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Exhibit R-2, RDT&E Budget Item Justification: PB 2014 Army **DATE:** April 2013

APPROPRIATION/BUDGET ACTIVITY					R-1 ITEM NOMENCLATURE							
2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>System Development & Demonstration (SDD)</i>					PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>							
COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 [#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
Total Program Element	-	26.316	43.395	39.468	-	39.468	46.553	48.381	46.256	47.738	Continuing	Continuing
812: <i>Mil HIV Vac&Drug Dev</i>	-	3.742	3.232	3.902	-	3.902	4.678	4.695	4.616	5.591	Continuing	Continuing
832: <i>Field Medical Systems Engineering Development</i>	-	14.336	23.971	23.049	-	23.049	26.936	28.955	28.466	28.413	Continuing	Continuing
849: <i>Infec Dis Drug/Vacc Ed</i>	-	8.238	13.771	12.517	-	12.517	14.939	14.325	13.059	13.619	Continuing	Continuing
VS8: <i>MEDEVAC Mission Equipment Package (MEP) - End Dev</i>	-	0.000	2.421	0.000	-	0.000	0.000	0.406	0.115	0.115	Continuing	Continuing

[#] FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

^{##} The FY 2014 OCO Request will be submitted at a later date

Note

FY14 funding adjustment was meet critical Army budget 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 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 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 to 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

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APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>System Development & Demonstration (SDD)</i>	R-1 ITEM NOMENCLATURE PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>
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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.

(PROJ VS8) program receives products that transition from VS7 and funds effort to complete research and development for the MEDEVAC Mission Essential Packages (MEPs) to support 256 Medical Evacuation legacy helicopters. The force design will increase the number of air frames in the force from 12 to 15 aircraft for 37 MEDEVAC companies to better meet operation needs.

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)	<u>FY 2012</u>	<u>FY 2013</u>	<u>FY 2014 Base</u>	<u>FY 2014 OCO</u>	<u>FY 2014 Total</u>
Previous President's Budget	27.132	43.395	46.634	-	46.634
Current President's Budget	26.316	43.395	39.468	-	39.468
Total Adjustments	-0.816	0.000	-7.166	-	-7.166
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.816	-			
• Adjustments to Budget Years	-	-	-7.166	-	-7.166

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Army									DATE: April 2013			
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 5: System Development & Demonstration (SDD)					R-1 ITEM NOMENCLATURE PE 0604807A: Medical Materiel/Medical Biological Defense Equipment - Eng Dev				PROJECT 812: Mil HIV Vac&Drug Dev			
COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 [#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
812: Mil HIV Vac&Drug Dev	-	3.742	3.232	3.902	-	3.902	4.678	4.695	4.616	5.591	Continuing	Continuing
Quantity of RDT&E Articles												
# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012												
## The FY 2014 OCO Request will be submitted at a later date												
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 2012	FY 2013	FY 2014	
Title: Military HIV Vaccine and Drug Development									3.742	3.232	3.902	
									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 2012 Accomplishments: Performed three inter-related studies to enhance our understanding of how the vaccine strategy used in the 2009 safety/efficacy trial 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 define what vaccine responses to try to generate for next increment studies.												
FY 2013 Plans: Refine vaccine administration schedule as well as clinical trial design based on data from previous clinical trials. Adjust plan for increment 1 future efficacy trial planned to begin in late 2014.												
FY 2014 Plans: Will continue to refine vaccine administration schedule as well as clinical trial design based on data from previous clinical trials. Will adjust plan for Regional well-controlled clinical trial large enough to demonstrate vaccine efficacy which initiated mid-2013 and												

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013	
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B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)		FY 2012	FY 2013
future Prime/Boost Regional Phase 3 Study to Confirm Safety and Effectiveness in a Diverse Population, planned to begin in early 2018.			
Accomplishments/Planned Programs Subtotals		3.742	3.232
C. Other Program Funding Summary (\$ in Millions) N/A			
Remarks			
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.			

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2014 Army												DATE: April 2013			
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>System Development & Demonstration (SDD)</i>						R-1 ITEM NOMENCLATURE PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>						PROJECT 812: <i>Mil HIV Vac&Drug Dev</i>			
Management Services (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Management Services Cost	Various	Various:Various	1.124	0.215		0.299		0.823		-		0.823	Continuing	Continuing	0.000
Subtotal			1.124	0.215		0.299		0.823		0.000		0.823			0.000
Product Development (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Cost	Various	Henry M. Jackson Foundation,:Various	27.742	2.537		2.145		0.953		-		0.953	Continuing	Continuing	Continuing
Subtotal			27.742	2.537		2.145		0.953		0.000		0.953			
Support (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Support Cost	Various	Various:Various	0.580	0.046		0.031		0.878		-		0.878	Continuing	Continuing	0.000
Subtotal			0.580	0.046		0.031		0.878		0.000		0.878			0.000
Test and Evaluation (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development T&E Cost	Various	Henry M. Jackson Foundation,:Various	23.446	0.944		0.757		1.248		-		1.248	Continuing	Continuing	Continuing
Subtotal			23.446	0.944		0.757		1.248		0.000		1.248			

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	All Prior Years	FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals	52.892	3.742		3.232		3.902		0.000		3.902			
Remarks													

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Exhibit R-4, RDT&E Schedule Profile: PB 2014 Army																DATE: April 2013											
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>System Development & Demonstration (SDD)</i>												R-1 ITEM NOMENCLATURE PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>								PROJECT 812: <i>Mil HIV Vac&Drug Dev</i>							

	FY 2012				FY 2013				FY 2014				FY 2015				FY 2016				FY 2017				FY 2018			
	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
Phase 2 study of Vaccine candidates																												
Initiate Phase 3 Study of Vaccine candidates																												
Increment 1 Efficacy Trial																												

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Exhibit R-4A, RDT&E Schedule Details: PB 2014 Army			DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>System Development & Demonstration (SDD)</i>	R-1 ITEM NOMENCLATURE PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>	PROJECT 812: <i>Mil HIV Vac&Drug Dev</i>	

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
Phase 2 study of Vaccine candidates	1	2014	2	2014
Initiate Phase 3 Study of Vaccine candidates	1	2015	1	2015
Increment 1 Efficacy Trial	4	2014	2	2015

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APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 5: System Development & Demonstration (SDD)					R-1 ITEM NOMENCLATURE PE 0604807A: Medical Materiel/Medical Biological Defense Equipment - Eng Dev				PROJECT 832: Field Medical Systems Engineering Development			
COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 [#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
832: Field Medical Systems Engineering Development	-	14.336	23.971	23.049	-	23.049	26.936	28.955	28.466	28.413	Continuing	Continuing
Quantity of RDT&E Articles												
# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012												
## The FY 2014 OCO Request will be submitted at a later date												
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 effectiveness 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 is also 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.												
Major contractors/intra-governmental agencies include: IGR Enterprises,Inc.;Army Medical Department Board Test Center;Se Qual Technologies,Inc.; Enginivity, Inc.;Ultrasound Diagnostics,Inc.;HemCon Medical Technologies,; 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 2012	FY 2013	FY 2014	
Title: Field Medical Systems Engineering Development PM Medical Devices									5.847	0.200	0.943	
									0	0		
Description: This project funds the engineering and manufacturing development of medical products for enhanced combat casualty care managed by PM Medical Devices.												
FY 2012 Accomplishments: The Burn Resuscitation Decision Device: conducted final environmental, operational and clinical testing on device for MS C submission. Wireless Medical Monitoring transitioned from Congressional Special Interest (CSI) project to an Army Core funded project and undergone a Milestone C review as well as prototype field testing. Plasma Knife: transitioned from 836 6.4 funding line												

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B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)		FY 2012	FY 2013	FY 2014
into 832 6.5 funding line. Finalized results of clinical and operational testing. Identified and addressed all refinements and undergo Milestone C review in 4Q. FY 2013 Plans: Simplified Automated Ventilator (SAVe): No further R&D funding required as this is now a commercial product. The Burn Resuscitation Decision Device: Prepare documentation for CPD and MS B/C. No further R&D required as this product will transition to procurement in FY 2013. MS B/C expected 2Q FY 2013. Total Intravenous Anesthesia (TIVA): This product was transitioned to tech watch in FY 2012. Wireless Medical Monitoring: no requirement and no RDTE planned. Plasma Knife: no further R&D funding required as this is now a commercial product. Noise-Immune Stethoscope: finalized and conducted a MS C review in FY 2012; no RDTE efforts for FY 2013. Oxygen Generator (15 LPM) System: 15LPM draft CDD completed and a request for proposals (RFP) award expected in March 2012. Continue development with a target to field in FY 2015. Replacement for the M-138 Steam Sterilizer: FY 2013 funding for testing of the device. Begin design and development of system in FY 2012 and continue development through FY 2013. One-Handed Tourniquet update: No RDTE efforts in FY 2012 or FY 2013. Replacement for the M-138 Steam Sterilizer: FY 2013 funding for testing of the device. Begin design and development of system in FY 2012 and continue development through FY 2013. One-Handed Tourniquet update: No RDTE efforts in FY 2012 or FY 2013. FY 2014 Plans: Oxygen Generator (15 LPM) System: Instead of ARMY only Request for Proposals (RFP) scheduled for March 2012, will cooperate with the Air Force 15 LPM developmental effort. Funding will only be for airworthiness certification and other Army-unique requirements; Air Force has funding to complete the project for their needs. Replacement for the M-138 Steam Sterilizer: Will continue planned testing of device designed and developed in previous years. Medical Equipment Sets COTS Modernization of Life Cycle Equipment: will continue development and testing to ensure the most current and cost effective devices are being utilized. Equipment is selected for modernization based on its own life cycle plan as part of a Sets, Kits and Outfits (SKO). Modernization also occurs if a product will be discontinued, new models will be available and new technology will be developed to meet the users need. TBI Diagnostic Assay System Increment II Point of Care Device: will plan to enter pivotal clinical trial and obtain FDA approval once transition from project 836.				
Title: Field Medical Systems Engineering Development PM Pharmaceuticals Articles: Description: Funding is provided for engineering and manufacturing development of medical products managed by PM Pharmaceuticals for enhanced combat casualty care and follow-on care, including rehabilitation. FY 2012 Accomplishments:		4.899 0	17.599 0	16.888

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B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)		FY 2012	FY 2013	FY 2014
Freeze-Dried Plasma: Began enrollment in a multi-center limited human safety/effectiveness clinical trial; and started improvement of manufacturing & laboratory capabilities to meet Food and Drug Administration requirements; and evaluated stability profile of the product. Cryopreserved Platelets (CPP) (formerly Platelet Derived Hemostatic Agent (PDHA): Continued enrollment/follow-up in a human safety/effectiveness clinical trial. FY 2013 Plans: Blood Pathogen Reduction/Inactivation transitioned to advanced development in FY 2012, transitioning from Army to be funded with Defense Health Program RDT&E funding; transitioned to Freeze-dried Plasma program to maintain current schedule and avoid delays. Freeze-Dried Plasma: Finalize Phase 3 test plan and protocols, recruit test sites for Phase 3 Pivotal clinical trial, and continue development of commercially sustainable current Good Manufacturing Practices compliant manufacturing capability. Accelerated fielding of a FDA-approved Freeze-Dried Plasma was validated in the June 2011 Army Surgeon General's Report by the Blast Injury Task Force. Cryopreserved Platelets: continue validation of current Good Manufacturing Practices manufacturing processes in support of U.S. Food and Drug Administration licensure. Develop Phase 3 clinical testing network and protocols if Phase 3 Pivotal clinical trial is required by the U.S. Food and Drug Administration. FY 2014 Plans: Cryopreserved Platelets: will complete Phase 2 safety and effectiveness clinical trial in cancer patients with platelet deficiency and continue development of Phase 3 clinical testing network and protocols, if Phase 3 Pivotal clinical trial is required by the U.S. Food and Drug Administration. Freeze-Dried Plasma Program: will continue development and validation of a sustainable current Good Manufacturing Practices manufacturing process in support of U.S. Food and Drug Administration licensure; and will initiate Phase 2b expanded safety and effectiveness clinical studies.				
Title: Field Medical Systems Engineering Development PM Integrated Clinical Systems (ICS) Articles: Description: This project funded the engineering and manufacturing development of medical products managed by PM ICS for enhanced combat casualty care and follow-on care, including rehabilitation. FY 2012 Accomplishments: Conducted final testing of Phase IV of Remote Access Device (RDA). Developed a universal security compliant access portal to serve as a standardized compliance wrapper for all vendors, medical technology, and even IT management products that may traverse between the .com and .mil networks. The Milestone Decision Authority (MDA) conducted an in process review for the RDA project in March 2011 .		0.737 0	0.000	0.000
Title: Field Medical Systems Engineering Development PM Medical Support Systems Articles:		2.853 0	6.172 0	5.218

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B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)			FY 2012	FY 2013	FY 2014
Description: This project funds the engineering and manufacturing development of medical products managed by PM Medical Support Systems for enhanced combat casualty care and follow-on care, including rehabilitation.					
FY 2012 Accomplishments: Collaborated with PM HBCT on medical equipment for the future treatment vehicle variant. Tested and evaluated the shock and litter isolation system for potential addition to Ground Ambulance and Air Ambulance Medical Equipment Sets (MES). Transitioned to Force Provider by fielding a Force Provider CSH. Fully tested the new 2-sided ISO shelter under the Joint shelter Program and finalized acquisition strategy in coordination with Program Manager's Force Provider program. Continued to develop Medical Evacuation Vehicles in coordination with Program Executive Office Combat Service Support vehicle developers.					
FY 2013 Plans: Transition from 836 and collaborate with PM HBCT on final integration/operational testing of the treatment table and blood refrigerator in the future treatment vehicle variant. As part of the medical equipment sets, transition cold chain technology, trauma tiered medical bag, water/waste water management system, and quad fold litter from 836 and complete operational evaluation. Continue modernization of medical equipment sets for preventive medicine, air and ground medical evacuation, and fresh water/waste water combat support hospital support. Transition ISO panel from 836 and complete operational testing. Transition from 836 and complete final operational evaluation of Force Provider CSH. Complete operational/technical testing of Future Medical Shelter System (hard-wall 1-sided and 2-sided shelters) for a materiel procurement decision. Continue collaboration with PEO Combat Service/Combat Service Support on finalization of MRAP medical vehicle evacuation platforms including a redesign of the Casualty Evacuation (CASEVAC) medical equipment set.					
FY 2014 Plans: As part of the medical equipment sets, will continue to perform form, fit and function of field medical sink, and will continue to evaluate commercial litters and cold chain storage devices. Will continue to evaluate modernization efforts and conduct airworthiness testing for medical equipment sets Medical Evacuation and Treatment Vehicles Medical Equipment Set and Mission Essential Package with products covering preventive medicine, air and ground medical evacuation, and fresh water/waste water systems. Will complete operational testing of the ISO operating room shelter and finalize Force Provider soft-walled shelter for procurement. Will continue collaboration with Program Executive Office Combat Support/Combat Support Service (PEO CS/CSS) and Program Executive Office Ground Combat Systems (PEO GCS) on development efforts for emerging medical vehicle evacuation/ casualty evacuation (CASEVAC) variants. Medical variants that will be collaborated on with PEO CS/CSS consist of medical shelters, Mine Resistant Ambush Protected (MRAP), Armored Multipurpose Vehicle (AMPV), and Joint Light Tactical Vehicle (JLTV). Will collaborate with PEO GCS on medical variants for the Heavy Brigade Combat Team (HBCT). Will complete operational testing of the Environmental Sentinel Biomonitor (ESB) when it transitions from project 836 and conduct a milestone C					

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B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)		FY 2012	FY 2013
(Engineering, Manufacturing and Development phase review). The ESB will assist preventative medicine personnel certify water capabilities by providing a presumptive screening capability that can rapidly identify toxicity in water.			
Accomplishments/Planned Programs Subtotals		14.336	23.971
FY 2014			
23.049			
C. Other Program Funding Summary (\$ in Millions) N/A			
Remarks			
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.			

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2014 Army												DATE: April 2013			
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 5: System Development & Demonstration (SDD)						R-1 ITEM NOMENCLATURE PE 0604807A: Medical Materiel/Medical Biological Defense Equipment - Eng Dev				PROJECT 832: Field Medical Systems Engineering Development					
Management Services (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Management Services Cost	Various	Various:Various	22.060	0.418		2.577		3.903		-		3.903	Continuing	Continuing	Continuing
Subtotal			22.060	0.418		2.577		3.903		0.000		3.903			
Product Development (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Freeze-dried Human Plasma	Various	HemCon Medical Technologies, Inc,:Tigard OR	17.525	5.796		6.000		6.727		-		6.727	Continuing	Continuing	Continuing
Hypertonic Saline Dextran	Various	National Institutes of Health, National Heart, Lung and Blood Institute (NHLBI):Various	15.100	-		-		-		-		-	Continuing	Continuing	Continuing
Medical Product Development Cost	Various	Various:Various	3.260	-		0.250		0.608		-		0.608	Continuing	Continuing	Continuing
Extended Life Red Blood Cell Product	Various	Hemerus Medical, LLC,:Various	3.140	-		-		-		-		-	Continuing	Continuing	Continuing
Cryopreserved Platelets	Various	Clinical Research Management, Inc:Hinckley, OH	0.000	-		-		1.200		-		1.200	0.000	1.200	0.000
Cryopreserved Platelets	Various	Multiple DoD activities and Dartmouth Hitchcock Med Ctr:North Potomac, MD	0.000	7.300		9.108		-		-		-	Continuing	Continuing	Continuing
Cryopreserved Platelets	Various	TBD:TBD	0.000	-		-		1.450		-		1.450	0.000	1.450	0.000
TBI Diagnostic Assay System - Increment II (benchtop/POC/ Bandits)	Various	Banyan BioMarkers, Inc:Alachua, FL	0.000	-		-		0.373		-		0.373	0.000	0.373	0.000

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2014 Army												DATE: April 2013			
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 5: System Development & Demonstration (SDD)						R-1 ITEM NOMENCLATURE PE 0604807A: Medical Materiel/Medical Biological Defense Equipment - Eng Dev						PROJECT 832: Field Medical Systems Engineering Development			
Product Development (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Subtotal			39.025	13.096		15.358		10.358		0.000		10.358			
Support (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	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., Various	5.557	-		-		-		-		-	Continuing	Continuing	Continuing
Medical Product Development Support Cost	Various	Various:Various	4.328	0.418		1.108		4.665		-		4.665	Continuing	Continuing	Continuing
Medical Equipment Sets Development	Various	Various:Various	0.000	-		-		0.456		-		0.456	0.000	0.456	0.000
Subtotal			9.885	0.418		1.108		5.121		0.000		5.121			
Test and Evaluation (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development T&E Cost	Various	Various:Various	7.292	0.404		4.928		2.403		-		2.403	Continuing	Continuing	Continuing
Cryopreserved Platelets	TBD	TBD:TBD	0.000	-		-		1.150		-		1.150	0.000	1.150	0.000
Medical Equipment Sets Development	Various	Various:Various	0.000	-		-		0.114		-		0.114	0.000	0.114	0.000
Subtotal			7.292	0.404		4.928		3.667		0.000		3.667			
Project Cost Totals			All Prior Years	FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total	Cost To Complete	Total Cost	Target Value of Contract
			78.262	14.336		23.971		23.049		0.000		23.049			
Remarks															

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Exhibit R-4, RDT&E Schedule Profile: PB 2014 Army																				DATE: April 2013							
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 5: System Development & Demonstration (SDD)												R-1 ITEM NOMENCLATURE PE 0604807A: Medical Materiel/Medical Biological Defense Equipment - Eng Dev								PROJECT 832: Field Medical Systems Engineering Development							

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Exhibit R-4A, RDT&E Schedule Details: PB 2014 Army			DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>System Development & Demonstration (SDD)</i>	R-1 ITEM NOMENCLATURE PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>	PROJECT 832: <i>Field Medical Systems Engineering Development</i>	

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
Burn Resuscitation Decision Device (MS-C) Proof of Concept	2	2012	2	2012
Wireless Medical Monitoring (MS-C) Proof of Concept	4	2012	4	2012
Cryopreserved Platelets (CPP) safety and effectiveness clinical studies	1	2015	4	2017
Freeze-dried Plasma Phase 2b safety and effectiveness clinical studies	2	2014	2	2016
Environmental Sentinel Biomonitor MS-C Proof of Concept	2	2014	2	2014

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Army									DATE: April 2013			
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 5: System Development & Demonstration (SDD)					R-1 ITEM NOMENCLATURE PE 0604807A: Medical Materiel/Medical Biological Defense Equipment - Eng Dev				PROJECT 849: Infec Dis Drug/Vacc Ed			
COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 [#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
849: Infec Dis Drug/Vacc Ed	-	8.238	13.771	12.517	-	12.517	14.939	14.325	13.059	13.619	Continuing	Continuing
Quantity of RDT&E Articles												
# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012												
## The FY 2014 OCO Request will be submitted at a later date												
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 determining if insects are infected with pathogenic organisms capable of infecting service members insect control/preventive medicine measures to limit exposure and disease transmission . It funds research that supports conclusive human clinical trials for large-scale human effectiveness (capacity to produce a desired size of an effect under ideal or optimal conditions) 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 2012	FY 2013	FY 2014	
Title: Infectious Disease Drug and Vaccine Engineering Development									8.238	13.771	12.517	
									0	0		
Description: Funding for research and development efforts for Drugs and Vaccines.												
FY 2012 Accomplishments:												
Conducted Clinical trials, developmental testing, and reviews of malarial/antimarial vaccines, drugs, diagnostics and insect repellents. Down-selected from candidate anti-malaria drugs (e.g. Tafenoquine and other drugs) to prepare for clinical trial activities for a safety/effectiveness human clinical trial (treatment indication) in a malaria endemic country. Conducted clinical trials, developmental testing, and appropriate reviews of grouped vaccines, drugs, and diagnostics (Leishmaniasis (a skin-based disease caused by a parasite and transmitted by sand flies), Dengue (a severe debilitating disease caused by a virus and transmitted by a mosquito), and other viral diseases: For Topical Antileishmanial Cream, began the clinical study report on the Tunisia large scale human safety/effectiveness trial, began enrollment efforts in the second large scale (> 300 subjects) human												

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013	
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>System Development & Demonstration (SDD)</i>		R-1 ITEM NOMENCLATURE PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>	PROJECT 849: <i>Infec Dis Drug/Vacc Ed</i>
B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)		FY 2012	FY 2013
<p>safety/effectiveness trial in Central/South America. For Dengue Tetravalent Vaccine (DTV), began study close out activities for expanded safety and effectiveness trial in children in Thailand; began a new DTV large scale (> 300 subjects) human trial in Thailand and Philippines to expand safety data and demonstrate effectiveness in children/adults.</p> <p>FY 2013 Plans: Review and analyze data from the on-going Adult Indication study begun in FY 2012 with industry partner Sanofi Pasteur and determine a Go/No Go Decision on continued product development for the Dengue Tetravalent Vaccine. Phase 3 clinical effectiveness studies are on-going with industry partner Sanofi Pasteur for the Dengue Tetravalent Vaccine, as well as Phase 3 studies for traveler/military indication. Complete preparation prior to initiating Phase 3 Pivotal clinical trial for Malaria Prophylaxis Drug. For Topical Antileishmanial Cream, complete Phase 2 safety and effectiveness New World clinical trial analysis and complete Phase 3 New World Pivotal clinical trial, and begin New World Treatment Protocol for Phase 3 site(s). The enteric JBAIDS assay transitions to advanced development and clinical trial planning begins. The Dengue Rapid Diagnostic Device (DRDD) (Hand Held Infectious Disease Diagnostics) transitions to advanced development and will be evaluated in a multi-site clinical performance study. Leishmania Rapid Diagnostic Device (LRDD) will continue the new world clinical trial started in FY 2012. The Leishmania Skin Test project will complete FDA approval and transition to procurement. The Antimalarial Drug, Artesunate Intravenous will transition from 808 and conduct MS C review.</p> <p>FY 2014 Plans: Dengue Tetravalent Vaccine (DTV): Will continue patient follow up and serology (study of blood serum) and immunology (study of body's immune system) testing to determine persistence of protection for phase 3 (safety and effectiveness Clinical trials on >300 subjects) endemic region studies, continue performance of military-specific needs US adult clinical studies, and continue studies to determine if the vaccine will protect against the disease. Malaria Prophylaxis Drug (drug to prevent from contracting Malaria): continue Pivotal clinical trials and begin efforts to determine if licensing in Austratlia is feasible. Topical Antileishmanial Cream (TLC, Paromomycin/Gentamicin): Will complete New World Phase 3 (safety and effectiveness clinical trials > 300 subjects) clinical trial and Treatment Protocol for Phase 3 site(s), and will complete Pivotal clinical trials in Tunisia and the U.S. Dengue Joint Biological Agent identification and Diagnostic System (JBAIDS): An updated Analysis of Alternatives (AoA and requirements analysis helped to determine that the Dengue JBAIDS capability does not meet user needs; therefore, the project has been terminated. Leishmania Rapid Diagnostic Device (LRDD): will conduct milestone C (Engineering, Manufacturing and Development phase review) review, obtain FDA approval, and begin fielding. The Leishmania Skin Test (LST) project: The response from the FDA indicating they would only support limited clinical utility and require additional product characterization and additional clinical trial requirements helped to determine that the LST capability does not meet user needs; therefore, the project has been terminated. Antimalarial Drug, Artesunate Intravenous: Plan to obtain FDA approval and begin fielding to prevent deaths from severe or complicated Malaria. Phase 3 (Safety and Effectiveness Clinical trials on 250 to 3000 subjects). Preventive Medicine advanced detection devices: for the control/mitigation of arthropod (insect) borne diseases, will begin field testing and evaluation. Preventive Medicine advanced pesticides : will begin field testing and evaluation. Preventive Medicine</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013	
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>System Development & Demonstration (SDD)</i>		R-1 ITEM NOMENCLATURE PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>	PROJECT 849: <i>Infec Dis Drug/Vacc Ed</i>
B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)		FY 2012	FY 2013
spatial repellents: will begin field testing and evaluation. Preventive Medicine arthropod collection devices: will begin field testing and evaluation. Infectious Disease Diagnostic products: will begin field testing and evaluation of several product candidates to include: Scrub Typhus, Rickettsiae, and Sand Fly Fever.			
Accomplishments/Planned Programs Subtotals		8.238	12.517
C. Other Program Funding Summary (\$ in Millions) N/A			
Remarks			
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.			

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2014 Army												DATE: April 2013			
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>System Development & Demonstration (SDD)</i>						R-1 ITEM NOMENCLATURE PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>						PROJECT 849: <i>Infec Dis Drug/Vacc Ed</i>			
Management Services (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Management Services Cost	Various	Various:Various	12.558	1.931		2.172		2.220		-		2.220	Continuing	Continuing	Continuing
Subtotal			12.558	1.931		2.172		2.220		0.000		2.220			
Product Development (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Cost	Various	Various:Various	21.423	3.171		4.034		5.107		-		5.107	Continuing	Continuing	Continuing
Topical Antileishmanial Drug	TBD	TBD:TBD	0.000	-		2.400		-		-		-	0.000	2.400	0.000
Subtotal			21.423	3.171		6.434		5.107		0.000		5.107			
Support (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Support Cost	Various	Various:Various	10.951	0.992		2.620		2.624		-		2.624	Continuing	Continuing	Continuing
Subtotal			10.951	0.992		2.620		2.624		0.000		2.624			
Test and Evaluation (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development T&E Cost	Various	Various:Various	31.778	2.144		2.545		1.182		-		1.182	Continuing	Continuing	Continuing

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2014 Army												DATE: April 2013			
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>System Development & Demonstration (SDD)</i>							R-1 ITEM NOMENCLATURE PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>					PROJECT 849: <i>Infec Dis Drug/Vacc Ed</i>			

Test and Evaluation (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Product Development of Dengue Tetravalent Vaccine	Various	TBD:TBD	0.000	-		-		1.384		-		1.384	0.000	1.384	0.000
Subtotal			31.778	2.144		2.545		2.566		0.000		2.566			

	All Prior Years	FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals	76.710	8.238		13.771		12.517		0.000		12.517			

Remarks

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Exhibit R-4, RDT&E Schedule Profile: PB 2014 Army			DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>System Development & Demonstration (SDD)</i>		R-1 ITEM NOMENCLATURE PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>	PROJECT 849: <i>Infec Dis Drug/Vacc Ed</i>

	FY 2012				FY 2013				FY 2014				FY 2015				FY 2016				FY 2017				FY 2018			
	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
DTV Phase 3 Adult Indication Studies																												
DTV Adult Indication Decision																												
DTV Milestone C (MS-C) Engineering, Manufacturing and Development phase review																												
DTV Biologic Licensing Application (BLA) Submission																												
Malaria Prophylaxis Phase 3 Safety and Effectiveness Pivotal Clinical Trial																												
Malaria Prophylaxis (MS-C) Engineering, Manufacturing and Development phase revi																												
Paromomycin/Gentamicin TLC (MS-C) Engineering, Manufacturing and Development pha																												
Paromomycin/Gentamicin TLC New Drug Application (NDA)																												
Paromomycin/Gentamicin TLC FDA Approval																												
Paromomycin/Gentamicin TLC (Fielding / Delivery)																												
Leishmania Rapid Diagnostic Device (MS-C) Engineering, Manufacturing and Develop																												
Leishmania Rapid Diagnostic Device FDA Approval																												
Leishmania Rapid Diagnostic Device (Fielding / Delivery)																												
Antimalarial Drug, Artesunate Intravenous New Drug Application (MS-C)																												

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Exhibit R-4, RDT&E Schedule Profile: PB 2014 Army																				DATE: April 2013								
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 5: System Development & Demonstration (SDD)										R-1 ITEM NOMENCLATURE PE 0604807A: Medical Materiel/Medical Biological Defense Equipment - Eng Dev										PROJECT 849: Infec Dis Drug/Vacc Ed								
	FY 2012				FY 2013				FY 2014				FY 2015				FY 2016				FY 2017				FY 2018			
	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
Antimalarial Drug, Artesunate Intravenous FDA Approval																												
Antimalarial Drug, Artesunate Intravenous (Fielding / Delivery)																												
Arthropod Detection Devices (Field Studies)																												
Arthropod Detection Devices (MSC)																												
Arthropod Detection Devices (Fielding / Delivery)																												
Advanced Pesticides (Field Studies)																												
Advanced Pesticides (MSC)																												
Advanced Pesticides (Fielding / Delivery)																												
Spatial Repellents (Field Studies)																												
Spatial Repellents (MSC) Engineering, Manufacturing and Development phase review																												
Spatial Repellents (Fielding / Delivery)																												
Arthropod Collection (Field Studies)																												
Arthropod Collection (MSC)																												
Arthropod Collection (Fielding / Delivery)																												

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Exhibit R-4A, RDT&E Schedule Details: PB 2014 Army			DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>System Development & Demonstration (SDD)</i>	R-1 ITEM NOMENCLATURE PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>	PROJECT 849: <i>Infec Dis Drug/Vacc Ed</i>	

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
DTV Phase 3 Adult Indication Studies	2	2012	2	2015
DTV Adult Indication Decision	4	2013	4	2013
DTV Milestone C (MS-C) Engineering, Manufacturing and Development phase review	4	2016	4	2016
DTV Biologic Licensing Application (BLA) Submission	4	2017	4	2017
Malaria Prophylaxis Phase 3 Safety and Effectiveness Pivotal Clinical Trial	4	2013	4	2015
Malaria Prophylaxis (MS-C) Engineering, Manufacturing and Development phase rev	4	2017	4	2017
Paromomycin/Gentamicin TLC (MS-C) Engineering, Manufacturing and Development pha	2	2015	2	2015
Paromomycin/Gentamicin TLC New Drug Application (NDA)	4	2015	4	2015
Paromomycin/Gentamicin TLC FDA Approval	4	2016	4	2016
Paromomycin/Gentamicin TLC (Fielding / Delivery)	1	2017	4	2018
Leishmania Rapid Diagnostic Device (MS-C) Engineering, Manufacturing and Develop	1	2014	1	2014
Leishmania Rapid Diagnostic Device FDA Approval	2	2014	2	2014
Leishmania Rapid Diagnostic Device (Fielding / Delivery)	4	2014	4	2015
Antimalarial Drug, Artesunate Intravenous New Drug Application (MS-C)	1	2013	1	2013
Antimalarial Drug, Artesunate Intravenous FDA Approval	1	2014	1	2014
Antimalarial Drug, Artesunate Intravenous (Fielding / Delivery)	1	2014	4	2017
Arthropod Detection Devices (Field Studies)	1	2014	2	2016
Arthropod Detection Devices (MSC)	2	2016	2	2016
Arthropod Detection Devices (Fielding / Delivery)	3	2016	3	2017
Advanced Pesticides (Field Studies)	4	2013	2	2016
Advanced Pesticides (MSC)	3	2016	3	2016

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Exhibit R-4A, RDT&E Schedule Details: PB 2014 Army			DATE: April 2013	
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>System Development & Demonstration (SDD)</i>		R-1 ITEM NOMENCLATURE PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>		PROJECT 849: <i>Infec Dis Drug/Vacc Ed</i>
		Start		End
Events	Quarter	Year	Quarter	Year
Advanced Pesticides (Fielding / Delivery)	3	2016	4	2017
Spatial Repellents (Field Studies)	3	2014	1	2017
Spatial Repellents (MSC) Engineering, Manufacturing and Development phase review	2	2017	2	2017
Spatial Repellents (Fielding / Delivery)	2	2017	4	2017
Arthropod Collection (Field Studies)	4	2013	3	2015
Arthropod Collection (MSC)	4	2015	4	2015
Arthropod Collection (Fielding / Delivery)	1	2016	3	2016

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Army									DATE: April 2013			
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 5: System Development & Demonstration (SDD)					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)	All Prior Years	FY 2012	FY 2013 [#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
VS8: MEDEVAC Mission Equipment Package (MEP) - End Dev	-	0.000	2.421	0.000	-	0.000	0.000	0.406	0.115	0.115	Continuing	Continuing
Quantity of RDT&E Articles												
# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012												
## The FY 2014 OCO Request will be submitted at a later date												
A. Mission Description and Budget Item Justification												
Funding for this project starts in FY 2013. Original models of Army Black Hawk MEDEVAC helicopters continue to play a major role in maintaining high US troop survival rates in Iraq and Afghanistan by evacuating wounded troops in less than one-hour. In 2009, a VCSA-approved force design update increased the number of air frames in the force from 12 to 15 aircraft for 37 MEDEVAC companies to better meet operational needs. In 2010, the Army Medical Department (AMEDD) accepted life-cycle management of the MEDEVAC MEP from PEO Aviation. In order to achieve required operational capability and enhance commonality across the MEDEVAC fleet, the MEDEVAC MEP program upgrades and retrofits the 256 MEDEVAC legacy helicopters to achieve the medical capability provided by the HH-60M, which is factory built for the MEDEVAC mission.												
B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)									FY 2012	FY 2013	FY 2014	
Title: MEDEVAC Mission Sensor Forward Looking Infrared Radar (FLIR) Articles: Description: MEDEVAC Mission Sensor (MMS) FLIR for UH-60 aircraft. One of the requirements for the UH-60A/L MEDEVAC is a sensor system that will assist the pilots in locating patient pick-up points and assist them in maintaining situational awareness in night and adverse weather conditions. The MMS is currently being qualified for use on the HH-60M aircraft. This system will be installed on UH-60 aircraft using the proven Sponson-Mount FLIR system, which is currently being used in Operation Enduring Freedom (OEF) for the MEDEVAC mission. FY 2013 Plans: Transition from VS7 and complete testing and integration of the Talon FLIR into the aircraft sponson to ensure maximum capability of the sensor, while minimizing impact to aircraft performance.									0.000	2.421 0	0.000	
									Accomplishments/Planned Programs Subtotals			0.000
C. Other Program Funding Summary (\$ in Millions)												
N/A												

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>System Development & Demonstration (SDD)</i>	R-1 ITEM NOMENCLATURE PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>	PROJECT VS8: <i>MEDEVAC Mission Equipment Package (MEP) - End Dev</i>
C. Other Program Funding Summary (\$ in Millions)		
Remarks		
D. Acquisition Strategy Develop in-house or industrial prototypes in government-managed programs to meet military MEDEVAC 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.		

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2014 Army												DATE: April 2013			
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 5: System Development & Demonstration (SDD)						R-1 ITEM NOMENCLATURE PE 0604807A: Medical Materiel/Medical Biological Defense Equipment - Eng Dev						PROJECT VS8: MEDEVAC Mission Equipment Package (MEP) - End Dev			
Product Development (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
MEDEVAC Mission Sensor Forward Looking Infrared	TBD	Redstone Arsenal,:AL	0.000	-		1.800		-		-		-	0.000	1.800	0.000
Subtotal			0.000	0.000		1.800		0.000		0.000		0.000	0.000	1.800	0.000
Support (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Support Cost	SS/UCA	Redstone Arsenal:AL	0.000	-		0.621		-		-		-	0.000	0.621	0.000
Subtotal			0.000	0.000		0.621		0.000		0.000		0.000	0.000	0.621	0.000
			All Prior Years	FY 2012	FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total	Cost To Complete	Total Cost	Target Value of Contract	
Project Cost Totals			0.000	0.000		2.421		0.000		0.000		0.000	0.000	2.421	0.000
Remarks															

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Exhibit R-4, RDT&E Schedule Profile: PB 2014 Army																DATE: April 2013			
APPROPRIATION/BUDGET ACTIVITY								R-1 ITEM NOMENCLATURE								PROJECT			
2040: Research, Development, Test & Evaluation, Army								PE 0604807A: Medical Materiel/Medical								VS8: MEDEVAC Mission Equipment			
BA 5: System Development & Demonstration (SDD)								Biological Defense Equipment - Eng Dev								Package (MEP) - End Dev			

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Exhibit R-4A, RDT&E Schedule Details: PB 2014 Army		DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 5: System Development & Demonstration (SDD)	R-1 ITEM NOMENCLATURE PE 0604807A: Medical Materiel/Medical Biological Defense Equipment - Eng Dev	PROJECT VS8: MEDEVAC Mission Equipment Package (MEP) - End Dev

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
MEDEVAC Mission Sensor (MMS) FLIR	2	2013	4	2013