Exhibit R-2, RDT&E Budget Item Justification: PB 2011 Army

DATE: February 2010

APPROPRIATION/BUDGET ACTIVITY

2040: Research, Development, Test & Evaluation, Army

BA 4: Advanced Component Development & Prototypes (ACD&P)

R-1 ITEM NOMENCLATURE

PE 0603807A: Medical Systems - Adv 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	29.572	35.886	28.132	0.000	28.132	37.128	22.643	17.388	17.620	Continuing	Continuing
808: DOD DRUG & VACC AD	5.535	6.829	7.225	0.000	7.225	12.332	9.361	8.931	9.014	Continuing	Continuing
811: MIL HIV VAC&DRUG DEV	0.145	1.460	2.923	0.000	2.923	2.908	1.449	0.965	0.961	Continuing	Continuing
836: Field Medical Systems Advanced Development	13.343	22.822	17.984	0.000	17.984	21.888	11.833	7.492	7.645	Continuing	Continuing
837: SOLDIER SYS PROT-AD	6.561	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
CS4: MEDICAL SYSTEMS ADV DEV INITIATIVES (CA)	3.988	4.775	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 development of medical materiel at the start of an official program of record, within the early system integration portion of the System Development and Demonstration phase of the acquisition life cycle using 6.4 funding. Program efforts support transition of promising Science and Technology candidate medical technologies (drugs, vaccines, medical devices, diagnostics, and mechanisms for detection and control of disease carrying insects) to larger scale testing in humans for safety and effectiveness. Programs are aligned to meet Future Force (F2) requirements stressed within concept documents and organizational structures. The PE provides funding for Food and Drug Administration (FDA) regulated human clinical trials to gain additional information about safety and effectiveness on the path to licensure for use in humans. The major enablers supported by this PE are: Combat Casualty Care devices and biologics (products derived from living organisms), with two major focuses: 1) enhance forward care at the first responder level while reducing the footprint of medical organizations for greater mobility and easier sustainment, and 2) provide enhanced post-evacuation care and rehabilitation. The F2 concept places Soldiers into a more austere environment with lengthened evacuation times (both arrival and transit). Supporting medics and first responders require greater lifesaving and extended stabilization capability to save lives. Soldier Performance Enhancers in the form of drugs and diagnostics will allow commanders to manage a Soldier's mental and physical performance. Performance enhancers will increase Soldier capabilities and reduce casualties resulting from high operational tempo, extreme environmental exposure, and loss of cognitive ability. Infectious disease efforts include testing candidate vaccines and preventive and therapeutic drugs to reduce the risk of service members contracting debilitating or fatal diseases, and/or to shorten recovery time. Technologies for identifying disease threats and mechanisms for controlling disease-carrying insects will reduce risk of exposure. Disease and non-battle injuries (DNBI) are the largest contributors to the combat support hospital footprint, and significant reductions of the medical footprint in theater can be achieved by reducing the number of DNBI affected Soldiers. Military Human Immunodeficiency Virus (HIV) Vaccine and Drug Development funds militarily relevant HIV medical countermeasures. These include component development of candidate vaccines 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.

Exhibit R-2, RDT&E Budget Item Justification: PB 2011 Army

APPROPRIATION/BUDGET ACTIVITY

R-1 ITEM NOMENCLATURE

2040: Research, Development, Test & Evaluation, Army

PE 0603807A: Medical Systems - Adv Dev

DATE: February 2010

BA 4: Advanced Component Development & Prototypes (ACD&P)

B. Program Change Summary (\$ in Millions)

	<u>FY 2009</u>	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Previous President's Budget	30.207	31.275	31.721	0.000	31.721
Current President's Budget	29.572	35.886	28.132	0.000	28.132
Total Adjustments	-0.635	4.611	-3.589	0.000	-3.589
 Congressional General Reductions 		-0.164			
 Congressional Directed Reductions 		0.000			
 Congressional Rescissions 	0.000	0.000			
 Congressional Adds 		4.775			
 Congressional Directed Transfers 		0.000			
 Reprogrammings 	0.000	0.000			
• SBIR/STTR Transfer	-0.635	0.000			
 Adjustments to Budget Years 	0.000	0.000	-3.589	0.000	-3.589

Change Summary Explanation

In FY 10, Funds increased (\$4611) due to Congressional directed research efforts. In FY 11, Funds realigned (\$3589) to higher priority requirements.

DATE: February 2010

9.014

Continuing

Continuing

APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)					NOMENCLA A: <i>Medical Sy</i>	ATURE vstems - Adv 1	Dev	PROJECT 808: DOD DRUG & VACC AD			
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

7.225

0.000

12.332

9.361

8.931

A. Mission Description and Budget Item Justification

808: DOD DRUG & VACC AD

Quantity of RDT&E Articles

Exhibit R-2A, RDT&E Project Justification: PB 2011 Army

5.535

6.829

7.225

This project funds development of candidate medical countermeasures for infectious diseases of military relevance. These efforts are in: vaccines, drugs, diagnostic kits/devices, and insect control measures. These funds support human clinical efficacy (capacity to produce a desired size of an effect under ideal or optimal conditions) trials of the drug/vaccine in larger groups that are designed to assess how well the drug/vaccine works, and to continue safety assessments in a larger group of volunteers. Funding supports both technical evaluations and human clinical testing to assure the safety and effectiveness of medical diagnostic kits and devices. This work, which is performed in military laboratories or civilian pharmaceutical firms, is directed toward the prevention of disease, early diagnosis, and speeding recovery once diagnosed. All clinical trials are conducted in accordance with U.S. Food and Drug Administration (FDA) regulations, a mandatory obligation for all military products placed into the hands of medical providers or service members. Product development priorities are determined based upon four major factors: (1) the extent and threat 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 and production).

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

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Program #1	5.535	0.000	0.000	0.000	0.000
In FY 09, reviews evaluations, and human clinical trials of malarial/anti-malarial vaccines, drugs, diagnostics, insect repellents, and grouped infectious disease (Dengue [a severe debilitating disease caused by a virus and transmitted by a mosquito] and Leishmania [a skin-based disease caused by a parasite and transmitted by sand flies]) vaccines and drugs. For Tafenoquine, developed/validated new laboratory assay to determine levels of antibodies from malaria infection using blood samples from a mefloquine (current FDA-approved malaria drug) challenge clinical study (supported by project 849) and evaluated potential sites for future human safety/efficacy trial, and conducted a Critical Design Review (CDR). The Artesunate drug transitioned from project 810 and a Critical Design Review (CDR) was conducted. The Dengue Tetravalent Vaccine (DTV) vaccine continued FDA required vaccine potency and stability testing of the product and all other DTV activities are transitioned to project					

Exhibit R-2A, RDT&E Project Justification: PB 2011 Army				DATE: Febr	ruary 2010	
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)	R-1 ITEM NOMENCLATURE PE 0603807A: Medical Systems - Adv	Dev	PROJECT 808: DOD D	RUG & VAC	C AD	
B. Accomplishments/Planned Program (\$ in Millions)			1			
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
849. The Topical Antileishmanial Cream opened a human treatment continued stability testing and produced new clinical drug lots, and p trials activities of this topical cream. The Leishmania Skin Test (LST data analysis for the expanded human safety/dose ranging/sensitization Design Review (CDR). The Pentostam drug transitioned to project 84 FY 2009 Accomplishments: FY 2009	roject 849 supports the overseas human (7), will complete follow-up and performe on trial in the U.S. and conducted a Critical					
FY 2010 Plans: FY 2010						
FY 2011 Base Plans: FY 2011 Base						
FY 2011 OCO Plans: FY 2011 OCO						
Program #2		0.000	6.687	0.000	0.000	0.00
In FY10, for Tafenoquine, down-select to best site for human safety/development/validation to understand the human body's immune respand as tool for determining future clinical trial enrollment size, and triproject 849. Monitor progress of a new military topical insect repelled suitability for entry into advanced development. For the Infectious I conduct market research of selected developmental and commercial of	conses when infected with malaria parasites cansition the entire Tafenoquine program to ent candidate in project 810 to determine its Disease Diagnostic (multiple candidates),					

UNCLASSIFIED

diseases of military interest to determine suitability for entry into advanced development. The DTV vaccine continues FDA required vaccine potency and stability testing and all other DTV activities are transitioned to project 849. For the Topical Antileishmanial Cream, continue a human treatment protocol in the U.S., the partner

Exhibit R-2A, RDT&E Project Justification: PB 2011 Army				DATE: Feb	ruary 2010	
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)	R-1 ITEM NOMENCLATURE PE 0603807A: Medical Systems - Adv	R-1 ITEM NOMENCLATURE PE 0603807A: Medical Systems - Adv Dev 808: DOD I				
B. Accomplishments/Planned Program (\$ in Millions)	·					
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
will continue stability testing and produce new clinical drug lots, and clinical trials activities of this topical cream. For LST, complete the dose ranging sensitization trial in the U.S., and conduct pre-trial activately/efficacy trial in a Leishmania endemic region.	inal report for the expanded human safety					
FY 2009 Accomplishments:						
FY 2009						
FY 2010 Plans:						
FY 2010						
FY 2011 Base Plans:						
FY 2011 Base						

In FY11, will prepare to accept transition of a new military topical insect repellent from project 810 at Milestone B into Engineering & Manufacturing Development phase. Will transition new malaria vaccine candidate from project 810 into Engineering & Manufacturing Development phase. For the Infectious Disease Diagnostic (multiple candidates), will prepare to accept transition of project into the Engineering & Manufacturing Development phase of advanced development. The DTV vaccine will continue FDA required vaccine potency and stability testing and all other DTV activities are transitioned to project 849. For Topical Antileishmanial Cream, will continue a human treatment protocol in the US, the industry partner will continue stability testing of the drug product, and project 849 supports the overseas human trials activities of the topical cream.

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0.000

0.000

7.225

0.000

7.225

R-1 Line Item #69 Page 5 of 41 373 of 1922

FY 2011 OCO Plans: FY 2011 OCO

Program #3

Exhibit R-2A, RDT&E Project Justification: PB 2011 Army	DATE: February 2010		
APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE	PROJECT	
2040: Research, Development, Test & Evaluation, Army	PE 0603807A: Medical Systems - Adv Dev	808: <i>DOD L</i>	DRUG & VACC AD
BA 4: Advanced Component Development & Prototypes (ACD&P)			

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

B. Accompnishments/1 familed 1 rogram (\$\pi\$ in Numbus)	EN 2000	TT 2010	FY 2011	FY 2011	FY 2011
	FY 2009	FY 2010	Base	осо	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 #4	0.000	0.142	0.000	0.000	0.000
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					
Accomplishments/Planned Programs Subtotals	5.535	6.829	7.225	0.000	7.225

Exhibit R-2A, RDT&E Project Justification: PB 2011 Army		DATE: February 2010
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)	R-1 ITEM NOMENCLATURE PE 0603807A: Medical Systems - Adv Dev	PROJECT 808: DOD DRUG & VACC AD
C. Other Program Funding Summary (\$ in Millions) N/A		
D. Acquisition Strategy Test and evaluate in-house and commercially developed products in extensive Protection Agency registration.	e government-managed clinical trials to gather data re	equired for FDA licensure and Environmental
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.

Exhibit R-3, RDT&E Project Cost Analysis: PB 2011 Army

DATE: February 2010

APPROPRIATION/BUDGET ACTIVITY

2040: Research, Development, Test & Evaluation, Army

BA 4: Advanced Component Development & Prototypes (ACD&P)

R-1 ITEM NOMENCLATURE

PE 0603807A: Medical Systems - Adv Dev

PROJECT

808: DOD DRUG & VACC AD

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	С	Nothing entered for Activity and Location. Location could not be determined.	5.952	1.750		1.869		0.000		1.869	Continuing	Continuing	0
		Subtotal	5.952	1.750		1.869		0.000		1.869			0.000

Remarks

Support (\$ in Millions)

				FY	FY 2010		FY 2011 Base		FY 2011 OCO				
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	С	Nothing entered for Activity and Location. Location could not be determined.	1.401	1.289		1.495		0.000		1.495	Continuing	Continuing	0
		Subtotal	1.401	1.289		1.495		0.000		1.495			0.000

Exhibit R-3, RDT&E Project Cost Analysis: PB 2011 Army

DATE: February 2010

APPROPRIATION/BUDGET ACTIVITY

R-1 ITEM NOMENCLATURE

PROJECT

2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)

PE 0603807A: Medical Systems - Adv Dev

808: DOD DRUG & VACC AD

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	С	Nothing entered for Activity and Location. Location could not be determined.	33.699	2.574		2.331		0.000		2.331	Continuing	Continuing	0
		Subtotal	33.699	2.574		2.331		0.000		2.331			0.000

Remarks

Management Services (\$ in Millions)

0		,											l l
				FY	2010		2011 ase	FY 2	2011 CO	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	С	Nothing entered for Activity and Location. Location could not be determined.	7.197	1.216		1.530		0.000		1.530	Continuing	Continuing	0
		Subtotal	7.197	1.216		1.530		0.000		1.530			0.000

Exhibit R-3, RDT&E Project Cost Analysis: PB 2011 Army			DATE: February 2010
APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE	PROJECT	
2040: Research, Development, Test & Evaluation, Army	PE 0603807A: Medical Systems - Adv Dev	808: <i>DOD D</i>	PRUG & VACC AD
BA 4: Advanced Component Development & Prototypes (ACD&P)			

Target Value of **Total Prior** FY 2011 FY 2011 FY 2011 Cost To **Years Cost** FY 2010 Base ocoTotal Complete **Total Cost** Contract 7.225 0.000 6.829 0.000 **Project Cost Totals** 48.249 7.225

Exhibit R-4, RDT&E Schedule Profile: PB 2011 Army

DATE: February 2010

APPROPRIATION/BUDGET ACTIVITY

R-1 ITEM NOMENCLATURE

PROJECT

2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)

PE 0603807A: Medical Systems - Adv Dev

808: DOD DRUG & VACC AD

		FY	200	9	F	Υ	201	0]	FY	201	1]	F Y 2	201	2]	F Y 2	2013	3	F	Y 2	201	4]	FY	201	5
	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
Leishmania Skin Test (CDR)	#																											
New Standard Military Topical Insect Repellant (MS-B)									#																			

Exhibit R-4A, RDT&E Schedule Details: PB 2011 Army **DATE:** February 2010 APPROPRIATION/BUDGET ACTIVITY **R-1 ITEM NOMENCLATURE** PROJECT

2040: Research, Development, Test & Evaluation, Army PE 0603807A: Medical Systems - Adv Dev

808: DOD DRUG & VACC AD BA 4: Advanced Component Development & Prototypes (ACD&P)

Schedule Details

	Sta	art	E	nd
Event	Quarter	Year	Quarter	Year
Leishmania Skin Test (CDR)	1	2009	1	2009
New Standard Military Topical Insect Repellant (MS-B)	1	2011	1	2011

DATE: February 2010

APPROPRIATION/BUDGET ACTI 2040: Research, Development, Test & I BA 4: Advanced Component Developm	Evaluation, Ar	•)		NOMENCLA A: <i>Medical S</i> y			PROJECT 811: MIL HI	V VAC&DRU	G DEV	
COST (\$ in Millions)	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		
811: MIL HIV VAC&DRUG DEV	2.923	0.000	2.923	2.908	1.449	0.965	0.961	Continuing	Continuing		

A. Mission Description and Budget Item Justification

Quantity of RDT&E Articles

Exhibit R-2A, RDT&E Project Justification: PB 2011 Army

This project funds development of militarily relevant human immunodeficiency virus (HIV) medical countermeasures. It provides for the planning and conduct of human clinical trials in a group of healthy volunteers to assess the drug/vaccine for safety, tolerability, how the drug/vaccine is distributed, metabolized, and excreted from the body, and to investigate the appropriate dose for therapeutic use. Development efforts are focused on militarily unique needs effecting manning, mobilization, and deployment. The major contractor is 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	0.145	0.000	0.000	0.000	0.000
In FY09, evaluated potential commercial drug/vaccine candidates for preliminary human trials and conduct Design Readiness Review (DRR).					
FY 2009 Accomplishments: FY 2009					
FY 2010 Plans: FY 2010					
FY 2011 Base Plans: FY 2011 Base					
FY 2011 OCO Plans: FY 2011 OCO					

Exhibit R-2A, RDT&E Project Justification: PB 2011 Army

APPROPRIATION/BUDGET ACTIVITY
2040: Research, Development, Test & Evaluation, Army

PE 0603807A: Medical Systems - Adv Dev
811: MIL HIV VAC&DRUG DEV

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

BA 4: Advanced Component Development & Prototypes (ACD&P)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Program #2	0.000	1.419	0.000	0.000	0.000
In FY10, will evaluate and down-select drug/vaccine candidates for preliminary human trials and conduct Design Readiness Review (DRR).					
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	0.000	0.000	2.923	0.000	2.923
In FY11, will seek new industry partnership for selected candidate(s) drug/vaccine for HIV medical treatment/prevention.					
FY 2009 Accomplishments: FY 2009					
FY 2010 Plans: FY 2010					
FY 2011 Base Plans: FY 2011 Base					

Exhibit R-2A, RDT&E Project Justification: PB 2011 Army

DATE: February 2010

APPROPRIATION/BUDGET ACTIVITY

2040: Research, Development, Test & Evaluation, Army

BA 4: Advanced Component Development & Prototypes (ACD&P)

R-1 ITEM NOMENCLATURE

PE 0603807A: Medical Systems - Adv Dev

PROJECT

811: MIL HIV VAC&DRUG DEV

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 #4	0.000	0.041	0.000	0.000	0.000
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					
Accomplishments/Planned Programs Subtotals	0.145	1.460	2.923	0.000	2.923

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

N/A

D. Acquisition Strategy

Test and evaluate commercially developed drug/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.

Exhibit R-3, RDT&E Project Cost Analysis: PB 2011 Army

DATE: February 2010

APPROPRIATION/BUDGET ACTIVITY

R-1 ITEM NOMENCLATURE

PROJECT

2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)

PE 0603807A: Medical Systems - Adv Dev

811: MIL HIV VAC&DRUG DEV

Product Development (\$ in Millions)

				FY	2010		2011 ase		2011 CO	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	С	Henry M. Jackson Foundation Rockville, MD	5.139	0.347		0.746		0.000		0.746	Continuing	Continuing	0
		Subtotal	5.139	0.347		0.746		0.000		0.746			0.000

Remarks

Support (\$ in Millions)

	,												
				FY	2010		2011 ase		2011 CO	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	С	Nothing entered for Activity and Location. Location could not be determined.	0.868	0.202		0.597		0.000		0.597	Continuing	Continuing	0
		Subtotal	0.868	0.202		0.597		0.000		0.597			0.000

Remarks

Not Applicable

Exhibit R-3, RDT&E Project Cost Analysis: PB 2011 Army

DATE: February 2010

APPROPRIATION/BUDGET ACTIVITY

R-1 ITEM NOMENCLATURE

PROJECT

2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)

PE 0603807A: Medical Systems - Adv Dev

811: MIL HIV VAC&DRUG DEV

Test and Evaluation (\$ in Millions)

				FY :	2010		2011 ase	FY 2	2011 CO	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	С	U.S. Component AFRIMS Bangkok, APO, AP 96546-5000	11.495	0.705		1.107		0.000		1.107	Continuing	Continuing	0
		Subtotal	11.495	0.705		1.107		0.000		1.107			0.000

Remarks

Not Applicable

Management Services (\$ in Millions)

	()	· ·· /		FY	2010	FY:	2011 ase	FY:	2011 CO	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.	С	Nothing entered for Activity and Location. Location could not be determined.	0.250	0.206		0.473		0.000		0.473	Continuing	Continuing	0
		Subtotal	0.250	0.206		0.473		0.000		0.473			0.000

Remarks

Not Applicable

Exhibit R-3, RDT&E Project Cost Analysis: PB 2011 Army		DATE: February 2010
APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE	PROJECT

2040: Research, Development, Test & Evaluation, Army

BA 4: Advanced Component Development & Prototypes (ACD&P)

PE 0603807A: Medical Systems - Adv Dev 811: MIL HIV VAC&DRUG DEV

	Total Prior Years Cost	FY 2	2010	FY :	2011 ase	FY 2011 OCO	FY 2011 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals	17.752	1.460		2.923		0.000	2.923			0.000

Exhibit R-4, RDT&E Schedule Profile: PB 2011 Army

DATE: February 2010

APPROPRIATION/BUDGET ACTIVITY

R-1 ITEM NOMENCLATURE

PROJECT

2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)

PE 0603807A: Medical Systems - Adv Dev

811: MIL HIV VAC&DRUG DEV

		FY	200	9]	FY	201	0]	F Y	201	1	F	Y 2	201	2	1	F Y 2	01.	3	F	Y :	201	4	I	Y 2	2015	;
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
HIV Vaccine Design Readiness Review (DRR)							#																					

Exhibit R-4A, RDT&E Schedule Details: PB 2011 Army			DATE: February 2010
APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE	PROJECT	
2040: Research, Development, Test & Evaluation, Army	PE 0603807A: Medical Systems - Adv Dev	811: <i>MIL HI</i>	V VAC&DRUG DEV
BA 4: Advanced Component Development & Prototypes (ACD&P)			

Schedule Details

	Sta	art	End		
Event	Quarter	Year	Quarter	Year	
HIV Vaccine Design Readiness Review (DRR)	3	2010	3	2010	

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Exhibit R-2A, RDT&E Project Justifi	ication: PB 20	JII Army							DATE: Febr	uary 2010	
APPROPRIATION/BUDGET ACTIV	VITY			R-1 ITEM N	NOMENCLA	TURE		PROJECT			
2040: Research, Development, Test & E				PE 0603807	A: Medical Sy	stems - Adv L	Dev	836: Field M	ledical System	is Advanced L	Development
BA 4: Advanced Component Developme	ent & Prototy _l	pes (ACD&P))								
			FY 2011	FY 2011	FY 2011						
COST (\$ in Millions)	FY 2009	FY 2010	Base	осо	Total	FY 2012	FY 2013	FY 2014	FY 2015	Cost To	
	Actual	Estimate	Estimate	Estimate	Estimate	Estimate	Estimate	Estimate	Estimate	Complete	Total Cost
836: Field Medical Systems Advanced	13.343	22.822	17.984	0.000	17.984	21.888	11.833	7.492	7.645	Continuing	Continuing
Development											
Quantity of RDT&E Articles											

A. Mission Description and Budget Item Justification

This project funds development of medical products for enhanced combat casualty care and follow-on care, including rehabilitation. This project funds human clinical trials to test the safety and effectiveness of biologics (products derived from living organisms) and devices necessary to meet medical requirements. When available, commercially-off-the-shelf (COTS) medical products are also tested and evaluated for transition to system development and demonstration. Consideration is also given to reducing the medical logistics footprint through smaller weight, volume, and equipment independence from supporting materials. All clinical trials are conducted in accordance with U.S. Food and Drug Administration (FDA) regulations. In FY10 Project 837 Soldier Sys Prot-AD will be consolidated into this Project, 836.Major contractors/intra-governmental agencies include: IGR Enterprises, Inc.; Army Medical Department Board Test Center; SeQual Technologies, Inc.; Ultrasonic Diagnostics, Inc.; HemCon Medical Technologies, Inc.; Hemerus Medical, LLC.; Fast Track Drugs & Biologics, LLC; Clinical Research Management, and Walter Reed Army Institute of Research (WRAIR) and Institute of Surgical Research (ISR) for user evaluation.

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

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Program #1	13.343	0.000	0.000	0.000	0.000
In FY09, the Ceramic Oxygen Generator (COG) transitioned to project 832 for Systems Development and Demonstration. Future Medical Shelter System (FMSS): down-selected to one system. Future Combat System (FCS): prepared for performance design review (PDR), and provided support to PM-Future Combat Systems Brigade Combat Team regarding Medical Mission package, treatment table, shelter, and patient movement items for form, fit, and function. Ultrasonic Brain Imager (UBI): conducted clinical user assessments, based on a down-select.Freeze-dried Plasma Program (hemorrhage treatment candidate): transitioned to project 832 for Systems Development and Demonstration. Intranasal Ketamine (low dose pain management via nasal spray): conducted a Pain Management Meeting with Combat Developer (representing Military requirements) and medical caregivers across roles of care to determine which pain management options are best for deployed hospitals, during medical					

Exhibit R-2A, RDT&E Project Justification: PB 2011 Army				DATE: Febr	uary 2010	
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)	R-1 ITEM NOMENCLATURE PE 0603807A: Medical Systems - Adv L	D ev	PROJECT 836: Field N	1edical System	s Advanced I	Development
B. Accomplishments/Planned Program (\$ in Millions)			'			
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
evacuation, and at far forward treatment facilities in austere environments (RBCXL) program (hemorrhage treatment candidate - a new blood collect shelf-life of red blood cells from 6 to 8 weeks): transitioned to project 832 (PDHA) (use of cryopreserved platelets for control of severe bleeding): co and conducted good manufacturing practices validation studies of the process of th	tion and storage system that extends the 2. Platelet Derived Hemostatic Agent onducted a feasibility clinical evaluation					
FY 2011 OCO Program #2		0.000	22.240	0.000	0.000	0.000
In FY10, will conduct human trial to assess intranasal ketamine drug effections will transition from project 840 and will conduct small human safety adults. Environmental Sentinel Biomonitor (ESB): transition increment 1 technology development project FH4, initiate development of increment 2 field water facilities. Field test one Ceramic Oxygen Generator system for Support Hospital (CSH). Transition Ultrasonic brain Imager product to proper Demonstration.	y and dose escalation study in health from project 837 and increment 2 from 2 ESB system for use in conjunction with the Force Provider Early Entry Combat	0.000	22.240	0.000	0.000	0.000

Exhibit R-2A, RDT&E Project Justification: PB 2011 Army				DATE: Febr	uary 2010	
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)	R-1 ITEM NOMENCLATURE PE 0603807A: Medical Systems - Adv D	Dev	PROJECT 836: Field M	edical System	s Advanced L	Development
B. Accomplishments/Planned Program (\$ in Millions)						
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
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 11, Total Intravenous Anesthesia (TIVA): will continue to perform documents for FDA clearance/approval. Auto Critical Care System (ACCI and Army DT/OT/AWC will also be conducted. The 510K will be submitt devices. Urinary Facilitation Device: will continue testing, reports, and rev System (Plasma Blade): if preclinical results are favorable will conduct en needed design modifications to produce a fieldable unit. Will also pursue needed. Plasma Knife: if preclinical results are favorable, will conduct env needed design modifications to produce a fieldable unit. Will also pursue needed. Hydrosurgery System: will conduct operational and environmental (RDA): will develop software, conduct testing, and refinement for MOC S Treatment Table for PM, HBCT Medical Mission Package for Treatment 832. Refrigerator for PM, HBCT for Medical Mission Package for Treatment 832. Shock and Vibration Isolation System for Patient Litters in Ground at will transition to Project 832. Shelter for PM, HBCT for Medical Mission will transition to Project 832. Passive Cold Chain Capability for Temperat	c.S): will conduct validation testing ed for FDA review for modified view for FDA approval.PEAK Surgical vironmental testing and identify any additional regulatory approvals as rironmental testing and identify any additional regulatory approvals as testing. Remote Diagnostic Access ensor Modual Development phase. Variants: will transition to Project tent Variant: will transition to Project and Air Medical Evacuation Vehicles: Package for Treatment Variant:	0.000	0.000	17.984	0.000	17.984

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Army				DATE: Febr	uary 2010	
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)	R-1 ITEM NOMENCLATURE PE 0603807A: <i>Medical Systems - Adv Dev</i>		PROJECT 836: Field M	ledical System	s Advanced L	Development
B. Accomplishments/Planned Program (\$ in Millions)			,			
	I	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
transition to Project 832. The intranasal ketamine drug effects study will Development and Demonstration .	transition to project 832 for Systems					
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	0.582	0.000	0.000	0.000
Small Business Innovative Research/Small Business Technology Transfe	er 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						

Exhibit R-2A, RDT&E Project Justification: PB 2011 Army			DATE: February 2010
APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE	PROJECT	
2040: Research, Development, Test & Evaluation, Army	PE 0603807A: Medical Systems - Adv Dev	836: Field M	ledical Systems Advanced Development
BA 4: Advanced Component Development & Prototypes (ACD&P)			

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

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Accomplishments/Planned Programs S	Subtotals 13.343	22.822	17.984	0.000	17.984

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.

Exhibit R-3, RDT&E Project Cost Analysis: PB 2011 Army

BA 4: Advanced Component Development & Prototypes (ACD&P)

DATE: February 2010

APPROPRIATION/BUDGET ACTIVITY

R-1 ITEM NOMENCLATURE

PROJECT

2040: Research, Development, Test & Evaluation, Army

PE 0603807A: Medical Systems - Adv Dev

836: Field Medical Systems Advanced Development

Product Development (\$ in Millions)

				FY :	2010		2011 ase		2011 CO	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
Clinical Research Management	С	Hinckley OH	0.000	0.000		1.133		0.000		1.133	Continuing	Continuing	0
Allied Technologies & Consulting LLC	С	Frederick MD	0.000	1.580		2.000		0.000		2.000	Continuing	Continuing	0
Aquila Alaska Corporation	С	Wasilla AK	0.000	0.000		0.000		0.000		0.000	Continuing	Continuing	0
SeQual Technologies	С	San Diego CA	0.000	0.000		0.000		0.000		0.000	Continuing	Continuing	0
No other contract exceeds \$1M	С	Nothing entered for Activity and Location. Location could not be determined.	15.169	5.449		0.000		0.000		0.000	Continuing	Continuing	0
		Subtotal	15.169	7.029		3.133		0.000		3.133			0.000

Exhibit R-3, RDT&E Project Cost Analysis: PB 2011 Army

BA 4: Advanced Component Development & Prototypes (ACD&P)

DATE: February 2010

APPROPRIATION/BUDGET ACTIVITY

R-1 ITEM NOMENCLATURE

PROJECT

2040: Research, Development, Test & Evaluation, Army

PE 0603807A: Medical Systems - Adv Dev

836: Field Medical Systems Advanced Development

Support (\$ in Millions)

				FY 2	2010	FY :	2011 ase	FY 2	2011 CO	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	С	Nothing entered for Activity and Location. Location could not be determined.	0.000	4.335		5.203		0.000		5.203	Continuing	Continuing	0
		Subtotal	0.000	4.335		5.203		0.000		5.203			0.000

Remarks

No product/contract costs greater than \$1M individually.

Test and Evaluation (\$ in Millions)

				FY 2	2010	FY 2 Ba	2011 ase	FY :	2011 CO	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 \$M individually.	С	Nothing entered for Activity and Location. Location could not be determined.	0.000	8.033		8.654		0.000		8.654	Continuing	Continuing	0
		Subtotal	0.000	8.033		8.654		0.000		8.654			0.000

Remarks

No product/contract costs greater than \$1M individually.

Exhibit R-3, RDT&E Project Cost Analysis: PB 2011 Army

DATE: February 2010

APPROPRIATION/BUDGET ACTIVITY

R-1 ITEM NOMENCLATURE

PROJECT

2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)

PE 0603807A: Medical Systems - Adv Dev

836: Field Medical Systems Advanced Development

Management Services (\$ in Millions)

				FY	2010	FY : Ba	2011 ase		2011 CO	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 \$M individually.	С	Nothing entered for Activity and Location. Location could not be determined.	28.754	3.425		0.994		0.000		0.994	Continuing	Continuing	0
		Subtotal	28.754	3.425		0.994		0.000		0.994			0.000

Remarks

	Total Prior Years Cost	FY 2010	FY:	2011 ase	FY :	2011 CO	FY 2011 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals	43.923	22.822	17.984		0.000		17.984			0.000

Exhibit R-4, RDT&E Schedule Profile: PB 2011 Army

DATE: February 2010

APPROPRIATION/BUDGET ACTIVITY R-1 ITEM NOMENCLATURE PROJECT

2040: Research, Development, Test & Evaluation, Army
BA 4: Advanced Component Development & Prototypes (ACD&P)

PE 0603807A: Medical Systems - Adv Dev
836: Field Medical Systems Advanced Development

		FY	200	9]	FY:	201	0]	FY 2	201	l	F	Y 2	201	2	J	F Y 2	013	3	F	Y	201	4	I	FY 2	201:	5
	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
Future Combat Systems (CDR)			#																									

Exhibit R-4A, RDT&E Schedule Details: PB 2011 Army			DATE: February 2010
APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE	PROJECT	
2040: Research, Development, Test & Evaluation, Army	PE 0603807A: Medical Systems - Adv Dev	836: Field M	ledical Systems Advanced Development
BA 4: Advanced Component Development & Prototypes (ACD&P)			

Schedule Details

	Sta	art	Eı	nd
Event	Quarter	Year	Quarter	Year
Future Combat Systems (CDR)	3	2009	3	2009

DATE: February 2010

APPROPRIATION/BUDGET ACTIV 2040: Research, Development, Test & E BA 4: Advanced Component Developme	Evaluation, Ar	•)	R-1 ITEM N PE 0603807	NOMENCLA A: <i>Medical Sy</i>		Dev	PROJECT 837: SOLDIN	ER SYS PROT	T-AD	
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
837: SOLDIER SYS PROT-AD	6.561	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Quantity of RDT&E Articles

Exhibit R-2A, RDT&E Project Justification: PB 2011 Army

This project funds development of preventive medicine materiel, including devices and medicines, in order to provide protection, sustainment, and enhancement of the physical and psychological capabilities of Soldiers across the Army's full spectrum operations. Focus is on the 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 837 will be consolidated into Project 836 Combat Medical Matl AD. Major contractors are Pacific Technologies, Inc, Redwood, WA, and Agave Biosystems Inc, Austin, TX.

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

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Program #1	6.561	0.000	0.000	0.000	0.000
Coliform Analyzer: In FY09, conduct technical testing and user evaluation and transition to project 834 for System Development and Demonstration. Environmental Sentinel Biomonitor (ESB): In 2Q FY09, conduct Milestone B (for increment 1 ESB system). In FY10, project 837 is consolidated into project 836. FY 2009 Accomplishments: FY 2009					
FY 2010 Plans: FY 2010					
FY 2011 Base Plans: FY 2011 Base					

Exhibit R-2A, RDT&E Project Justification: PB 2011 Army			DATE: Febr	ruary 2010	
	R-1 ITEM NOMENCLATURE PE 0603807A: <i>Medical Systems - Adv Dev</i>	PROJECT 837: SOLDI	ER SYS PROT	Г-AD	
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						
	Accomplishments/Planned Programs Subtotals	6.561	0.000	0.000	0.000	0.000

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

N/A

D. Acquisition Strategy

Test and evaluate materiel in-house and commercially developed preventative medicine materiel to meet FDA and EPA regulatory requirements.

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.

Exhibit R-3, RDT&E Project Cost Analysis: PB 2011 Army

DATE: February 2010

APPROPRIATION/BUDGET ACTIVITY

R-1 ITEM NOMENCLATURE

PROJECT

2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)

PE 0603807A: Medical Systems - Adv Dev

837: SOLDIER SYS PROT-AD

Product Development (\$ in Millions)

				FY	2010	FY : Ba	2011 ase	FY :	2011 CO	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	С	Nothing entered for Activity and Location. Location could not be determined.	3.661	0.000		0.000		0.000		0.000	Continuing	Continuing	0
		Subtotal	3.661	0.000		0.000		0.000		0.000			0.000

Remarks

Support (\$ in Millions)

				FY	2010		2011 ase	FY O	2011 CO	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	С	Nothing entered for Activity and Location. Location could not be determined.	0.247	0.000		0.000		0.000		0.000	Continuing	Continuing	0
		Subtotal	0.247	0.000		0.000		0.000		0.000			0.000

Exhibit R-3, RDT&E Project Cost Analysis: PB 2011 Army

DATE: February 2010

APPROPRIATION/BUDGET ACTIVITY

R-1 ITEM NOMENCLATURE

PROJECT

2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)

PE 0603807A: Medical Systems - Adv Dev

837: SOLDIER SYS PROT-AD

Test and Evaluation (\$ in Millions)

				FY	2010	FY :	2011 ase		2011 CO	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	С	Research and development; stability and potency testing Location could not be determined.	1.276	0.000		0.000		0.000		0.000	Continuing	Continuing	0
		Subtotal	1.276	0.000		0.000		0.000		0.000			0.000

Remarks

Management Services (\$ in Millions)

				FY	2010	FY 2 Ba	2011 ase	FY 2	2011 CO	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	С	Nothing entered for Activity and Location. Location could not be determined.	2.472	0.000		0.000		0.000		0.000	Continuing	Continuing	0
		Subtotal	2.472	0.000		0.000		0.000		0.000			0.000

Exhibit R-3, RDT&E Project Cost Analysis: PB 2011 Army		DATE: February 2010
APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE	PROJECT
2040: Research, Development, Test & Evaluation, Army	PE 0603807A: Medical Systems - Adv Dev	837: SOLDIER SYS PROT-AD
BA 4: Advanced Component Development & Prototypes (ACD&P)		

Target Value of **Total Prior** FY 2011 FY 2011 FY 2011 Cost To **Years Cost** FY 2010 Base ocoTotal Complete **Total Cost** Contract **Project Cost Totals** 0.000 0.000 0.000 0.000 7.656 0.000

Exhibit R-4, RDT&E Schedule Profile: PB 2011 Army

DATE: February 2010

APPROPRIATION/BUDGET ACTIVITY

2040: Research, Development, Test & Evaluation, Army

BA 4: Advanced Component Development & Prototypes (ACD&P)

R-1 ITEM NOMENCLATURE

PE 0603807A: Medical Systems - Adv Dev

PROJECT

837: SOLDIER SYS PROT-AD

	J	FY	200	9 FY 2010]	FY 2011		J	F Y 2	201	2	FY 2013		3	FY 2014		4	I	TY 2	2015	5						
	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
Environmental Sentinel Biomonitor (2nd QTR FY 09)	#																											

Exhibit R-4A, RDT&E Schedule Details: PB 2011 Army			DATE: February 2010
APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE	PROJECT	
2040: Research, Development, Test & Evaluation, Army	PE 0603807A: Medical Systems - Adv Dev	837: <i>SOLDII</i>	ER SYS PROT-AD
BA 4: Advanced Component Development & Prototypes (ACD&P)			

Schedule Details

	Sta	art	Eı	nd
Event	Quarter	Year	Quarter	Year
Environmental Sentinel Biomonitor (2nd QTR FY 09)	1	2009	1	2009

Exhibit R-2A, RDT&E Project Justif	ication: PB 2	011 Army							DATE: Febr	uary 2010	
APPROPRIATION/BUDGET ACTIV 2040: Research, Development, Test & E BA 4: Advanced Component Development)	R-1 ITEM N PE 0603807	NOMENCLA A: Medical Sy	_	ICAL SYSTEMS ADV DEV INITIATIVE.						
COST (\$ in Millions)	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		
CS4: MEDICAL SYSTEMS ADV DEV INITIATIVES (CA)	3.988	4.775	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 Interest Item funding for medical systems advanced development initiatives

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

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Program #1	0.113	0.000	0.000	0.000	0.000
Small Business Innovative Research/Small Business Technology Transfer Program					
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	0.775	0.000	0.000	0.000	0.000
Congressionally directed project to conduct advanced development research in Leishmaniasis Skin Test Antigen.					

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Army				DATE: Febr	uary 2010	
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)	R-1 ITEM NOMENCLATURE PE 0603807A: Medical Systems - Adv Dev	,	PROJECT CS4: MEDIO (CA)	CAL SYSTEMS	S ADV DEV I	NITIATIVES
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		1.550	0.000	0.000	0.000	0.000
Congressionally directed project to conduct advanced development re- Monitoring system	search in Garment Based Physiological					
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		1.550	2.400	0.000	0.000	0.000

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Army				DATE: Febr	uary 2010		
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)	R-1 ITEM NOMENCLATURE PE 0603807A: Medical Systems - Adv I	Dev	PROJECT CS4: MEDI (CA)	CAL SYSTEMS	SYSTEMS ADV DEV INITIA		
B. Accomplishments/Planned Program (\$ in Millions)							
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total	
Congressionally directed project to conduct advanced development resea	rch in Wireless Med monitoring 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							
Program #5		0.000	1.175	0.000	0.000	0.000	
Congressionally directed project to conduct execution of a Quality System Activities	ms Program for FDA Regulation						
FY 2009 Accomplishments: FY 2009							
FY 2010 Plans: FY 2010							
FY 2011 Base Plans: FY 2011 Base							
FY 2011 OCO Plans: FY 2011 OCO							

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Army			DATE: February 2010
APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE	PROJECT	
2040: Research, Development, Test & Evaluation, Army	PE 0603807A: Medical Systems - Adv Dev	CS4: MEDIO	CAL SYSTEMS ADV DEV INITIATIVES
BA 4: Advanced Component Development & Prototypes (ACD&P)		(CA)	

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

FY	Y 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Program #6	0.000	1.200	0.000	0.000	0.000
Congressionally directed project to study Model for Green Laboratories and Clean Rooms					
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	3.988	4.775	0.000	0.000	0.000

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

N/A

D. Acquisition Strategy

N/A

E. Performance Metrics

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