY 2012 Management Services (\$ in Millions) oco **FY 2011** Base Total **Total Prior** Target Contract Method Performing Years Award Award Award Cost To Value of Cost Complete Cost Category Item **Activity & Location** Cost Date Cost Date Date **Total Cost** Contract & Type Cost Cost No product/contract costs Various: Various 0.672 0.091 0.215 0.215 Continuing Continuing 0.000 Various greater than \$1M individually Subtotal 0.672 0.091 0.215 0.215 0.000 FY 2012 FY 2012 FY 2012 **Product Development (\$ in Millions)** FY 2011 Base oco Total **Total Prior** Contract Target Method Performing Years Award Award Award Cost To Value of **Cost Category Item Activity & Location** Cost Cost Date Cost Date Cost Date Cost Complete **Total Cost** Contract & Type Henry M. Jackson **Product Development** Various 21.570 3.231 2.655 2.655 Continuing Continuing Continuina Foundation.:Various Subtotal 21.570 3.231 2.655 2.655 FY 2012 FY 2012 FY 2012 Support (\$ in Millions) oco FY 2011 Base Total **Total Prior** Contract Target Years **Cost To** Method Performing Award Award Award Value of **Cost Category Item** & Type **Activity & Location** Cost Cost Date Cost Date Cost Date Cost Complete **Total Cost** Contract No product/contract costs Various Continuing Continuing Various:Various 0.487 0.046 0.046 0.046 0.000 greater than \$1M individually 0.046 0.046 0.046 0.000 Subtotal 0.487 FY 2012 FY 2012 FY 2012 Test and Evaluation (\$ in Millions) FY 2011 Base oco Total **Total Prior** Target Contract Method Performing Years Award Award Award **Cost To** Value of **Cost Category Item** & Type **Activity & Location** Cost Cost Date Cost Date Cost Date Cost Complete **Total Cost** Contract Henry M. Jackson 0.950 0.950 Continuing **Product Development** Various 21.570 1.088 Continuing Continuing Foundation.:Various Subtotal 21.570 1.088 0.950 0.950

Army Page 5 of 27 R-1 Line Item #111

| Exhibit R-3, RDT&E Project Cost Analysis: PB 2012 Army | DATE: February 2011 | | |
|--|--|----------------|-----------------|
| APPROPRIATION/BUDGET ACTIVITY | R-1 ITEM NOMENCLATURE | PROJECT | |
| 2040: Research, Development, Test & Evaluation, Army | PE 0604807A: Medical Materiel/Medical | 812: MIL HI | IV VAC&DRUG DEV |
| BA 5: Development & Demonstration (SDD) | Biological Defense Equipment - Eng Dev | | |

| To | otal Prior | | | | | | | | | Target |
|---------------------|------------|-------|------|---------|------|------|---------|----------|------------|----------|
| • | Years | | | FY 2012 | FY 2 | 2012 | FY 2012 | Cost To | 1 | Value of |
| | Cost | FY 2 | 2011 | Base | 00 | co | Total | Complete | Total Cost | Contract |
| Project Cost Totals | 44.299 | 4.456 | | 3.866 | - | | 3.866 | | | |

Remarks

DATE: February 2011

APPROPRIATION/BUDGET ACTIVITY

2040: Research, Development, Test & Evaluation, Army

Exhibit R-4, RDT&E Schedule Profile: PB 2012 Army

BA 5: Development & Demonstration (SDD)

R-1 ITEM NOMENCLATURE

PE 0604807A: Medical Materiel/Medical Biological Defense Equipment - Eng Dev PROJECT

812: MIL HIV VAC&DRUG DEV

| | | FY 2010 | | | FY | 201 | 1 | FY 2012 | | 2 | | FY 2 | 2013 | | | FY 2 | 2014 | | | FY 2 | 2015 | 5 | | FY 2 | 2016 | i | | |
|--|---|---------|---|---|----|-----|---|---------|---|---|---|------|------|---|---|------|------|---|---|------|------|---|---|------|------|---|---|---|
| | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| HIV Vaccine Critical Design Review (CDR) | | | | | | | | | | | | | | | • | | | | | | | | | | | | | |

Page 7 of 27 R-1 Line Item #111 Army

| Exhibit R-4A, RDT&E Schedule Details: PB 2012 Army | DATE: February 2011 | | |
|--|--|-------------|-----------------|
| APPROPRIATION/BUDGET ACTIVITY | R-1 ITEM NOMENCLATURE | PROJECT | |
| 2040: Research, Development, Test & Evaluation, Army | PE 0604807A: Medical Materiel/Medical | 812: MIL HI | IV VAC&DRUG DEV |
| BA 5: Development & Demonstration (SDD) | Biological Defense Equipment - Eng Dev | | |

Schedule Details

| | St | art | E | nd |
|--|---------|------|---------|------|
| Events | Quarter | Year | Quarter | Year |
| HIV Vaccine Critical Design Review (CDR) | 3 | 2010 | 3 | 2010 |

Army Page 8 of 27 R-1 Line Item #111

| Exhibit R-2A, RDT&E Project Jus | stification: PB | 3 2012 Army | | | | | | DATE : February 2011 | | | | | | |
|--|-----------------|-------------|-----------------|----------------|---|--------------|-----------------|-----------------------------|---------|---------------------|------------|--|--|--|
| APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 5: Development & Demonstration (SDD) | | | | | OMENCLAT 7A: Medical I Defense Equi | Materiel/Med | Medical Systent | cal Systems Engineering | | | | | | |
| COST (\$ in Millions) | FY 2010 | FY 2011 | FY 2012 Base | FY 2012 OCO | FY 2012 Total | FY 2013 | FY 2014 | FY 2015 | FY 2016 | Cost To Complete | Total Cost | | | |
| 832: Field Medical Systems Engineering Development | 15.104 | 17.791 | 14.807 | - | 14.807 | 23.719 | 27.720 | 27.835 | 28.141 | Continuing | Continuing | | | |
| Quantity of RDT&E Articles | | | | | | | | | | | | | | |

A. Mission Description and Budget Item Justification

This project funds the engineering and manufacturing development of medical products for enhanced combat casualty care and follow-on care, including rehabilitation. This project funds pivotal (conclusive) human clinical trials or mechanical engineering evaluations for efficacy of devices or biologics (products derived from living organisms) to fulfill unique military requirements. Mature commercial-off-the-shelf (COTS) medical products are also evaluated for military use. Consideration will also be given to reducing the medical sustainment footprint through smaller weight and cube volume, or equipment independence from supporting materiel. This work is frequently completed through a laboratory/contractor team with the contractor obtaining the U.S. Food and Drug Administration (FDA) licensure for sale of the product.

In FY10, Project 834 Soldier Sys Prot-ED was consolidated into Project 832.

Major contractors/intra-governmental agencies include: IGR Enterprises, Inc.; Army Medical Department Board Test Center; SeQual Technologies, Inc.; Enginivity, Inc.; Ultrasound Diagnostics, Inc.; HemCon Medical Technologies, Inc.; Cerdak Ltd; Hemerus Medical, LLC; Fast Track Drugs & Biologics, LLC; Integrated Medical Systems, Inc; the National Institutes of Health National Heart, Lung and Blood Institute (NHLBI), and the U.S. Army Aeromedical Research Laboratory Walter Reed Army Institute of Research (WRAIR) and Institute of Surgical Research (ISR) for user evaluation. Other military agencies include Program Executive Office (PEO) Soldier, PEO Combat Service Support (CSS), and Naval Undersea Warfare Center.

| B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each) | FY 2010 | FY 2011 | FY 2012 | |
|--|---------|---------|---------|---|
| Title: Medical Materiel/Medical Biological Defense Equipment- Engineering Development FY 10 and 11 | 15.104 | 17.791 | - | |
| Articles: | 0 | 0 | | |
| Description: This project funds in FY 10 and 11 the engineering and manufacturing development of medical products for enhanced combat casualty care and follow-on care, including rehabilitation. | | | | |
| FY 2010 Accomplishments: | | | | |
| Ceramic Oxygen Generator: conducted developmental and operational testing to obtain Milestone C. Follow on testing and report | | | | |
| analysis was performed to facilitate FDA and UL approval and ascertain that production capabilities adhere to good manufacturing | | | | |
| practices. Further analyses were performed to facilitate FDA and UL approval and ascertain that production capabilities adhere | | | | |
| to good manufacturing processes. In 2Q FY10 for the RVPSAOG submitted final reports for FDA clearance. Field Sterilizer: | | | | |
| completed analysis and validation report of down selected products in OT&E trials for final selection and movement to production | | | | |
| and deployment. Ultrasonic Brain Imager (UBI): transitioned from project 836, began safety and effectiveness human clinical trial, | | | | ı |

Army Page 9 of 27 R-1 Line Item #111

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|--|---|---|--------------|--------------|---------|
| Exhibit R-2A, RDT&E Project Justification: PB 2012 Army | | | DATE: Fe | bruary 2011 | |
| APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 5: Development & Demonstration (SDD) | R-1 ITEM NOMENCLATURE PE 0604807A: Medical Materiel/Medical Biological Defense Equipment - Eng Dev | PROJEC 832: Fiel Developi | d Medical Sy | stems Engine | eering |
| B. Accomplishments/Planned Programs (\$ in Millions, Article | Quantities in Each) | | FY 2010 | FY 2011 | FY 2012 |
| conducted a human factor evaluation of the prototype, and conducted a human factor evaluation of the prototype, and conducted Dried Plasma Program: initiated a multi-center safety/efficient product. Red blood cell extended life program: prepared and compared Safety Study: completed the study. Continued testing of commer Analyzers continued testing and evaluation for final report in 3Q F transportation testing. Verified stethoscope will be able to stand operational temperature, drop and vibration, as well as air-worthing transitioned from project 834. | cacy human clinical trial, and performed stability studie apleted enrollment in human safety/efficacy study. Wo cial lab equipment: expanded study to include Hemat FY10. Noise immune stethoscope: conducted environi up to the military environment. Conducted storage an | es on oundstat ology mental/ d | | | |
| FY 2011 Plans: In FY11, Freeze-dried Plasma: start enrollment in the multi-cente profile of the product. Red Blood Cell Extended Life Program: cor and prepare and submit report to the FDA. Platelet Derived Hemolenrollment/follow-up in the human safety/efficacy trial. Intranasal transition from project 836 and conduct pre-clinical trial activities: Hypertonic Saline Dextran (treatment of shock due to blood loss) shock. Continue market analysis and surveys for candidate resus clinical user evaluation and operational testing. Remote Diagnost MOC Sensor Modual Development phase of this device. Treatmed Variants: Transition from Project 836. Transition to production for HBCT for Medical Mission Package for Treatment Variant: Transitesting. Shelter for PM, HBCT Treatment Variant: Transition from Shock and Vibration Isolation System for Patient Litters in Ground 836. Conduct Shock and Vibration Isolation System for patient littourniquet update: Conduct study to update medical set and down Sensitive Medical Materiel: Transition from Project 836. Conduct | mplete the human safety/efficacy study, conduct data estatic Agent (PDHA): transition from project 836 to be Ketamine (low dose pain management via nasal sprafor human drug use in aeromedical evacuation and but support human expanded safety/efficacy trial for treatitive fluids for treatment of shock. Enhanced SAVe ic Access: Conduct Prototype field testing and refine ent Table for PM, HBCT Medical Mission Package for ruse on PM, HBCT Treatment Variant. Refrigerator for the stition from Project 836. Conduct environmental and of Project 836. Evaluate alternatives in operational set d and Air Medical Evacuation Vehicles: Transition from terms - air worthiness and ground vehicle testing. One-in select product. Passive Cold Chain Capability for Temperature and user testing. | analysis, egin ay): urn patients. atment of : Conduct ment for Treatment or PM, perational ting. n Project handed | | | |
| Title: Field Medical Systems Engineering Development FY 12 PN Description: This project funds in FY 12 the engineering and ma combat casualty care managed by PM Medical Devices. | | anced | - | - | 6.033 |
| FY 2012 Plans: : The Burn Resuscitation Decision Device: Will conduct final environments submission. Wireless Medical Monitoring will transition from Congression. | | | | | |

UNCLASSIFIED

Army Page 10 of 27 R-1 Line Item #111

| | 01102110011122 | | | | |
|--|--|----------------------------------|-------------|--------------|---------|
| Exhibit R-2A, RDT&E Project Justification: PB 2012 Army | | | DATE: Fe | bruary 2011 | |
| APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 5: Development & Demonstration (SDD) | R-1 ITEM NOMENCLATURE PE 0604807A: Medical Materiel/Medical Biological Defense Equipment - Eng Dev | PROJEC 832: Field Developm | Medical Sys | stems Engine | eering |
| B. Accomplishments/Planned Programs (\$ in Millions, Article Quan | ntities in Each) | | FY 2010 | FY 2011 | FY 2012 |
| project and will undergo a Milestone C review as well as prototype field line into 832 6.5 funding line. Will finalize results of clinical and operation and undergo Milestone C review in 4Q. | | | | | |
| Title: Field Medical Systems Engineering Development FY 12 PM Phar | maceuticals | | - | - | 5.034 |
| Description: This project funds in FY 12 the engineering and manufact Pharmaceuticals for enhanced combat casualty care and follow-on care | | d by PM | | | |
| FY 2012 Plans: Freeze-dried Plasma: Will begin enrollment in a multi-center limited hur & laboratory capabilities to meet Food and Drug Administration requirer Cryopreserved Platelets (CPP) (formerly Platelet Derived Hemostatic Albuman safety/efficacy trial. | ments; and will evaluate stability profile of the pro- | oduct. | | | |
| Title: Field Medical Systems Engineering Development FY 12 PM Integ | grated Clinical Systems (ICS) | | - | - | 0.737 |
| Description: This project funds in FY 12 the engineering and manufact ICS for enhanced combat casualty care and follow-on care, including re | | d by PM | | | |
| FY 2012 Plans: Will conduct final testing of Phase IV of Remote Acess Device (RDA). V to serve as a standardized compliance wrapper for all vendors, medical traverse between the .com and .mil networks. The Milestone Decision A RDA project in March 2011. | technology, and even IT management products | that may | | | |
| Title: Field Medical Systems Engineering Development FY 12 PM Medical Systems Engineer | ical Support Systems | | - | - | 3.003 |
| Description: This project funds in FY 12 the engineering and manufact Medical Support Systems for enhanced combat casualty care and follows: | | ed by PM | | | |
| FY 2012 Plans: PM will collaborate with PM HBCT on medical equipment for the future shock and litter isolation system for potential addition to Ground Ambula Continue to transition to Force Provider by fielding a Force Provider CS Joint shelter Program and finalize acquisition strategy in coordination w | ance and Air Ambulance Medical Equipment Se H. PM will fully test the new 2-sided ISO shelter | ts (MES). under the | | | |

UNCLASSIFIED

Army Page 11 of 27 R-1 Line Item #111

| Exhibit R-2A, RDT&E Project Justification: PB 2012 Army | | | DATE: February 2011 |
|---|--|--------------|-----------------------------|
| APPROPRIATION/BUDGET ACTIVITY | R-1 ITEM NOMENCLATURE | PROJECT | |
| 2040: Research, Development, Test & Evaluation, Army | PE 0604807A: Medical Materiel/Medical | 832: Field N | Medical Systems Engineering |
| BA 5: Development & Demonstration (SDD) | Biological Defense Equipment - Eng Dev | Developme | nt |

| B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each) | FY 2010 | FY 2011 | FY 2012 |
|--|---------|---------|---------|
| continue to develop Medical Evacuation Vehicles in coordination with Program Executive Office Combat Service Support vehicle developers. | | | |
| Accomplishments/Planned Programs Subtotals | 15.104 | 17.791 | 14.807 |

C. Other Program Funding Summary (\$ in Millions)

N/A

D. Acquisition Strategy

Develop in-house or industrial prototypes in government-managed programs to meet military and regulatory requirements for production and fielding.

E. Performance Metrics

Performance metrics used in the preparation of this justification material may be found in the FY 2010 Army Performance Budget Justification Book, dated May 2010.

Army Page 12 of 27 R-1 Line Item #111

Exhibit R-3, RDT&E Project Cost Analysis: PB 2012 Army

APPROPRIATION/BUDGET ACTIVITY

2040: Research, Development, Test & Evaluation, Army

BA 5: Development & Demonstration (SDD)

R-1 ITEM NOMENCLATURE

PE 0604807A: Medical Materiel/Medical

Biological Defense Equipment - Eng Dev

DATE: February 2011

PROJECT

832: Field Medical Systems Engineering

Development

| Management Services | (\$ in Millio | ns) | | FY 2 | 2011 | | 2012 se | | 2012 CO | FY 2012 Total | | | |
|--|------------------------------|-----------------------------------|------------------------------|-------|---------------|-------|---------------|------|---------------|------------------|---------------------|------------|--------------------------------|
| Cost Category Item | Contract Method & Type | Performing Activity & Location | Total Prior Years Cost | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | Cost To Complete | Total Cost | Target Value of Contract |
| No product/contract costs greater than \$1Million individually | Various | Various:Various | 20.127 | 1.429 | | 0.418 | | - | | 0.418 | Continuing | Continuing | Continuing |
| | | Subtotal | 20.127 | 1.429 | | 0.418 | | - | | 0.418 | | | |

| Product Development (| \$ in Millio | ns) | | FY 2 | 2011 | FY 2 Ba | | | 2012 CO | FY 2012 Total | | | |
|--|------------------------------|---|------------------------------|-------|---------------|------------|---------------|------|---------------|------------------|---------------------|------------|--------------------------------|
| Cost Category Item | Contract Method & Type | Performing Activity & Location | Total Prior Years Cost | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | Cost To Complete | Total Cost | Target Value of Contract |
| Rotary Valve Pressure Swing Adsorption oxygen Generator | Various | Sequal Technologies,Inc.,:Variou | 3.497 | - | | - | | - | | - | Continuing | Continuing | Continuing |
| Hypertonic Saline Dextran | Various | National Institutes of Health, National Heart, Lung and Blood Institute (NHLBI):Various | 4.800 | 5.500 | | - | | - | | - | Continuing | Continuing | Continuing |
| Freeze-dried Human Plasma | Various | HemCon Medical Technologies, Inc,:Tigard OR | 10.405 | 0.500 | | 5.796 | | - | | 5.796 | Continuing | Continuing | Continuing |
| Extended Life Red Blood Cell Product | Various | Hemerus Medical, LLC,:Various | 1.895 | 0.500 | | - | | - | | - | Continuing | Continuing | Continuing |
| Virtual Imaging | Various | Virtual Imaging:various | 1.450 | - | | - | | - | | - | Continuing | Continuing | Continuing |
| No product/contract costs greater than \$1M individually | Various | Various:various | 1.260 | 2.000 | | - | | - | | - | Continuing | Continuing | Continuing |
| Cryopreserved Platelets | Various | Multiple DoD activities and Dartmouth Hitchcock Med Ctr:North Potomac, MD | - | - | | 7.757 | | - | | 7.757 | Continuing | Continuing | Continuing |
| | | Subtotal | 23.307 | 8.500 | | 13.553 | | - | | 13.553 | | | |

Exhibit R-3, RDT&E Project Cost Analysis: PB 2012 Army

APPROPRIATION/BUDGET ACTIVITY

2040: Research, Development, Test & Evaluation, Army

BA 5: Development & Demonstration (SDD)

R-1 ITEM NOMENCLATURE

PE 0604807A: Medical Materiel/Medical Biological Defense Equipment - Eng Dev

DATE: February 2011

PROJECT

832: Field Medical Systems Engineering Development

| Support (\$ in Millions) | | | | FY 2 | 2011 | FY 2 Ba | 2012 se | | 2012 CO | FY 2012 Total | | | |
|---|------------------------------|--|------------------------------|-------|---------------|------------|---------------|------|---------------|------------------|---------------------|------------|--------------------------------|
| Cost Category Item | Contract Method & Type | Performing Activity & Location | Total Prior Years Cost | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | Cost To Complete | Total Cost | Target Value of Contract |
| Regulatory Support | Various | Clinical Research Management,Inc,.:Variou | 2.757 | 1.400 | | - | | - | | - | Continuing | Continuing | Continuing |
| No product/contract costs greater then \$1 Million individually | Various | Various:Various | 1.788 | 2.354 | | 0.418 | | - | | 0.418 | Continuing | Continuing | Continuing |
| | | Subtotal | 4.545 | 3.754 | | 0.418 | | - | | 0.418 | | | |

| Test and Evaluation (\$ | in Millions | s) | | FY 2 | 2011 | FY 2 Ba | | | 2012 CO | FY 2012 Total | | | |
|---|------------------------------|-----------------------------------|------------------------------|-------|---------------|------------|---------------|------|---------------|------------------|---------------------|------------|--------------------------------|
| Cost Category Item | Contract Method & Type | Performing Activity & Location | Total Prior Years Cost | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | Cost To Complete | Total Cost | Target Value of Contract |
| No product/contract costs greater than \$1 Million individually | Various | Various:Various | 3.417 | 4.108 | | 0.418 | | - | | 0.418 | Continuing | Continuing | Continuing |
| | | Subtotal | 3.417 | 4.108 | | 0.418 | | - | | 0.418 | | | |

| <u> </u> | | | | | | | | |
|---------------------|-------------|---------|---------|---------|---------|----------|-------------------|----------|
| - | Total Prior | | | | | | ' | Target |
| | Years | | FY 2012 | FY 2012 | FY 2012 | Cost To | ' | Value of |
| | Cost | FY 2011 | Base | oco | Total | Complete | Total Cost | Contract |
| Project Cost Totals | 51 396 | 17 791 | 14 807 | _ | 14 807 | | | |

Remarks

| xhibit R-4, RDT&E Schedule Profile: PB 2012 | Army | y | | | | | | | | | | | | | | | | | | | | | ΑT | E: F | eb | ruar | y 2 | 011 | | |
|--|------|----|-----|---|---|----|------------------|-----|-------------------------------|-------------|------|-----|-----|------|----|-----|---|---|----|----------------------|------|----|----|------|-----|------|------|------|------|----|
| PPROPRIATION/BUDGET ACTIVITY 040: Research, Development, Test & Evaluation, A 5: Development & Demonstration (SDD) | Arm | ny | | | | P | E 06 | 048 | I NO 807A al Def | \: <i>\</i> | Medi | cal | Mat | erie | | | | | 8 | ROJ 32: F evel | iela | Me | | al S | yst | ems | : En | gine | erin | ng |
| | | FY | 201 | 0 | | FY | 201 ⁻ | 1 | | F | Y 20 |)12 | | | FY | 201 | 3 | | FY | 201 | 4 | | F | Y 20 | 15 | | | FY : | 2016 | 6 |
| | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 1 | | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| (1) Ceramic Oxygen Gen Sys (MS-C) | | _ | | | | | , | | | | | | , | | | | | | | | | | | | | | | , | | |
| (6) Ultrasonic Brain Imager (MS-C) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Total Intravenous Anesthesia (TIVA) (MS-C) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Burn Resuscitation Decision Device (MS-C) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Wireless Medical Monitoring (MS-C) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Plasma Knife (MS-C) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| Exhibit R-4A, RDT&E Schedule Details: PB 2012 Army | | DATE: February 2011 |
|--|--|--|
| APPROPRIATION/BUDGET ACTIVITY | R-1 ITEM NOMENCLATURE | PROJECT |
| 2040: Research, Development, Test & Evaluation, Army | PE 0604807A: Medical Materiel/Medical | 832: Field Medical Systems Engineering |
| BA 5: Development & Demonstration (SDD) | Biological Defense Equipment - Eng Dev | Development |

Schedule Details

| | St | art | E | ind |
|--|---------|------|---------|------|
| Events | Quarter | Year | Quarter | Year |
| (1) Ceramic Oxygen Gen Sys (MS-C) | 3 | 2010 | 3 | 2010 |
| (6) Ultrasonic Brain Imager (MS-C) | 1 | 2010 | 1 | 2010 |
| Total Intravenous Anesthesia (TIVA) (MS-C) | 4 | 2012 | 4 | 2012 |
| Burn Resuscitation Decision Device (MS-C) | 1 | 2012 | 1 | 2012 |
| Wireless Medical Monitoring (MS-C) | 3 | 2012 | 3 | 2012 |
| Plasma Knife (MS-C) | 1 | 2012 | 1 | 2012 |

| Exhibit R-2A, RDT&E Project Just | ification: PE | 3 2012 Army | | | | | DATE: February 2011 | | | | | |
|--|-------------------------|-------------|-----------------|----------------|--|---------|---------------------|---------|---------|---------------------|------------|--|
| APPROPRIATION/BUDGET ACTIV 2040: Research, Development, Test BA 5: Development & Demonstration | R-1 ITEM N PE 060480 | | Materiel/Med | dical | PROJECT 849: INFEC DIS DRUG/VACC ED | | | | | | | |
| COST (\$ in Millions) | FY 2010 | FY 2011 | FY 2012 Base | FY 2012 OCO | FY 2012 Total | FY 2013 | FY 2014 | FY 2015 | FY 2016 | Cost To Complete | Total Cost | |
| 849: INFEC DIS DRUG/VACC ED | 13.193 | 12.227 | 8.487 | - | 8.487 | 13.631 | 14.728 | 15.131 | 15.178 | Continuing | Continuing | |
| Quantity of RDT&E Articles | | | | | | | | | | | | |

A. Mission Description and Budget Item Justification

This project funds development of candidate medical countermeasures for militarily relevant infectious diseases. These products fall within four major areas: vaccines, drugs, diagnostic kits/devices, and insect control measures to limit exposure and disease transmission. It funds research that supports conclusive human clinical trials for large-scale human efficacy testing, expanded human safety clinical trials, long-term animal studies, and related manufacturing tests. This work, which is jointly performed by military laboratories, civilian contracted pharmaceutical firms and foreign research partners, is directed toward the prevention of disease, early diagnosis, and speeding recovery once diagnosed. Medical products approved for human use must successfully complete a series of clinical trials that are required and regulated by the U.S. Food and Drug Administration (FDA). FDA approval is a mandatory obligation for all military products placed into the hands of medical providers or service members for human use. Development priority is based upon four major factors: (1) the extent of the disease within the Combatant Commands' theater of operations, (2) the clinical severity of the disease, (3) the technical maturity of the proposed solution, and (4) the affordability of the solution (development, production, and sustainment). Malaria, dysentery, hepatitis, and dengue diseases (a severe debilitating disease transmitted by mosquitoes), which are found in Africa Command, Central Command. European Command, Southern Command, and Pacific Command areas are at the top of the infectious diseases requirements list.

| B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each) | FY 2010 | FY 2011 | FY 2012 |
|---|---------|---------|---------|
| Title: FY 10 Malaria Drug/ Vaccine Engineering Development | 6.018 | 4.568 | - |
| Articles: | 0 | 0 | |
| Description: This project funds in FY 10 development of candidate medical countermeasures for militarily relevant infectious diseases. | | | |
| FY 2010 Accomplishments: Conducted clinical trials, developmental testing, and reviews of malarial/antimalarial vaccines, drugs, diagnostics and insect repellents. For Tafenoquine, conducted data analysis and prepared a final report on the small human challenge clinical trial, and began pre-trial activities for a large-scale safety/efficacy human clinical trial (treatment indication) in a malaria endemic country. | | | |
| FY 2011 Plans: Will conduct clinical trials, developmental testing, and reviews of malarial/antimalarial vaccines, drugs, diagnostics and insect repellents. For Tafenoquine, will complete pre-trial activities for a large-scale safety/efficacy human clinical trial (treatment indication) in a malaria endemic country. | | | |
| Title: FY 10 Infectious Disease Drug and Vaccine Engineering Development | 7.175 | 7.659 | 8.487 |
| Articles: | 0 | 0 | |

Army Page 17 of 27 R-1 Line Item #111

| | UNCLASSIFIED | | | | |
|--|---|--|------------|-------------|---------|
| Exhibit R-2A, RDT&E Project Justification: PB 2012 Army | | | DATE: Fe | bruary 2011 | |
| APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 5: Development & Demonstration (SDD) | R-1 ITEM NOMENCLATURE PE 0604807A: Medical Materiel/Medical Biological Defense Equipment - Eng Dev | PROJEC 849: INF | EC DIS DRU | G/VACC ED | |
| B. Accomplishments/Planned Programs (\$ in Millions, Artic | le Quantities in Each) | | FY 2010 | FY 2011 | FY 2012 |
| Description: FY 10 funding for research and development effor | ts described below. | | | | |
| FY 2010 Accomplishments: Topical Antileishmanial Cream [Leishmaniasis is a skin-based of continued subject enrollment/follow-up in the Tunisia large scale activities of the second large scale human safety/efficacy trial in scale (<35 subjects) pharmacokinetic (drug metabolism) human drug treatment of skin lesions caused by the Leishmania parasit submission efforts. Since industry partner has chosen not to su in the U.S. For Dengue Tetravalent Vaccine [Dengue is a sever mosquito], completed subject follow-up and began data analysis prepared the study report on the human safety and immune reschildren and adult) on the expanded human safety and immune the expanded safety and efficacy trial in children in Thailand. For specimens kept under cold storage and monitoring of industry p | e (> 300 subjects) human safety/efficacy trial and began Central/South America, and completed study start of the trials in France, Peru and Panama. For Pentostam (in te), monitored progress of industry partner's FDA licenthmit for FDA Licensure, continued a human treatment are debilitating disease caused by a virus and transmitters on the expanded human safety and immunity trial in It ponse trial (adults) in the U.S., prepared the study reported | n pretrial hree small htravenous sure protocol ed by a Puerto Rico, orts (infant, vities for | | | |
| FY 2011 Plans: In FY11, for Topical Antileishmanial Cream, analyze the data ar safety/efficacy trial, continued pretrial activities for enrollment in trial in Central/South America, and will analyze the data and pre pharmacokinetic (drug metabolism) human trials in France, Per protocol in the U.S. For DTV vaccine, will complete the study re Rico and begin the expanded safety and efficacy trial in children study blood specimens kept under cold storage and monitoring | the second large scale (> 300 subjects) human safety epare the final report for the three small scale (<35 subjects) and Panama. For Pentostam, will continue a human eport on the expanded human safety and immunity trial in Thailand. For Hepatitis E vaccine will continue ma | /efficacy lects) treatment in Puerto intenance of | | | |
| FY 2012 Plans: Will conduct Clinical trials, developmental testing, and reviews of repellents. Will down-select from candidate anti-malaria drugs (activities for a safety/efficacy human clinical trial (treatment indical developmental testing, and appropriate reviews of grouped vaccious disease caused by a parasite and transmitted by sand flies), Detransmitted by a mosquito), and other viral diseases: For Topical Transmitted by a mosquito), and other viral diseases. | (e.g. Tafenoquine and other drugs) to prepare for clinic cation) in a malaria endemic country. Will conduct clin cines, drugs, and diagnostics (Leishmaniasis (a skin-ba engue (a severe debilitating disease caused by a virus al Antileishmanial Cream, begin the clinical study repo | al trial ical trials, ased and t on the | | | |

UNCLASSIFIED

Army Page 18 of 27 R-1 Line Item #111

Tunisia large scale human safety/efficacy trial, begin enrollment efforts in the second large scale (> 300 subjects) human safety/efficacy trial in Central/South America. For Dengue Tetravalent Vaccine (DTV) begin study close out activities for expanded

| Exhibit R-2A, RDT&E Project Justification: PB 2012 Army | DATE: February 2011 | |
|---|--|-----------------------------|
| APPROPRIATION/BUDGET ACTIVITY | R-1 ITEM NOMENCLATURE | PROJECT |
| 2040: Research, Development, Test & Evaluation, Army | PE 0604807A: Medical Materiel/Medical | 849: INFEC DIS DRUG/VACC ED |
| BA 5: Development & Demonstration (SDD) | Biological Defense Equipment - Eng Dev | |

| B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each) | FY 2010 | FY 2011 | FY 2012 |
|--|---------|---------|---------|
| safety and efficacy trial in children in Thailand; begin a new DTV large scale (> 300 subjects) human trial in Thailand and Philippines to expand safety data and demonstrate efficacy in children/adults. | | | |
| Accomplishments/Planned Programs Subtotals | 13.193 | 12.227 | 8.487 |

C. Other Program Funding Summary (\$ in Millions)

N/A

D. Acquisition Strategy

Test and evaluate in-house and commercially developed products in government-managed trials to meet FDA requirements and Environmental Protection Agency registration.

E. Performance Metrics

Performance metrics used in the preparation of this justification material may be found in the FY 2010 Army Performance Budget Justification Book, dated May 2010.

Page 19 of 27 R-1 Line Item #111

Exhibit R-3, RDT&E Project Cost Analysis: PB 2012 Army DATE: February 2011 APPROPRIATION/BUDGET ACTIVITY **R-1 ITEM NOMENCLATURE PROJECT** 2040: Research, Development, Test & Evaluation, Army PE 0604807A: Medical Materiel/Medical 849: INFEC DIS DRUG/VACC ED BA 5: Development & Demonstration (SDD) Biological Defense Equipment - Eng Dev FY 2012 FY 2012 FY 2012 Management Services (\$ in Millions) oco **FY 2011** Base Total **Total Prior** Target Contract Method Performing Years Award Award Award Cost To Value of Complete **Cost Category Item Activity & Location** Cost Date Cost Date Cost Date **Total Cost** Contract & Type Cost Cost No product/contract costs Various: Various 8.115 2.008 1.931 1.931 Continuing Various Continuing Continuing greater than \$1M individually Subtotal 8.115 2.008 1.931 1.931 FY 2012 FY 2012 FY 2012 **Product Development (\$ in Millions)** FY 2011 Base oco Total **Total Prior** Contract Target Method Performing Years Award Award Award Cost To Value of **Cost Category Item Activity & Location** Cost Date Cost Cost Date Cost Complete **Total Cost** & Type Cost Date Contract No product/contract costs Various Various:Various 15.268 3.116 3.171 3.171 Continuing Continuing Continuina greater than \$1M individually Subtotal 15.268 3.116 3.171 3.171 FY 2012 FY 2012 FY 2012 Support (\$ in Millions) oco FY 2011 Base Total **Total Prior** Contract Target **Cost To** Method **Performing** Years Award Award Award Value of **Cost Category Item** & Type **Activity & Location** Cost Cost Date Cost Date Cost Date Cost Complete **Total Cost** Contract No product/contract costs Continuing Continuing Various Various:Various 6.097 2.492 1.000 1.000 Continuing greater than \$1M individually 2.492 1.000 1.000 Subtotal 6.097 FY 2012 FY 2012 FY 2012 Test and Evaluation (\$ in Millions) FY 2011 Base oco Total **Total Prior** Target Contract Method Performing Years Award Award Award **Cost To** Value of **Activity & Location Cost Category Item** & Type Cost Cost Date Cost Date Cost Date Cost Complete **Total Cost** Contract No product/contract costs 2.385 Continuing Various Various:Various 22.231 4.611 2.385 Continuing Continuing greater than \$1M individually

2.385

2.385

Army Page 20 of 27 R-1 Line Item #111

22.231

4.611

Subtotal

| Exhibit R-3, RDT&E Project Cost Analysis: PB 2012 Army | | | DATE: February 2011 |
|--|--|------------|---------------------|
| APPROPRIATION/BUDGET ACTIVITY | R-1 ITEM NOMENCLATURE | PROJECT | |
| 2040: Research, Development, Test & Evaluation, Army | PE 0604807A: Medical Materiel/Medical | 849: INFEC | DIS DRUG/VACC ED |
| BA 5: Development & Demonstration (SDD) | Biological Defense Equipment - Eng Dev | | |

| To | otal Prior | | | | | | | | | Target |
|---------------------|------------|--------|------|---------|-----|------|---------|----------|-------------------|----------|
| | Years | | | FY 2012 | FY: | 2012 | FY 2012 | Cost To | | Value of |
| | Cost | FY 2 | 2011 | Base | 0 | CO | Total | Complete | Total Cost | Contract |
| Project Cost Totals | 51.711 | 12.227 | | 8.487 | - | | 8.487 | | | |

Remarks

Exhibit R-4, RDT&E Schedule Profile: PB 2012 Army **DATE:** February 2011 APPROPRIATION/BUDGET ACTIVITY R-1 ITEM NOMENCLATURE PROJECT 2040: Research, Development, Test & Evaluation, Army PE 0604807A: Medical Materiel/Medical 849: INFEC DIS DRUG/VACC ED

BA 5: Development & Demonstration (SDD) Biological Defense Equipment - Eng Dev

| | | FY 2010 | | | FY 2010 | | | FY 2010 | | | FY 2010 | | | | | FY | 201 | 11 | | F | Y 20 | 12 | | | FY 2 | 201 | 3 | FY 2014 | | | 2014 FY 2015 | | | 5 | | FY | 201 | 6 |
|--|---|---------|---|---|---------|---|---|---------|---|-----|---------|-----|---|---|---|----|-----|----|--|---|------|----|---|---|------|-----|---|---------|---|---|--------------|---|--|---|--|----|-----|---|
| | 1 | 2 | (| 3 | 4 | 1 | 2 | 3 | 4 | . 1 | 1 | 2 : | 3 | 4 | 1 | 2 | 3 | 4 | | 1 | 2 | 3 | 4 | • | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | | | | | | |
| Dengue Tetravalent Vaccine (CDR) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | · | | | | | | |
| Dengue Tetravalent Vaccine Phase 3 Expanded Safety Study | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Dengue Tetravalent Vaccine (MS-C) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Malaria Prophylaxis (MS-C) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Paromomycin/Gentamicin Topical Antileishmanial Cream (CDR) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Paromomycin/Gentamicin Topical Antileishmanial Cream Phase 3 Expa | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Paromomycin/Gentamicin Topical Antileishmanial Cream MS-C | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Paromomycin/Gentamicin Topical Antileishmanial Cream NDA | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Paromomycin/Gentamicin Topical Antileishmanial Cream LRIP | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Paromomycin/Gentamicin Topical Antileishmanial Cream F/D | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Leishmania Rapid Diagnostic Device MS-C | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Leishmania Rapid Diagnostic Device FDA Approval | | | | | | | | | | | | | | | | | | | | | | | | | | - | | | | | | | | | | | | |
| Leishmania Rapid Diagnostic Device Fielding/ Delivery | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Exhibit R-4A, RDT&E Schedule Details: PB 2012 Army

DATE: February 2011

APPROPRIATION/BUDGET ACTIVITY R-1 ITEM NOMENCLATURE PROJECT

2040: Research, Development, Test & Evaluation, Army PE 0604807A: Medical Materiel/Medical 849: INFEC DIS DRUG/VACC ED

BA 5: Development & Demonstration (SDD)

Biological Defense Equipment - Eng Dev

Schedule Details

| | Sta | art | En | ıd |
|---|---------|------|---------|------|
| Events | Quarter | Year | Quarter | Year |
| Dengue Tetravalent Vaccine (CDR) | 3 | 2011 | 4 | 2015 |
| Dengue Tetravalent Vaccine Phase 3 Expanded Safety Study | 3 | 2011 | 4 | 2016 |
| Dengue Tetravalent Vaccine (MS-C) | 3 | 2016 | 3 | 2016 |
| Malaria Prophylaxis (MS-C) | 4 | 2016 | 4 | 2016 |
| Paromomycin/Gentamicin Topical Antileishmanial Cream (CDR) | 4 | 2011 | 4 | 2013 |
| Paromomycin/Gentamicin Topical Antileishmanial Cream Phase 3 Expa | 2 | 2011 | 1 | 2013 |
| Paromomycin/Gentamicin Topical Antileishmanial Cream MS-C | 2 | 2014 | 2 | 2014 |
| Paromomycin/Gentamicin Topical Antileishmanial Cream NDA | 3 | 2014 | 3 | 2014 |
| Paromomycin/Gentamicin Topical Antileishmanial Cream LRIP | 4 | 2014 | 3 | 2015 |
| Paromomycin/Gentamicin Topical Antileishmanial Cream F/D | 4 | 2014 | 4 | 2014 |
| Leishmania Rapid Diagnostic Device MS-C | 4 | 2012 | 4 | 2012 |
| Leishmania Rapid Diagnostic Device FDA Approval | 1 | 2013 | 1 | 2013 |
| Leishmania Rapid Diagnostic Device Fielding/Delivery | 2 | 2013 | 4 | 2016 |

Army Page 23 of 27 R-1 Line Item #111

DATE: Fabruson: 2011

| EXHIBIT R-2A, RD I & Project Ju | istification: PE | 3 2012 Army | / | | | | | | DAIE: Febi | ruary 2011 | | | |
|--|------------------|-------------|-----------------|----------------|------------------|--------------------------------------|---------|---------------------------------------|------------|---------------------|------------|--|--|
| APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 5: Development & Demonstration (SDD) | | | | | | TURE Materiel/Med ipment - Eng | | PROJECT A11: LSTAT MEDICAL TECHNOLOGY | | | | | |
| COST (\$ in Millions) | FY 2010 | FY 2011 | FY 2012 Base | FY 2012 OCO | FY 2012 Total | FY 2013 | FY 2014 | FY 2015 | FY 2016 | Cost To Complete | Total Cost | | |
| A11: LSTAT MEDICAL TECHNOLOGY (CA) | 0.800 | - | - | - | - | - | - | - | - | 0.000 | 0.800 | | |
| Quantity of RDT&E Articles | | | | | | | | | | | | | |

A. Mission Description and Budget Item Justification

Exhibit D 24 DDT9 F Drainet Instification, DD 2042 Array

The LSTAT is a life support piece of combat medical equipment. It is a litter with imbedded life support equipment, which is capable of sustaining an injured soldier for an extended period of time. This equipment will allow a soldier to be transported while maintaining all medical surveillance and diagnostics continually intact.

| B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each) | FY 2010 | FY 2011 | FY 2012 |
|--|---------|---------|---------|
| Title: LSTAT Medical Technology | 0.800 | - | - |
| Articles: | 0 | | |
| Description: This is a Congressional Interest Item. | | | |
| FY 2010 Accomplishments: Advanced Product development research was conducted on the LSTAT. | | | |
| Accomplishments/Planned Programs Subtotals | 0.800 | _ | - |

C. Other Program Funding Summary (\$ in Millions)

N/A

D. Acquisition Strategy

N/A

E. Performance Metrics

Performance metrics used in the preparation of this justification material may be found in the FY 2010 Army Performance Budget Justification Book, dated May 2010.

Army Page 24 of 27 R-1 Line Item #111

Exhibit R-3, RDT&E Project Cost Analysis: PB 2012 Army

APPROPRIATION/BUDGET ACTIVITY

2040: Research, Development, Test & Evaluation, Army

BA 5: Development & Demonstration (SDD)

R-1 ITEM NOMENCLATURE

PE 0604807A: Medical Materiel/Medical

Biological Defense Equipment - Eng Dev

DATE: February 2011

PROJECT

A11: LSTAT MEDICAL TECHNOLOGY (CA)

| Product Development (| luct Development (\$ in Millions) | | | | 2011 | FY 2 Ba | 2012 se | FY 2 | | FY 2012 Total | | | |
|---|-----------------------------------|-----------------------------------|------------------------------|------|---------------|------------|---------------|------|---------------|------------------|---------------------|------------|--------------------------------|
| Cost Category Item | Contract Method & Type | Performing Activity & Location | Total Prior Years Cost | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | Cost To Complete | Total Cost | Target Value of Contract |
| No product/contract cost greater than \$1M individually | SS/LH | IMS Systems:Signal Hill, CA | 4.471 | - | | - | | - | | - | Continuing | Continuing | Continuing |
| | | Subtotal | 4.471 | - | | - | | - | | - | | | |
| | | Total Prio Years Cost | | FY 2 | 2011 | FY 2 Ba | 2012 se | FY 2 | | FY 2012 Total | Cost To | Total Cost | Target Value of Contract |
| | | Project Cost Totals | 4.471 | - | | - | | - | | - | | | |

Remarks

Page 25 of 27

| EXHIBIT R-2A, RDT&E Project Justification: PB 2012 Army | | | | | | | | | | DATE: February 2011 | | | |
|---|--|--|-----------|-------------|-----------------|-------|-----------------------------------|------------------|---------|---------------------|----------|------------|--|
| APPROPRIATION/BUDGET ACTIVITY | | | | R-1 ITEM N | IOMENCLA | TURE | | PROJECT | | | | | |
| | APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 5: Development & Demonstration (SDD) | | PE 060480 | 7A: Medical | Materiel/Med | dical | CS5: MED MATERIEL/MED BIO DEFENSE | | | | | | |
| | BA 5: Development & Demonstration | Development & Demonstration (SDD) Biological Defense Equipment - Eng Dev | | | | | ı Dev | INITIATIVES (CA) | | | | | |
| | COST (f in Millions) | FY 2012 FY 2012 FY 20 | FY 2012 | | | | | Cost To | | | | | |
| | COST (\$ in Millions) | FY 2010 | FY 2011 | Base | oco | Total | FY 2013 | FY 2014 | FY 2015 | FY 2016 | Complete | Total Cost | |
| | CS5: MED MATERIEL/MED BIO | 4.179 | _ | _ | _ | _ | _ | _ | _ | _ | 0.000 | 4.179 | |

A. Mission Description and Budget Item Justification

DEFENSE INITIATIVES (CA)
Quantity of RDT&E Articles

Congressional Special Interest funding for medical materiel/medical biological defense initiatives - Engineering Development.

| B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each) | FY 2010 | FY 2011 | FY 2012 |
|---|---------|---------|---------|
| Title: Army Portable Oxygen Concentration System | 1.190 | - | - |
| Articles: | 0 | | |
| Description: This is a Congressional Interest Item. | | | |
| FY 2010 Accomplishments: | | | |
| Conducted advanced development research in Army Portable Oxygen Concentration System | | | |
| Title: Military applications for Medical Grade Chitosan | 2.989 | - | - |
| Articles: | 0 | | |
| Description: Congressional Interest Item. | | | |
| FY 2010 Accomplishments: | | | |
| Conducted advanced development research project to conduct military applications for Medical Grade Chitosan | | | |
| Accomplishments/Planned Programs Subtotals | 4.179 | - | - |

C. Other Program Funding Summary (\$ in Millions)

N/A

D. Acquisition Strategy

N/A

E. Performance Metrics

Performance metrics used in the preparation of this justification material may be found in the FY 2010 Army Performance Budget Justification Book, dated May 2010.

Army Page 26 of 27 R-1 Line Item #111

| Exhibit R-2A, RDT&E Project Justification: PB 2012 Army DATE: February 2011 | | | | | | | | | | | | |
|--|---------|---------|-----------------|----------------|--|---------|---------|---------|--|---------------------|------------|--|
| | | | | | R-1 ITEM NOMENCLATURE PE 0604807A: Medical Materiel/Medical Biological Defense Equipment - Eng Dev | | | | PROJECT VS8: MEDEVAC MISSION EQUIPMENT PACKAGE (MEP) - END DEV | | | |
| COST (\$ in Millions) | FY 2010 | FY 2011 | FY 2012 Base | FY 2012 OCO | FY 2012 Total | FY 2013 | FY 2014 | FY 2015 | FY 2016 | Cost To Complete | Total Cost | |
| VS8: MEDEVAC MISSION EQUIPMENT PACKAGE (MEP) - END DEV | - | - | - | - | - | 1.573 | 0.934 | 0.748 | 0.372 | Continuing | Continuing | |
| Quantity of RDT&E Articles | | | | | | | | | | | | |

A. Mission Description and Budget Item Justification

No FY12 Funding for this project

B. Accomplishments/Planned Programs (\$ in Millions)

N/A

C. Other Program Funding Summary (\$ in Millions)

N/A

D. Acquisition Strategy

N/A

E. Performance Metrics

Performance metrics used in the preparation of this justification material may be found in the FY 2010 Army Performance Budget Justification Book, dated May 2010.

Page 27 of 27 Army R-1 Line Item #111