

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2 Exhibit)							February 2006		
BUDGET ACTIVITY		PE NUMBER AND TITLE							
5 - System Development and Demonstration		0604807A - Medical Materiel/Medical Biological Defense Equipm							
COST (In Thousands)	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	Cost to Complete	Total Cost
Total Program Element (PE) Cost	19315	16487	14509	15934	35243	33830	15580	0	185181
812 MIL HIV VAC&DRUG DEV	3565	4141	4561	4701	4735	4573	4573	0	33947
832 COMBAT MEDICAL MATL ED	4258	812	3762	5337	14996	14299	5518	0	63830
834 SOLDIER SYS PROT-ED	1010	0	3012	1870	1798	1698	1691	0	17540
849 INFEC DIS DRUG/VACC ED	3390	593	3174	4026	13714	13260	3798	0	48871
A11 LSTAT MEDICAL TECHNOLOGY (CA)	1727	1971	0	0	0	0	0	0	5703
A12 BIOMEDICAL ENGINEERING TECH & ADV MATERIALS (CA)	0	4633	0	0	0	0	0	0	5588
A14 CHITOSAN BANDAGE COMPONENT (CA)	2012	3351	0	0	0	0	0	0	5363
A15 BIOTERRORISM EDUCATION (CA)	957	0	0	0	0	0	0	0	957
A16 CHEMICAL-BIOLOGICAL CASUALTY TREATMENT (CA)	2396	0	0	0	0	0	0	0	2396
MD3 CARTLEDGE INFUSER	0	986	0	0	0	0	0	0	986
<p><u>A. Mission Description and Budget Item Justification:</u> 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. It supports products successfully transitioned through the Systems Development and Demonstration In-Process Review (IPR). This largely includes Phase 3 human clinical trials, along with related stability and production manufacturing testing for medical pharmaceuticals, biologics, and devices. Added operational testing and evaluation (OT&E) for military unique requirements is evaluated and fulfilled as required.</p> <p>Disease and non-battle injuries (DNBI) are the largest contributor to the medical footprint. Infectious disease vaccines and preventive drugs reduce the risk of service members' contracting debilitating or fatal diseases, which reduces levels of DNBI affected soldiers - and in turn, negates the requirement for supporting echelon 3 facilities in the theater of operations, as well as mitigates 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 Future Force (F2) units will act as a force multiplier, due to the retention of uniquely skilled and combat tested soldiers in the theater.</p> <p>Combat Casualty Care devices and medicines have the major effects of: (1) enhancing forward care at the first responder level and, (2) reducing the medical footprint. The result is a far greater mobile and more easily sustained medical force. 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.</p> <p>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.</p>									

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2 Exhibit)		February 2006
BUDGET ACTIVITY 5 - System Development and Demonstration	PE NUMBER AND TITLE 0604807A - Medical Materiel/Medical Biological Defense Equipm	
<p>The U.S. Army Medical Research and Materiel Command manages this program.</p> <p>Project 812, Military HIV Vaccine and Development funds militarily relevant human immunodeficiency virus (HIV) research.</p> <p>Major contractors/intra-governmental agencies include Cambridge Consultants Corporation, IGR Enterprises, Army Medical Department Board Test Center, and SeQual Technologies, Inc.</p>		

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2 Exhibit)				February 2006
BUDGET ACTIVITY 5 - System Development and Demonstration		PE NUMBER AND TITLE 0604807A - Medical Materiel/Medical Biological Defense Equipm		
	FY 2005	FY 2006	FY 2007	
<u>B. Program Change Summary</u>				
Previous President's Budget (FY 2006)	19325	5627	14418	
Current BES/President's Budget (FY 2007)	19315	16487	14509	
Total Adjustments	-10	10860	91	
Congressional Program Reductions		-73		
Congressional Rescissions		-167		
Congressional Increases		11100		
Reprogrammings	-10			
SBIR/STTR Transfer				
Adjustments to Budget Years			91	
FY 2006 - Congressional Plus-Up (\$11,100) - Cartledge Infuser (\$1,000); Biothreat Database Program (\$1,000); Oxygen Generation Advanced Development (\$1,700); Battlefield Respirator and Ventilator (BRAV) (\$2,000); Life Support for Trauma and Transport (LSTAT) (\$2,000); Chitosan Bandage Component (\$3,400).				

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)								February 2006	
BUDGET ACTIVITY 5 - System Development and Demonstration				PE NUMBER AND TITLE 0604807A - Medical Materiel/Medical Biological Defense Equipm				PROJECT 812	
COST (In Thousands)	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	Cost to Complete	Total Cost
812 MIL HIV VAC&DRUG DEV	3565	4141	4561	4701	4735	4573	4573	0	33947
<p><u>A. Mission Description and Budget Item Justification:</u> This project funds Congressionally mandated, militarily relevant human immunodeficiency virus (HIV) medical countermeasures. These funds provide for engineering and manufacturing development of multiple candidate vaccines and drugs to permit large-scale field testing. Development efforts are focused on militarily unique needs affecting manning, mobilization, and deployment.</p> <p>The major contractor is Henry M. Jackson Foundation for the Advancement of Military Medicine, Rockville, MD.</p>									
<u>Accomplishments/Planned Program</u>						<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>	
In FY05, completed enrollment for the multi-year Phase 3 clinical trial of the Prime-Boost HIV Vaccine in Thailand. In FY06, complete immunizations and enter the observation and follow-up phase of the Phase 3 trial. Conduct a Design Readiness Review. In FY07, continue the observation and follow-up phase of the Phase 3 study in Thailand.						3565	4141	4561	
Total						3565	4141	4561	
<p><u>C. Acquisition Strategy</u> Test and evaluate commercially developed vaccine candidates in government-managed trials.</p>									

ARMY RDT&E COST ANALYSIS (R3)										February 2006		
BUDGET ACTIVITY				PE NUMBER AND TITLE							PROJECT	
5 - System Development and Demonstration				0604807A - Medical Materiel/Medical Biological Defense Equipm							812	
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Product Development	Cooperative Agreement	Henry M. Jackson Foundation, Rockville, MD	4400	2530		2923		3243		0	10896	0
Subtotal:			4400	2530		2923		3243		0	10896	0
II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			233	38		42		45		0	358	0
Subtotal:			233	38		42		45		0	358	0
III. Test And Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Test and Evaluation	Government Laboratory	Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD	806	927		1092		1180		0	4005	0
Subtotal:			806	927		1092		1180		0	4005	0
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater			165	70		84		93		0	412	0

ARMY RDT&E COST ANALYSIS (R3)								February 2006				
BUDGET ACTIVITY			PE NUMBER AND TITLE								PROJECT	
5 - System Development and Demonstration			0604807A - Medical Materiel/Medical Biological Defense Equipm								812	
than \$1M individually												
Subtotal:			165	70		84		93		0	412	0
Project Total Cost:			5604	3565		4141		4561		0	15671	0

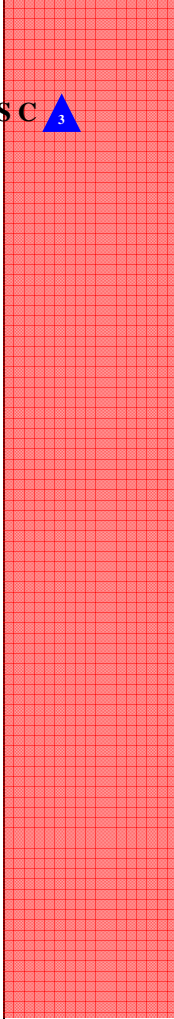







Schedule Profile (R4 Exhibit)																February 2006																							
BUDGET ACTIVITY 5 - System Development and Demonstration								PE NUMBER AND TITLE 0604807A - Medical Materiel/Medical Biological Defense Equipm																PROJECT 812															
Event Name								FY 05				FY 06				FY 07				FY 08				FY 09				FY 10				FY 11							
								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				
(1) HIV Vaccine								Design				Readiness Review																											

Schedule Detail (R4a Exhibit)						February 2006	
BUDGET ACTIVITY 5 - System Development and Demonstration			PE NUMBER AND TITLE 0604807A - Medical Materiel/Medical Biological Defense Equipm				PROJECT 812
<u>Schedule Detail</u>	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011</u>
HIV Vaccine Design Readiness Review (DRR)		2Q					

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)								February 2006	
BUDGET ACTIVITY 5 - System Development and Demonstration				PE NUMBER AND TITLE 0604807A - Medical Materiel/Medical Biological Defense Equipm				PROJECT 832	
COST (In Thousands)	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	Cost to Complete	Total Cost
832 COMBAT MEDICAL MATL ED	4258	812	3762	5337	14996	14299	5518	0	63830
<p>A. Mission Description and Budget Item Justification: This project funds technical development of candidate medical products for the advancement of combat casualty care, especially far forward on the battlefield with first responders, combat lifesavers, and field medics. This primarily funds Phase 3 human clinical trials or mechanical engineering evaluations for efficacy of devices or biologics unique to military operational requirements. This work is frequently completed through a joint laboratory and contractor team with the contractor obtaining ultimate U.S. Food and Drug Administration (FDA) licensure. These products (enhanced location and diagnostic devices of patients and more potent resuscitative biologics) will decrease mortality rates and increase soldiers' morale and willingness to place themselves in danger. Additionally, several products, Dental Field Treatment and Operating System (DEFTOS), Ventilated Assist Device, and Oxygen Generator will reduce medical organizational sustainment footprint through smaller weight and cube or equipment independence from supporting materiel. Priority is given to those products that provide the greatest clinical benefit balanced with the technical and financial risks.</p> <p>Major contractors/intra-governmental agencies include: Bell Dental Inc., Cambridge Consultants Corporation, IGR Enterprises, Army Medical Department Board Test Center, Smisson-Cartledge Biomedical, SeQual Technologies, Inc., and Enginivity, Inc.</p>									
<u>Accomplishments/Planned Program</u>						<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>	
Conduct testing & milestone reviews for the following field medical treatment and treatment aid devices: (1) Dental Field Treatment & Operating System (DEFTOS): In FY05, deployed first 30 units of production item to IRAQ. Conducting a long term user evaluation.(2) Thawed Blood Processing System (TBPS): In FY05, terminated development program. (3) Ceramic Oxygen Generator (COG): In FY05, fabricated first portable Oxygen Generator prototype. In FY06, conduct user and technical testing and conduct Milestone B review. In FY07, develop the engineering pre-production prototype and obtain FDA clearance. (4) Rotary Valve Pressure Swing Adsorption Oxygen Generator (RVPSAOG): In FY05, reduced oxygen generator weight and size. Determined current air compressor unsuitable. Found potentially more reliable candidate. In FY06, conduct Milestone B in-progress review. Develop engineering pre-production prototype and conduct technical and user testing and evaluation. In FY07, conduct Milestone C in-progress review. Initiate low rate production. (5) Ventilatory Assist Device (VAD): In FY05, conducted technical and user testing, made required modifications, and held Milestone C in-progress review. Supported the fielding process.(6) Cartledge Infuser (CI): In FY05, finalized prototype design. In FY06 conduct technical/user testing, and obtain FDA clearance for infuser system. FY07, conduct Milestone C. (7) Battery Powered IV Fluid Warmer: In FY07, develop engineering model, conduct user evaluation and conduct Milestone C.						4258	812	3762	
Total						4258	812	3762	
<p>C. Acquisition Strategy Evaluate commercially developed materiel in government-managed trials.</p>									

ARMY RDT&E COST ANALYSIS (R3)										February 2006		
BUDGET ACTIVITY			PE NUMBER AND TITLE							PROJECT		
5 - System Development and Demonstration			0604807A - Medical Materiel/Medical Biological Defense Equipm							832		
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Rotary Valve Pressure Swing Adsorption oxygen Generator		Sequal Technologies, Inc., San Diego, CA	482	1298		413		800		0	2511	0
Cartledge Infuser		Smisson-Cartledge Biomedical L.L.C., Macon, GA	3110	0		0		0		0	3110	0
Subtotal:			3592	1298		413		800		0	5621	0
II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Not Applicable			0	0		0		0		0	0	0
Subtotal:			0	0		0		0		0	0	0
III. Test And Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Not Applicable			0	0		0		0		0	0	0
Subtotal:			0	0		0		0		0	0	0
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			11753	2960		399		2962		Continue	0	0

ARMY RDT&E COST ANALYSIS (R3)							February 2006		
BUDGET ACTIVITY 5 - System Development and Demonstration		PE NUMBER AND TITLE 0604807A - Medical Materiel/Medical Biological Defense Equipm						PROJECT 832	
Subtotal:		11753	2960		399		2962	Continue	0
Project Total Cost:		15345	4258		812		3762	Continue	0

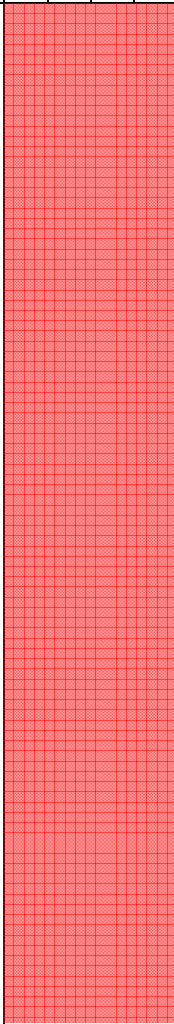

Schedule Profile (R4 Exhibit)																	February 2006																			
BUDGET ACTIVITY					PE NUMBER AND TITLE																	PROJECT														
5 - System Development and Demonstration					0604807A - Medical Materiel/Medical Biological Defense Equipm																	832														
Event Name					FY 05				FY 06				FY 07				FY 08				FY 09				FY 10				FY 11							
					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				
(1) Ceramic Oxygen Gen Sys, (2) Ceramic Oxygen GenSys									MS B 				MS C 																							
(3) Ventilatory Assist Device									MS C 																											
(4) Rotary Valve Press Swing Oxy, (5) Rotary Valve Press Swing Oxy									MS B 																								MS C 			
(6) Cartledge Infuser																																	MS C 			
(7) Battery Powered Iv Fld Warm, (8) Battery Powered Iv Fld Warm																																	MS B 			

Schedule Detail (R4a Exhibit)					February 2006		
BUDGET ACTIVITY 5 - System Development and Demonstration		PE NUMBER AND TITLE 0604807A - Medical Materiel/Medical Biological Defense Equipm					PROJECT 832
<u>Schedule Detail</u>	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011</u>
Dental Field Treatment and Operating System (FRPND)							
Ceramic Oxygen Generator Systems (MS B); (MS C)		3Q	4Q				
Rotary Valve Pressure Swing Oxygen (MS B); (MS C)		3Q	4Q				
Ventilatory Assist Device (MS C)	2Q						
Cartledge Infuser (MS C)			3Q				
Battery Powered IV Fluid Warmer (MS B, MS C)		3Q	3Q				

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)								February 2006	
BUDGET ACTIVITY 5 - System Development and Demonstration				PE NUMBER AND TITLE 0604807A - Medical Materiel/Medical Biological Defense Equipm				PROJECT 834	
COST (In Thousands)	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	Cost to Complete	Total Cost
834 SOLDIER SYS PROT-ED	1010	0	3012	1870	1798	1698	1691	0	17540
<p><u>A. Mission Description and Budget Item Justification:</u> This project supports system development and demonstration of preventive medicine materiels to include devices, medicines in order to provide protection, sustainment, and enhancement of the physical and psychological capabilities of soldiers engaged in combat operations across varied 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.</p> <p>A major contractor is Allermed Laboratories, Inc., San Diego, CA.</p>									
<u>Accomplishments/Planned Program</u>						<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>	
In FY05, funded the Air Worthiness Certification of the Special Medical Emergency Evacuation Device (SMEED) and Life Support for Trauma and Transport (LSTAT) Next Generation. FY07, begin the development of coliform analyzer. Conduct Milestone B.						279	0	3012	
In FY05, began termination phase of contract for Leishmania skin tests.						731	0	0	
Total						1010	0	3012	
<p><u>C. Acquisition Strategy</u> Test and evaluate in-house and commercially developed vaccine candidates in government-managed trials to meet FDA requirements.</p>									

ARMY RDT&E COST ANALYSIS (R3)										February 2006		
BUDGET ACTIVITY				PE NUMBER AND TITLE						PROJECT		
5 - System Development and Demonstration				0604807A - Medical Materiel/Medical Biological Defense Equipm						834		
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			1834	483		0		1439		0	3206	0
Congressional Add in Support of Chem-Bio Protection			4550	0		0		0		0	4550	0
Subtotal:			6384	483		0		1439		0	7756	0
II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			42	32		0		89		0	163	0
Subtotal:			42	32		0		89		0	163	0
III. Test And Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			241	239		0		545		0	1025	0
Subtotal:			241	239		0		545		0	1025	0
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			645	256		0		939		0	1840	0

ARMY RDT&E COST ANALYSIS (R3)							February 2006		
BUDGET ACTIVITY 5 - System Development and Demonstration		PE NUMBER AND TITLE 0604807A - Medical Materiel/Medical Biological Defense Equipm						PROJECT 834	
Subtotal:		645	256		0		939	0	1840
Project Total Cost:		7312	1010		0		3012	0	10784

Schedule Profile (R4 Exhibit)																	February 2006																		
BUDGET ACTIVITY 5 - System Development and Demonstration								PE NUMBER AND TITLE 0604807A - Medical Materiel/Medical Biological Defense Equipm																	PROJECT 834										
Event Name								FY 05				FY 06				FY 07				FY 08				FY 09				FY 10				FY 11			
								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
(1) Coliform Analyzer												MS B																							

Schedule Detail (R4a Exhibit)						February 2006	
BUDGET ACTIVITY 5 - System Development and Demonstration			PE NUMBER AND TITLE 0604807A - Medical Materiel/Medical Biological Defense Equipm				PROJECT 834
<u>Schedule Detail</u>	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011</u>
Coliform Analyzer (MS B)			1Q				

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)								February 2006	
BUDGET ACTIVITY 5 - System Development and Demonstration				PE NUMBER AND TITLE 0604807A - Medical Materiel/Medical Biological Defense Equipm				PROJECT 849	
COST (In Thousands)	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	Cost to Complete	Total Cost
849 INFEC DIS DRUG/VACC ED	3390	593	3174	4026	13714	13260	3798	0	48871
<p>A. Mission Description and Budget Item Justification: This project funds technical development of candidate medical countermeasures for infectious diseases that occur within militarily relevant areas of the world. These products fall within three major areas: vaccines, drugs, and diagnostic kits. The funds support Phase 3 human clinical trials for large-scale efficacy testing, long-term animal studies, and related manufacturing tests. This work, which is jointly performed by military laboratories and civilian contracted pharmaceutical firms, is directed toward the prevention of disease, early diagnosis if contracted, and speeding recovery once diagnosed. These trials are required to meet U.S. Food and Drug Administration (FDA) regulatory approval guidance, a mandatory obligation for all military products placed into the hands of medical providers or service members. Priority is based upon four major factors: the extent of the disease within the Combatant Command's theater of operations, the clinical severity of the disease, the technical maturity of the proposed solution, and the affordability of the solution (development and production). Consequently, malaria, dysentery, hepatitis, and dengue diseases (which are found in Central Command, European Command, Southern Command, and Pacific Command areas) rise to the top of the requirement list.</p>									
<u>Accomplishments/Planned Program</u>						<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>	
Clinical trials, developmental testing, and appropriate reviews of malarial/antimalarial vaccines, drugs, and diagnostics: In FY05, continued the FDA-mandated Phase 1 safety trial of the Antimalarial Drug, Tafenoquine; with user approval, shifted the acquisition strategy for Tafenoquine to development for acute treatment and post-exposure prophylaxis of Plasmodium vivax malaria. In FY06, complete mandated Phase 1 safety trial, conduct a Design Readiness Review to re-baseline product development plan for tafenoquine and initiate the necessary clinical field trials to bring Tafenoquine to FDA licensure. In FY07, continue field testing of Tafenoquine.						2955	510	3042	
Prepare for conducting clinical studies, trials, and appropriate reviews of grouped vaccines, drugs, and diagnostics (Hepatitis E Vaccine, Combined Camouflage Face Paint/Insect Repellent): In FY05, completed data analysis of the Hepatitis field trial and met with industry partner to determine future development strategy. Contractor for the Combined Camouflage Face Paint/Insect Repellent (CCFP) completed pre-clinical testing of the new stick formulation. In FY06, conduct a Design Readiness Review (DRR) to re-baseline Hepatitis E development based on agreement with industry partner. Conduct a DRR for the CCFP and initiate clinical testing of the new CCFP formulation. In FY07, complete clinical testing and data analysis for the CCFP.						435	83	132	
Total						3390	593	3174	
<p>C. Acquisition Strategy Test and evaluate in-house and commercially developed products in government-managed trials to meet FDA requirements and Environmental Protection Agency registration.</p>									

ARMY RDT&E COST ANALYSIS (R3)										February 2006		
BUDGET ACTIVITY				PE NUMBER AND TITLE						PROJECT		
5 - System Development and Demonstration				0604807A - Medical Materiel/Medical Biological Defense Equipm						849		
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			5791	1247		206		1094		Continue	7185	Continue
Subtotal:			5791	1247		206		1094		Continue	7185	Continue
II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			440	70		71		63		Continue	644	Continue
Subtotal:			440	70		71		63		Continue	644	Continue
III. Test And Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			8839	1506		173		1474		Continue	10211	Continue
Subtotal:			8839	1506		173		1474		Continue	10211	Continue
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			2399	567		143		543		Continue	3652	Continue
Subtotal:			2399	567		143		543		Continue	3652	Continue

ARMY RDT&E COST ANALYSIS (R3)							February 2006				
BUDGET ACTIVITY		PE NUMBER AND TITLE							PROJECT		
5 - System Development and Demonstration		0604807A - Medical Materiel/Medical Biological Defense Equipm							849		
Project Total Cost:		17469	3390		593		3174		Continue	21692	Continue

Schedule Profile (R4 Exhibit)																	February 2006																			
BUDGET ACTIVITY					PE NUMBER AND TITLE																	PROJECT														
5 - System Development and Demonstration					0604807A - Medical Materiel/Medical Biological Defense Equipm																	849														
Event Name					FY 05				FY 06				FY 07				FY 08				FY 09				FY 10				FY 11							
					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				
(1) Malaria Rapid Diagnostic Device					MS C				1																											
(2) Tafenoquine Antimalarial Drug					Design Readiness Review				2																											
(3) Comb Camoufl Face Paint/Insect Rep					Design Readiness Review				3																											
(4) Hepatitis E Vaccine					Design Readiness Review				4																											

Schedule Detail (R4a Exhibit)						February 2006	
BUDGET ACTIVITY 5 - System Development and Demonstration		PE NUMBER AND TITLE 0604807A - Medical Materiel/Medical Biological Defense Equipm					PROJECT 849
<u>Schedule Detail</u>	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011</u>
Malaria Rapid Diagnostic Device (MS C)	4Q						
Tafenoquine antimalarial drug Design Readiness Review (DRR)		1Q					
Combined Camouflage Face Paint/Insect Repellent (DRR)		1Q					
Hepatitis E Vaccine (DRR)		1Q					