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Exhibit R-2, RDT&E Budget Item Justification: PB 2011 Army									DATE: February 2010		
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							
COST (\$ in Millions)	FY 2009 Actual	FY 2010 Estimate	FY 2011 Base Estimate	FY 2011 OCO Estimate	FY 2011 Total Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
Total Program Element	41.081	41.794	34.474	0.000	34.474	30.059	45.077	52.751	54.061	Continuing	Continuing
812: MIL HIV VAC&DRUG DEV	4.550	4.448	4.456	0.000	4.456	4.434	3.380	4.986	5.250	Continuing	Continuing
832: Field Medical Systems Engineering Development	14.392	15.634	17.791	0.000	17.791	16.849	27.054	31.800	32.264	Continuing	Continuing
834: SOLDIER SYS PROT-ED	1.726	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
849: INFEC DIS DRUG/VACC ED	13.236	13.634	12.227	0.000	12.227	8.776	14.643	15.965	16.547	Continuing	Continuing
A11: LSTAT MEDICAL TECHNOLOGY (CA)	2.393	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
CS5: MED MATERIEL/MED BIO DEFENSE INITIATIVES (CA)	4.784	8.078	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

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 phase through completion of the Milestone C Decision Review. When available, commercially-off-the-shelf (COTS) medical products are also tested and evaluated for military use. This PE primarily includes pivotal (conclusive) human clinical trials necessary for licensure by the US Food and Drug Administration, along with related product stability, production manufacturing, supportability analysis, and operational testing for biologics (products derived from living organisms) and devices to demonstrate that products are safe and effective. Combat Casualty Care devices and medicines: (1) enhance care at the first responder level to save lives, and (2) provide more effective post evacuation medical care and rehabilitation to shorten recovery time. The F2 concept places Soldiers into a more austere environment with lengthened evacuation times (both arrival and transit). This requires medics and first responders to improve their ability to save lives and extend stabilization. Reduction in weight, cube, and sustainment allows medical units to increase mobility and maintain contact with their supported Units of Action. Soldier performance enhancers in the form of drugs or diagnostics, allow commanders to increase Soldiers cognitive awareness and stamina. This improves Soldiers operational capabilities and has the potential to reduce casualties. Disease and non-battle injuries (DNBI) are the largest contributor to the medical footprint. Infectious disease vaccines and preventive drugs reduce the risk of warfighters contracting debilitating or fatal diseases, reducing levels of DNBI affected Soldiers and in turn, significantly reducing a large portion of the requirement for supporting combat support hospitals in the theater of operations, and the strain placed on the Army's personnel replacement and logistical systems. This is especially important due to the higher risk posed by the ever expanding urban warfare environments. The reduction of patient evacuation requirements within the current and Future Force (F2) units will act as a force multiplier, due to the retention of uniquely skilled and combat tested Soldiers in the theater. Military Human Immunodeficiency Virus

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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)					
(HIV) Vaccine and Drug Development funds militarily relevant HIV medical countermeasures. These include advanced component development of candidate vaccines and drugs for large-scale field testing.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 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Previous President's Budget	45.222	33.893	34.527	0.000	34.527
Current President's Budget	41.081	41.794	34.474	0.000	34.474
Total Adjustments	-4.141	7.901	-0.053	0.000	-0.053
• Congressional General Reductions		-0.219			
• Congressional Directed Reductions		0.000			
• Congressional Rescissions	0.000	0.000			
• Congressional Adds		8.120			
• Congressional Directed Transfers		0.000			
• Reprogrammings	0.000	0.000			
• SBIR/STTR Transfer	-0.951	0.000			
• Adjustments to Budget Years	0.000	0.000	-0.053	0.000	-0.053
Change Summary Explanation					
Congressional Program reduction in FY 09 was due to Plasma Sterilizer project was moved to 0603002A, medical, project number MK8.Congressional increases in FY 10 was directed research in following areas:Army Portable Oxygen system, \$1.2 Million.Nanophotonic biosensor Detection of BioAgents and Pathogens, \$1.520 Million.Plasma Sterilizer, \$2.4 Million.Military applications for Medical Grade Chitosan, \$3.0 Million.					

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Army								DATE: February 2010			
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>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>			
COST (\$ in Millions)	FY 2009 Actual	FY 2010 Estimate	FY 2011 Base Estimate	FY 2011 OCO Estimate	FY 2011 Total Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
812: <i>MIL HIV VAC&DRUG DEV</i>	4.550	4.448	4.456	0.000	4.456	4.434	3.380	4.986	5.250	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 Program (\$ in Millions)											
							FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Program #1 In FY09, completed the observation and follow-up phase of the expanded safety/efficacy trial (> 16,000 subjects) in Thailand and begin data analysis for this HIV Vaccine (conduct Design Readiness Review (DRR). <i>FY 2009 Accomplishments:</i> FY 2009 <i>FY 2010 Plans:</i> FY 2010 <i>FY 2011 Base Plans:</i> FY 2011 Base <i>FY 2011 OCO Plans:</i> FY 2011 OCO							4.550	0.000	0.000	0.000	0.000

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Army				DATE: February 2010		
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B. Accomplishments/Planned Program (\$ in Millions)						
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Program #2 In FY10, prepare 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 2009 Accomplishments: FY 2009 FY 2010 Plans: FY 2010 FY 2011 Base Plans: FY 2011 Base FY 2011 OCO Plans: FY 2011 OCO		0.000	4.327	0.000	0.000	0.000
Program #3 In FY11, will 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 2009 Accomplishments: FY 2009 FY 2010 Plans: FY 2010		0.000	0.000	4.456	0.000	4.456

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Army				DATE: February 2010	
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B. Accomplishments/Planned Program (\$ in Millions)					
	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
<i>FY 2011 Base Plans:</i> FY 2011 Base <i>FY 2011 OCO Plans:</i> FY 2011 OCO					
Program #4 Small Business Innovative Research/Small Business Technology Transfer Programs. <i>FY 2009 Accomplishments:</i> FY 2009 <i>FY 2010 Plans:</i> FY 2010 <i>FY 2011 Base Plans:</i> FY 2011 Base <i>FY 2011 OCO Plans:</i> FY 2011 OCO	0.000	0.121	0.000	0.000	0.000
Accomplishments/Planned Programs Subtotals	4.550	4.448	4.456	0.000	4.456
C. Other Program Funding Summary (\$ in Millions) N/A					
D. Acquisition Strategy Test and evaluate commercially developed vaccine candidates in government-managed trials.					

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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 2011 Army											DATE: February 2010		
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>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>					
Product Development (\$ in Millions)													
				FY 2010		FY 2011 Base		FY 2011 OCO		FY 2011 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
Product Development	C	Henry M. Jackson Foundation Rockville, MD	15.280	3.093		3.231		0.000		3.231	Continuing	Continuing	0
Subtotal			15.280	3.093		3.231		0.000		3.231			0.000
Remarks													
Support (\$ in Millions)													
				FY 2010		FY 2011 Base		FY 2011 OCO		FY 2011 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 \$1M individually	C	Nothing entered for Activity and Location. Location could not be determined.	0.394	0.047		0.046		0.000		0.046	0	.579	0
Subtotal			0.394	0.047		0.046		0.000		0.046	0.000	0.579	0.000
Remarks													

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2011 Army											DATE: February 2010		
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Test and Evaluation (\$ in Millions)													
				FY 2010		FY 2011 Base		FY 2011 OCO		FY 2011 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
Test and Evaluation	C	Walter Reed Army Institute of Research (WRAIR) Silver Spring, MD	4.950	1.213		1.088		0.000		1.088	0	8.464	0
Subtotal			4.950	1.213		1.088		0.000		1.088	0.000	8.464	0.000
Remarks													
Management Services (\$ in Millions)													
				FY 2010		FY 2011 Base		FY 2011 OCO		FY 2011 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 \$1M individually	C	Nothing entered for Activity and Location. Location could not be determined.	0.483	0.095		0.091		0.000		0.091	0	.854	0
Subtotal			0.483	0.095		0.091		0.000		0.091	0.000	0.854	0.000
Remarks													

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2011 Army										DATE: February 2010		
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		Total Prior Years Cost	FY 2010		FY 2011 Base		FY 2011 OCO		FY 2011 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals		21.107	4.448		4.456		0.000		4.456			0.000
Remarks												

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Exhibit R-4A, RDT&E Schedule Details: PB 2011 Army			DATE: February 2010	
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	PROJECT 812: MIL HIV VAC&DRUG DEV		
Schedule Details				
	Start		End	
Event	Quarter	Year	Quarter	Year
Prime-Boost HIV Vaccine (DRR)	3	2009	3	2009
HIV Vaccine (CDR)	3	2010	3	2010

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COST (\$ in Millions)	FY 2009 Actual	FY 2010 Estimate	FY 2011 Base Estimate	FY 2011 OCO Estimate	FY 2011 Total Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
832: <i>Field Medical Systems Engineering Development</i>	14.392	15.634	17.791	0.000	17.791	16.849	27.054	31.800	32.264	Continuing	Continuing
Quantity of RDT&E Articles											
A. Mission Description and Budget Item Justification <p>This project funds 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 commercially-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 will be 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.</p>											
B. Accomplishments/Planned Program (\$ in Millions)											
						FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total	
Program #1						14.392	0.000	0.000	0.000	0.000	
In FY 09, Ceramic Oxygen Generator (COG): transitioned from project 836, conducted technical and user evaluations, obtained FDA clearance, conducted a Milestone C review in Qtr 3 FY 09 and transitioned to Production and Deployment. Rotary Valve Pressure Swing Adsorption Oxygen Generator (RVPSAOG): conducted Milestone C review of Omni II, and initiated low rate production, with an estimated completion of Qtr 4 FY 09. Battery Powered IV Fluid Warmer: In Qtr 4 FY 09 conducted a Milestone C review and transition to Production and Deployment. Field Sterilizer: following multiple vendor review, conducted technical and user evaluation to determine the best solution. 120 LPM (liter per minute) Oxygen Generator: initiated request for											

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B. Accomplishments/Planned Program (\$ in Millions)						
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
proposal for review of production capabilities - performance characteristics will be reviewed to determine if a commercial-off-the-shelf (COTS) solution can meet current capabilities defined or if research and development refinement of a COTS system is feasible. Freeze-dried Plasma Program: transitioned from project 836 and based on a down-select, manufacture clinical lots of a freeze-dried plasma product, and began pre-trial activities for a safety/efficacy human clinical trial. Red Blood Cell Extended Life (RBCXL) program (severe bleeding treatment candidate - a new blood collection and storage system that extends the shelf-life of red blood cells from 6 to 8 weeks): transitioned from 836 and began a human safety/efficacy study, and performed good manufacturing practices validation of the blood collection and storage system. Lab, Blood Bank, and Anatomical testing for COTS equipment to meet essential characteristics and enhance technology. Testing completed Qtr 1 FY09. Woundstat Safety Study: completed testing and moved to production.						
FY 2009 Accomplishments: FY 2009						
FY 2010 Plans: FY 2010						
FY 2011 Base Plans: FY 2011 Base						
FY 2011 OCO Plans: FY 2011 OCO						
Program #2 Continued accomplishments for FY 09. Dental Field Unit:In FY09, completed request for proposal for review of production capabilities - performance characteristics was reviewed to determine if a commercial-off-the-shelf (COTS) solution can meet current capabilities defined or if research and development refinement of a COTS		0.000	0.000	0.000	0.000	0.000

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B. Accomplishments/Planned Program (\$ in Millions)						
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
system is feasible. Noise Immune Stethoscope: In 4Q FY09, transitioned from project 879 and successfully conducted Milestone C. FY 2009 Accomplishments: FY 2009 FY 2010 Plans: FY 2010 FY 2011 Base Plans: FY 2011 Base FY 2011 OCO Plans: FY 2011 OCO						
Program #3 In FY 10, COG: conduct developmental and operational testing to obtain Milestone C. Follow on testing and report analysis will be performed to facilitate FDA and UL approval and ascertain that production capabilities adhere to good manufacturing practices. Further analysis may be performed to facilitate FDA and UL approval and ascertain that production capabilities adhere to good manufacturing processes. In 2Q FY10 for the RVPSAOG submit final reports for FDA clearance.Field Sterilizer: complete analysis and validation report of down select products in OT&E trials for final selection and movement to production and deployment. Ultrasonic Brain Imager (UBI): transition from project 836, begin safety and effectiveness human clinical trial, conduct a human factor evaluation of the prototype, and conduct a Milestone C for transition to Production and Deployment.Freeze Dried Plasma Program: initiate a multi-center safety/efficacy human clinical trial, and perform stability studies on product. Red blood cell extended life program: will prepare and complete enrollment in human safety/efficacy study. Woundstat Safety Study: complete the study.Continue testing of commercial lab equipment: expand study to include Hematology Analyzers, continue testing and evaluation for final report in 3Q FY10. Noise immune		0.000	15.196	0.000	0.000	0.000

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B. Accomplishments/Planned Program (\$ in Millions)						
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
stethoscope: conduct environmental/ transportation testing. Verify stethoscope will be able to stand up to the military environment. Conduct storage and operational temperature, drop and vibration, as well as air-worthiness testing. Life Support for Trauma and Transport (LSTAT): transition from project 834, conduct Milestone C 3Q and transition to Production and Deployment. FY 2009 Accomplishments: FY 2009 FY 2010 Plans: FY 2010 FY 2011 Base Plans: FY 2011 Base FY 2011 OCO Plans: FY 2011 OCO						
Program #4 In FY11, Freeze-dried Plasma: will start enrollment in the multi-center limited human safety/efficacy clinical trial and evaluate stability profile of the product. Red Blood Cell Extended Life Program: will complete the human safety/efficacy study, conduct data analysis, and prepare and submit report to the FDA. Platelet Derived Hemostatic Agent (PDHA):will transition from project 836 to begin enrollment/follow-up in the human safety/efficacy trial. Intranasal Ketamine (low dose pain management via nasal spray): will transition from project 836 and conduct pre-clinical trial activities for human drug use in aeromedical evacuation and burn patients. Hypertonic Saline Dextran (treatment of shock due to blood loss): will support human expanded safety/efficacy trial for treatment of shock. Will continue market analysis and surveys for candidate resuscitative fluids for treatment of shock. Enhanced SAVE: will conduct clinical user evaluation and operational testing. Remote Diagnostic Access: will conduct Prototype field testing and refinement for MOC Sensor Modual Development		0.000	0.000	17.791	0.000	17.791

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B. Accomplishments/Planned Program (\$ in Millions)						
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
phase of this device.Treatment Table for PM, HBCT Medical Mission Package for Treatment Variants: will transition from Project 836. Will transition to production for use on PM, HBCT Treatment Variant. Refrigerator for PM, HBCT for Medical Mission Package for Treatment Variant: will transition from Project 836. Will conduct environmental and operational testing. Shelter for PM, HBCT Treatment Variant: will transition from Project 836. Will evaluate alternatives in operational setting. Shock and Vibration Isolation System for Patient Litters in Ground and Air Medical Evacuation Vehicles: will transition from Project 836. Will conduct Shock and Vibration Isolation System for patient litters - air worthiness and ground vehicle testing. FY 2009 Accomplishments: FY 2009 FY 2010 Plans: FY 2010 FY 2011 Base Plans: FY 2011 Base FY 2011 OCO Plans: FY 2011 OCO						
Program #5 Continued FY 11 projects: One-handed tourniquet update: Conduct study to update medical set and down select product. Passive Cold Chain Capability for Temperature Sensitive Medical Materiel: will transition from Project 836. Will conduct environmental testing and user testing. FY 2009 Accomplishments: FY 2009		0.000	0.000	0.000	0.000	0.000

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B. Accomplishments/Planned Program (\$ in Millions)						
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
FY 2010 Plans: FY 2010						
FY 2011 Base Plans: FY 2011 Base						
FY 2011 OCO Plans: FY 2011 OCO						
Program #6 Small Business Innovative Research/Small Business Technology Transfer Programs.		0.000	0.438	0.000	0.000	0.000
FY 2009 Accomplishments: FY 2009						
FY 2010 Plans: FY 2010						
FY 2011 Base Plans: FY 2011 Base						
FY 2011 OCO Plans: FY 2011 OCO						
Accomplishments/Planned Programs Subtotals		14.392	15.634	17.791	0.000	17.791

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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.		

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2011 Army										DATE: February 2010			
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				PROJECT 832: Field Medical Systems Engineering Development				
Product Development (\$ in Millions)													
				FY 2010		FY 2011 Base		FY 2011 OCO		FY 2011 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	C	Sequal Technologies Inc., San Diego, CA	3.197	0.000		0.000		0.000		0.000	Continuing	Continuing	0
Hypertonic Saline Dextran	C	National Institutes of Health National Heart, Lung and Blood Institute (NHLBI)	0.000	4.800		5.500		0.000		5.500	Continuing	Continuing	0
Freeze-dried Human Plasma	C	HemCon Medical Technologies Inc, Tigard, OR	0.000	7.150		0.500		0.000		0.500	Continuing	Continuing	0
Extended Life Red Blood Cell Product	C	Hemerus Medical LLC, St. Paul, MN	0.000	0.745		0.500		0.000		0.500	Continuing	Continuing	0
Virtual Imaging	C	Nothing entered for Activity and Location. Location could not be determined.	0.000	0.450		0.000		0.000		0.000	Continuing	Continuing	0
No product/contract costs greater than \$1M individually	C	Nothing entered for Activity and Location. Location could not be determined.	0.000	0.000		2.000		0.000		2.000	Continuing	Continuing	0
Subtotal			3.197	13.145		8.500		0.000		8.500			0.000
Remarks													

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2011 Army											DATE: February 2010		
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>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>					
Support (\$ in Millions)													
				FY 2010		FY 2011 Base		FY 2011 OCO		FY 2011 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	C	Clinical Research Management Inc., Hinckley, OH	0.000	1.400		1.400		0.000		1.400	Continuing	Continuing	0
No product/contract costs greater then \$1 Million individually	C	Nothing entered for Activity and Location. Location could not be determined.	0.000	0.186		2.354		0.000		2.354	Continuing	Continuing	0
Subtotal			0.000	1.586		3.754		0.000		3.754			0.000
Remarks													
Test and Evaluation (\$ in Millions)													
				FY 2010		FY 2011 Base		FY 2011 OCO		FY 2011 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
Not Applicable	C	Nothing entered for Activity and Location. Location could not be determined.	0.000	0.399		4.108		0.000		4.108	Continuing	Continuing	0
Subtotal			0.000	0.399		4.108		0.000		4.108			0.000
Remarks													

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2011 Army											DATE: February 2010		
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>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>					
Management Services (\$ in Millions)													
				FY 2010		FY 2011 Base		FY 2011 OCO		FY 2011 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 \$1M individually	C	Nothing entered for Activity and Location. Location could not be determined.	18.173	0.504		1.429		0.000		1.429	Continuing	Continuing	0
Subtotal			18.173	0.504		1.429		0.000		1.429			0.000
Remarks													
			Total Prior Years Cost	FY 2010		FY 2011 Base		FY 2011 OCO		FY 2011 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals			21.370	15.634		17.791		0.000		17.791			0.000
Remarks													

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Exhibit R-4, RDT&E Schedule Profile: PB 2011 Army																		DATE: February 2010													
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												PROJECT 832: Field Medical Systems Engineering Development							

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Exhibit R-4A, RDT&E Schedule Details: PB 2011 Army			DATE: February 2010	
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	PROJECT 832: Field Medical Systems Engineering Development		
Schedule Details				
	Start		End	
Event	Quarter	Year	Quarter	Year
(1) Ceramic Oxygen Gen Sys (MS-C)	2	2009	2	2009
(2) Rotary Valve Press Swing Oxy (MS-C)	3	2009	3	2009
(3) Battery Powered Iv Fld Warm (MS-C)	3	2009	3	2009
(4) Field Sterilizer (MS-B)	3	2009	3	2009
(6) Ultrasonic Brain Imager (MS-C)	1	2010	1	2010
(7) Freeze-dried Human Plasma - clinical lots	2	2010	3	2011
(8)Red Blood Cell Extend Life - submit for FDA approval	1	2011	3	2011
(14) Noise Immune Stethoscope, (MS-C)	3	2009	3	2009
(15) Life Support for Trauma and Transport (LSTAT) (MS-C)	3	2010	3	2010

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Army								DATE: February 2010			
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>Development & Demonstration (SDD)</i>				R-1 ITEM NOMENCLATURE PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>				PROJECT 834: <i>SOLDIER SYS PROT-ED</i>			
COST (\$ in Millions)	FY 2009 Actual	FY 2010 Estimate	FY 2011 Base Estimate	FY 2011 OCO Estimate	FY 2011 Total Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
834: <i>SOLDIER SYS PROT-ED</i>	1.726	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
Quantity of RDT&E Articles											
A. Mission Description and Budget Item Justification This project funds system development and demonstration of preventive medicine materiel, to include devices and medicines, in order to provide protection, sustainment, and enhancement of the physical and psychological capabilities of Soldiers engaged in combat operations across environmental conditions. The focus is on reduction of personnel losses due to preventable disease and non-battle injuries through development of environmental and physiological performance monitors and other preventive medicine countermeasures. In FY10, Project 834 will be consolidated into Project 832 Combat Medical Matl ED. Major contractors/performers are Pacific Technologies, Inc, Redwood, WA; Integrated Medical Systems, Inc, Signal Hill, CA, and the U.S. Army Aeromedical Research Laboratory, Fort Rucker, AL.											
B. Accomplishments/Planned Program (\$ in Millions)											
							FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Program #1 Coliform Analyzer: In FY09, transition from project 837, performed operational testing, conduct Milestone C 4Q, and transition to Production and Deployment. In FY09, complete development of LSTAT-Lite, produce test articles, and conduct airworthiness, operational, and environmental testing. In FY10, transition to project 832. In FY09, conduct air worthiness testing on commercial off the shelf and non-developmental medical devices for military field use. <i>FY 2009 Accomplishments:</i> FY 2009 <i>FY 2010 Plans:</i> FY 2010							1.726	0.000	0.000	0.000	0.000

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Army				DATE: February 2010					
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>Development & Demonstration (SDD)</i>	R-1 ITEM NOMENCLATURE PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>	PROJECT 834: <i>SOLDIER SYS PROT-ED</i>							
<u>B. Accomplishments/Planned Program (\$ in Millions)</u>									
					FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
<i>FY 2011 Base Plans:</i> FY 2011 Base <i>FY 2011 OCO Plans:</i> FY 2011 OCO									
Accomplishments/Planned Programs Subtotals					1.726	0.000	0.000	0.000	0.000
<u>C. Other Program Funding Summary (\$ in Millions)</u>									
N/A									
<u>D. Acquisition Strategy</u>									
Test and evaluate in-house and commercially developed preventative medicine materiel to meet FDA and EPA regulatory requirements.									
<u>E. Performance Metrics</u>									
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 2011 Army											DATE: February 2010		
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>Development & Demonstration (SDD)</i>				R-1 ITEM NOMENCLATURE PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>				PROJECT 834: <i>SOLDIER SYS PROT-ED</i>					
Product Development (\$ in Millions)													
				FY 2010		FY 2011 Base		FY 2011 OCO		FY 2011 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 \$1M individually	C	Nothing entered for Activity and Location. Location could not be determined.	3.688	0.000		0.000		0.000		0.000	Continuing	Continuing	0
Congressional Add in Support of Chem-Bio Protection	C	Nothing entered for Activity and Location. Location could not be determined.	4.550	0.000		0.000		0.000		0.000	Continuing	Continuing	0
Subtotal			8.238	0.000		0.000		0.000		0.000			0.000
Remarks													
Support (\$ in Millions)													
				FY 2010		FY 2011 Base		FY 2011 OCO		FY 2011 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 \$1M individually	C	Nothing entered for Activity and Location. Location could not be determined.	0.163	0.000		0.000		0.000		0.000	Continuing	Continuing	0
Subtotal			0.163	0.000		0.000		0.000		0.000			0.000

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2011 Army											DATE: February 2010		
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>Development & Demonstration (SDD)</i>				R-1 ITEM NOMENCLATURE PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>				PROJECT 834: <i>SOLDIER SYS PROT-ED</i>					
Support (\$ in Millions)													
				FY 2010		FY 2011 Base		FY 2011 OCO		FY 2011 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
Remarks													
Test and Evaluation (\$ in Millions)													
				FY 2010		FY 2011 Base		FY 2011 OCO		FY 2011 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 \$1M individually	C	Nothing entered for Activity and Location. Location could not be determined.	1.046	0.000		0.000		0.000		0.000	Continuing	Continuing	0
Subtotal			1.046	0.000		0.000		0.000		0.000			0.000
Remarks													

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2011 Army											DATE: February 2010		
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>Development & Demonstration (SDD)</i>				R-1 ITEM NOMENCLATURE PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>				PROJECT 834: <i>SOLDIER SYS PROT-ED</i>					
Management Services (\$ in Millions)													
				FY 2010		FY 2011 Base		FY 2011 OCO		FY 2011 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 \$1M individually	C	Nothing entered for Activity and Location. Location could not be determined.	1.792	0.000		0.000		0.000		0.000	Continuing	Continuing	0
Subtotal			1.792	0.000		0.000		0.000		0.000			0.000
Remarks													
			Total Prior Years Cost	FY 2010		FY 2011 Base		FY 2011 OCO		FY 2011 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals			11.239	0.000		0.000		0.000		0.000			0.000
Remarks													

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Exhibit R-4A, RDT&E Schedule Details: PB 2011 Army			DATE: February 2010	
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>Development & Demonstration (SDD)</i>	R-1 ITEM NOMENCLATURE PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>	PROJECT 834: <i>SOLDIER SYS PROT-ED</i>		
Schedule Details				
	Start		End	
Event	Quarter	Year	Quarter	Year
Coliform Analyzer (MS C)	3	2009	3	2009

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Army								DATE: February 2010			
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>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>			
COST (\$ in Millions)	FY 2009 Actual	FY 2010 Estimate	FY 2011 Base Estimate	FY 2011 OCO Estimate	FY 2011 Total Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
849: <i>INFEC DIS DRUG/VACC ED</i>	13.236	13.634	12.227	0.000	12.227	8.776	14.643	15.965	16.547	Continuing	Continuing
Quantity of RDT&E Articles											
A. Mission Description and Budget Item Justification <p>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.</p>											
B. Accomplishments/Planned Program (\$ in Millions)											
						FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total	
Program #1 In FY 09, conducted Clinical trials, developmental testing, and reviews of malarial/antimalarial vaccines, drugs, diagnostics and insect repellents. For Tafenoquine, conducted enrollment for small human clinical challenge trial exposing volunteers to the malaria parasite (using current FDA-approved malaria drug mefloquine) to gather a baseline of the human body's immune responses to malaria and collect blood samples to be used in the validation of a laboratory assay to be used as a tool to determine the rate of malaria infection. For Combined Camouflage Face Paint (CCFP), completed the Soldier acceptability clinical study, finalized the study report, and conducted a Milestone C for transition to Production and Deployment.						7.536	0.000	0.000	0.000	0.000	

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Army			DATE: February 2010			
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	PROJECT 849: INFEC DIS DRUG/VACC ED				
B. Accomplishments/Planned Program (\$ in Millions)						
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
FY 2009 Accomplishments: FY 2009						
FY 2010 Plans: FY 2010						
FY 2011 Base Plans: FY 2011 Base						
FY 2011 OCO Plans: FY 2011 OCO						
Program #2 For FY 10, conducted clinical trials, developmental testing, and reviews of malarial/antimalarial vaccines, drugs, diagnostics and insect repellents. For Tafenoquine, conduct data analysis and prepare a final report on the small human challenge clinical trial, and will begin pre-trial activities for a large-scale safety/efficacy human clinical trial (treatment indication) in a malaria endemic country. FY 2009 Accomplishments: FY 2009 FY 2010 Plans: FY 2010 FY 2011 Base Plans: FY 2011 Base		0.000	6.459	0.000	0.000	0.000

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Army				DATE: February 2010		
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		PROJECT 849: INFEC DIS DRUG/VACC ED		
B. Accomplishments/Planned Program (\$ in Millions)						
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
FY 2011 OCO Plans: FY 2011 OCO						
Program #3 For FY 11, conduc 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. FY 2009 Accomplishments: FY 2009 FY 2010 Plans: FY 2010 FY 2011 Base Plans: FY 2011 Base FY 2011 OCO Plans: FY 2011 OCO		0.000	0.000	4.568	0.000	4.568
Program #4 For FY 09, 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, transitioned from project 808. The overseas human clinical trial activities continued enrollment in the Tunisian large scale (> 300 subjects) pivotal human safety/efficacy treatment trial, began enrollment in three small (<35 subjects) pharmacokinetic (drug metabolism) human trials in France, Peru and Panama, and prepared for a second large scale (> 300 subjects) human trial in Central/South America. For		5.700	0.000	0.000	0.000	0.000

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Army				DATE: February 2010		
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		PROJECT 849: INFEC DIS DRUG/VACC ED		
B. Accomplishments/Planned Program (\$ in Millions)						
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Pentostam (intravenous drug treatment of skin lesions caused by the Leishmania parasite), continued medical consult and database management in support of the industry partner's FDA licensure submission efforts. For the Dengue Tetravalent Vaccine (DTV) vaccine, transitioned from project 808 the overseas human clinical trial activities and completed enrollment and continued monitoring the expanded human safety and immunity trial in Puerto Rico, completed data analysis in the human safety and immune response trial (adults) in the U.S, completed subject follow-up for the expanded human safety and immune response trials (three trials: infant, children and adult) in Thailand, and began preliminary data analysis, and continued pre-trial planning for an expanded safety and efficacy trial in children in Thailand, For Hepatitis E vaccine, continued maintenance of study blood specimens kept under cold storage and continued monitoring of our industry partner's Hepatitis E vaccine development effort.						
FY 2009 Accomplishments: FY 2009						
FY 2010 Plans: FY 2010						
FY 2011 Base Plans: FY 2011 Base						
FY 2011 OCO Plans: FY 2011 OCO						
Program #5 In FY10, Topical Antileishmanial Cream, continue subject enrollment/follow-up in the Tunisia large scale (> 300 subjects) human safety/efficacy trial and begin the second large scale human safety/efficacy trial in Central/South America, and complete the three small scale (<35 subjects) pharmacokinetic (drug metabolism) human trials in France, Peru and Panama. For Pentostam, monitor progress of industry partner's FDA licensure submission		0.000	6.793	0.000	0.000	0.000

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Army				DATE: February 2010	
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		PROJECT 849: INFEC DIS DRUG/VACC ED	
B. Accomplishments/Planned Program (\$ in Millions)					
	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
efforts. For Dengue Tetravalent Vaccine, complete subject follow-up and begin the data analysis on the expanded human safety and immunity trial in Puerto Rico, complete the study report on the human safety and immune response trial (adults) in the U.S., complete the study reports (infant, children and adult) on the expanded human safety and immune response trial in Thailand, and complete pre-trial activities for the expanded safety and efficacy trial in children in Thailand. For Hepatitis E vaccine, maintenance of study blood specimens kept under cold storage and monitoring of industry partner's Hepatitis E vaccine development effort. FY 2009 Accomplishments: FY 2009 FY 2010 Plans: FY 2010 FY 2011 Base Plans: FY 2011 Base FY 2011 OCO Plans: FY 2011 OCO					
Program #6 In FY11, for Topical Antileishmanial Cream, will analyze the data and prepare the final report on the Tunisia large scale human safety/efficacy trial, will continue enrollment/follow-up in the second large scale (> 300 subjects) human safety/efficacy trial in Central/South America, and will analyze the data and prepare the final report for the three small scale (<35 subjects) pharmacokinetic (drug metabolism) human trials in France, Peru and Panama. For Pentostam, will monitor progress of industry partner's FDA licensure submission efforts. For DTV vaccine, will complete the study report on the expanded human safety and immunity trial in Puerto Rico and begin the expanded safety and efficacy trial in children in Thailand. For Hepatitis E vaccine will continue	0.000	0.000	7.659	0.000	7.659

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Army			DATE: February 2010			
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	PROJECT 849: INFEC DIS DRUG/VACC ED				
B. Accomplishments/Planned Program (\$ in Millions)						
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
maintenance of study blood specimens kept under cold storage and monitoring of industry partner's Hepatitis E vaccine development effort. FY 2009 Accomplishments: FY 2009 FY 2010 Plans: FY 2010 FY 2011 Base Plans: FY 2011 Base FY 2011 OCO Plans: FY 2011 OCO						
Program #7 Small Business Innovative Research/Small Business Technology Transfer Programs. FY 2009 Accomplishments: FY 2009 FY 2010 Plans: FY 2010 FY 2011 Base Plans: FY 2011 Base FY 2011 OCO Plans: FY 2011 OCO		0.000	0.382	0.000	0.000	0.000

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Army				DATE: February 2010				
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>Development & Demonstration (SDD)</i>	R-1 ITEM NOMENCLATURE PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>	PROJECT 849: <i>INFECTION DIS DRUG/VACCINATION</i>						
<u>B. Accomplishments/Planned Program (\$ in Millions)</u>								
				FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Accomplishments/Planned Programs Subtotals				13.236	13.634	12.227	0.000	12.227
<u>C. Other Program Funding Summary (\$ in Millions)</u> N/A								
<u>D. Acquisition Strategy</u> Test and evaluate in-house and commercially developed products in government-managed trials to meet FDA requirements and Environmental Protection Agency registration.								
<u>E. Performance Metrics</u> 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 2011 Army											DATE: February 2010		
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>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>					
Product Development (\$ in Millions)													
				FY 2010		FY 2011 Base		FY 2011 OCO		FY 2011 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 \$1M individually	C	Nothing entered for Activity and Location. Location could not be determined.	8.389	3.480		3.116		0.000		3.116	Continuing	Continuing	0
Subtotal			8.389	3.480		3.116		0.000		3.116			0.000
Remarks													
Support (\$ in Millions)													
				FY 2010		FY 2011 Base		FY 2011 OCO		FY 2011 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 \$1M individually	C	Nothing entered for Activity and Location. Location could not be determined.	0.595	2.783		2.492		0.000		2.492	Continuing	Continuing	0
Subtotal			0.595	2.783		2.492		0.000		2.492			0.000
Remarks													

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2011 Army										DATE: February 2010	
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				PROJECT 849: INFEC DIS DRUG/VACC ED			

Test and Evaluation (\$ in Millions)

				FY 2010		FY 2011 Base		FY 2011 OCO		FY 2011 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 \$1M individually	C	Nothing entered for Activity and Location. Location could not be determined.	12.265	4.936		4.611		0.000		4.611	Continuing	Continuing	0
Subtotal			12.265	4.936		4.611		0.000		4.611			0.000

Remarks

Management Services (\$ in Millions)

				FY 2010		FY 2011 Base		FY 2011 OCO		FY 2011 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 \$1M individually	C	Nothing entered for Activity and Location. Location could not be determined.	3.592	2.435		2.008		0.000		2.008	Continuing	Continuing	0
Subtotal			3.592	2.435		2.008		0.000		2.008			0.000

Remarks

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2011 Army							DATE: February 2010					
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>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>					
		Total Prior Years Cost	FY 2010		FY 2011 Base		FY 2011 OCO		FY 2011 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals		24.841	13.634		12.227		0.000		12.227			0.000
Remarks												

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Exhibit R-4A, RDT&E Schedule Details: PB 2011 Army			DATE: February 2010	
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>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				
	Start		End	
Event	Quarter	Year	Quarter	Year
Combination Camouflage Face Paint/Insect Repellent (MS-C)	3	2009	3	2009

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Army								DATE: February 2010			
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>Development & Demonstration (SDD)</i>				R-1 ITEM NOMENCLATURE PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>				PROJECT A11: <i>LSTAT MEDICAL TECHNOLOGY (CA)</i>			
COST (\$ in Millions)	FY 2009 Actual	FY 2010 Estimate	FY 2011 Base Estimate	FY 2011 OCO Estimate	FY 2011 Total Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
A11: <i>LSTAT MEDICAL TECHNOLOGY (CA)</i>	2.393	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
Quantity of RDT&E Articles											
A. Mission Description and Budget Item Justification 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 Program (\$ in Millions)											
							FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Program #1 Congressional Add <i>FY 2009 Accomplishments:</i> FY 2009 <i>FY 2010 Plans:</i> FY 2010 <i>FY 2011 Base Plans:</i> FY 2011 Base <i>FY 2011 OCO Plans:</i> FY 2011 OCO							2.393	0.000	0.000	0.000	0.000
Accomplishments/Planned Programs Subtotals							2.393	0.000	0.000	0.000	0.000

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Army		DATE: February 2010
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>Development & Demonstration (SDD)</i>	R-1 ITEM NOMENCLATURE PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>	PROJECT A11: <i>LSTAT MEDICAL TECHNOLOGY (CA)</i>
<u>C. Other Program Funding Summary (\$ in Millions)</u> N/A		
<u>D. Acquisition Strategy</u> N/A		
<u>E. Performance Metrics</u> 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 2011 Army											DATE: February 2010		
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>Development & Demonstration (SDD)</i>				R-1 ITEM NOMENCLATURE PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>				PROJECT A11: <i>LSTAT MEDICAL TECHNOLOGY (CA)</i>					
Product Development (\$ in Millions)													
				FY 2010		FY 2011 Base		FY 2011 OCO		FY 2011 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	C	Nothing entered for Activity and Location. Location could not be determined.	2.078	0.000		0.000		0.000		0.000	Continuing	Continuing	0
Subtotal			2.078	0.000		0.000		0.000		0.000			0.000
Remarks													
			Total Prior Years Cost	FY 2010		FY 2011 Base		FY 2011 OCO		FY 2011 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals			2.078	0.000		0.000		0.000		0.000			0.000
Remarks													

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Army								DATE: February 2010			
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>Development & Demonstration (SDD)</i>				R-1 ITEM NOMENCLATURE PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>				PROJECT CS5: <i>MED MATERIEL/MED BIO DEFENSE INITIATIVES (CA)</i>			
COST (\$ in Millions)	FY 2009 Actual	FY 2010 Estimate	FY 2011 Base Estimate	FY 2011 OCO Estimate	FY 2011 Total Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
CS5: <i>MED MATERIEL/MED BIO DEFENSE INITIATIVES (CA)</i>	4.784	8.078	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
Quantity of RDT&E Articles											
A. Mission Description and Budget Item Justification Congressional Special Interest funding for medical materiel/medical biological Defense initiatives.											
B. Accomplishments/Planned Program (\$ in Millions)											
							FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Program #1 Congressionally directed advanced development research in Advanced Packaging Solutions for Biotherapeutics. <i>FY 2009 Accomplishments:</i> FY 2009 <i>FY 2010 Plans:</i> FY 2010 <i>FY 2011 Base Plans:</i> FY 2011 Base <i>FY 2011 OCO Plans:</i> FY 2011 OCO							1.550	0.000	0.000	0.000	0.000
Program #2 Congressionally directed advanced development research in Lightweight Trauma Module							2.400	0.000	0.000	0.000	0.000

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Army			DATE: February 2010		
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	PROJECT CS5: MED MATERIEL/MED BIO DEFENSE INITIATIVES (CA)			
B. Accomplishments/Planned Program (\$ in Millions)					
	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
FY 2009 Accomplishments: FY 2009					
FY 2010 Plans: FY 2010					
FY 2011 Base Plans: FY 2011 Base					
FY 2011 OCO Plans: FY 2011 OCO					
Program #3 Congressionally directed advanced development research in Rotary Valve Pressure Swing Absorption Oxygen Generator	0.834	0.000	0.000	0.000	0.000
FY 2009 Accomplishments: FY 2009					
FY 2010 Plans: FY 2010					
FY 2011 Base Plans: FY 2011 Base					
FY 2011 OCO Plans: FY 2011 OCO					
Program #4	0.000	2.390	0.000	0.000	0.000

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Army				DATE: February 2010		
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		PROJECT CS5: MED MATERIEL/MED BIO DEFENSE INITIATIVES (CA)		
B. Accomplishments/Planned Program (\$ in Millions)						
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Congressionally directed advanced development research in Plasma Sterilizer. FY 2009 Accomplishments: FY 2009 FY 2010 Plans: FY 2010 FY 2011 Base Plans: FY 2011 Base FY 2011 OCO Plans: FY 2011 OCO						
Program #5 Congressionally directed advanced development research in Nanophotonic biosensor Detection of bioagents and Pathogens FY 2009 Accomplishments: FY 2009 FY 2010 Plans: FY 2010 FY 2011 Base Plans: FY 2011 Base FY 2011 OCO Plans: FY 2011 OCO		0.000	1.510	0.000	0.000	0.000

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Army				DATE: February 2010		
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		PROJECT CS5: MED MATERIEL/MED BIO DEFENSE INITIATIVES (CA)		
B. Accomplishments/Planned Program (\$ in Millions)						
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Program #6 Congressionally directed advanced development research in Army Portable Oxygen Concentration System FY 2009 Accomplishments: FY 2009 FY 2010 Plans: FY 2010 FY 2011 Base Plans: FY 2011 Base FY 2011 OCO Plans: FY 2011 OCO		0.000	1.190	0.000	0.000	0.000
Program #7 Congressionally directed advanced development research project to conduct military applications for Medical Grade Chitosan FY 2009 Accomplishments: FY 2009 FY 2010 Plans: FY 2010 FY 2011 Base Plans: FY 2011 Base		0.000	2.988	0.000	0.000	0.000

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Army				DATE: February 2010	
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 5: <i>Development & Demonstration (SDD)</i>		R-1 ITEM NOMENCLATURE PE 0604807A: <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>		PROJECT CS5: <i>MED MATERIEL/MED BIO DEFENSE INITIATIVES (CA)</i>	
<u>B. Accomplishments/Planned Program (\$ in Millions)</u>					
				FY 2009	FY 2010
				FY 2011 Base	FY 2011 OCO
				FY 2011 Total	
<i>FY 2011 OCO Plans:</i> FY 2011 OCO					
Accomplishments/Planned Programs Subtotals				4.784	8.078
				0.000	0.000
				0.000	0.000
<u>C. Other Program Funding Summary (\$ in Millions)</u> N/A					
<u>D. Acquisition Strategy</u> N/A					
<u>E. Performance Metrics</u> 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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