ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2 Exhibit)

February 2002

BUDGET ACTIVITY	PE NUMBER AND TITLE
5 - Engineering and manufacturing development	**0604807A - Medical Materiel/Medical Biological Defense Equipm**

COST (In Thousands)		FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
Total Program Element (PE) Cost		6089	9153	12625	8799	8720	7625	7585	Continuing	Continuing
812	MIL HIV VAC&DRUG DEV	147	0	0	0	0	0	0	Continuing	Continuing
832	COMBAT MEDICAL MATL ED	2148	5001	8328	3543	3467	4038	4101	0	39117
834	SOLDIER SYS PROT-ED	660	879	818	1828	1823	2149	1945	Continuing	Continuing
849	INFEC DIS DRUG/VACC ED	3134	3273	3479	3428	3430	1438	1539	Continuing	Continuing

A. Mission Description and Budget Item Justification: This Engineering and Manufacturing Development Program funds: (1) improved medical equipment and drugs essential to enhance deployability and survivability by counteracting lethal and human performance degrading effects of infectious diseases; and (2) medical equipment essential to meeting medical requirements on the integrated battlefield, with emphasis on decreased size and weight, yet supporting large numbers of combat casualties. Additionally, foreign medical materiel may be procured for exploitation of advanced technology and development to meet Army medical defense goals. This program supports the full-scale development of vaccines, prophylactic and therapeutic drugs, resuscitation fluids, and drug products for human immunodeficiency virus (HIV). This program funds engineering and manufacturing development for both large and small combat casualty care end items for location of casualty, diagnosis, rapid intensive care delivery, intensive care evacuation platforms, and rapidly mobile, lightweight surgical facilities and equipment. Additionally, the program funds engineering and manufacturing development of medical equipment that provides protection against physiological, psychological, or environmental factors that degrade physical performance. This program is managed by the U.S. Army Medical Research and Materiel Command. This program supports the Legacy to Objective transition path of the Transformation Campaign Plan (TCP).

Core projects without R-2A Exhibits which contain less than $1M in FY 2003 are described below:

Project 812, Military HIV Vaccine and Drug Development - Funds militarily relevant HIV medical countermeasures including engineering and manufacturing development of sufficient candidate vaccines and drugs to permit large-scale field testing and education/training materials.

Project 834, Soldier System Protection (Engineering Development) - Supports engineering development of preventive medicine materiel, including devices, pharmacologicals, and other tools to provide protection, sustainment, and enhancement of the physiological and psychological capabilities of soldiers in the face of combat operations under all environmental conditions.

B. Program Change Summary	FY 2001	FY 2002	FY 2003
Previous President's Budget (FY2002 PB)	6261	8228	12551
Appropriated Value	6318	9228	0
Adjustments to Appropriated Value	0	0	0
a. Congressional General Reductions	0	-75	74
b. SBIR / STTR	-171	0	0
c. Omnibus or Other Above Threshold Adjustments	0	0	0
d. Below Threshold Reprogramming	0	0	0
e. Rescissions	-58	0	0
Adjustments to Budget Years Since FY2002 PB	0	0	0
Current Budget Submit (FY 2003 PB)	6089	9153	12625

Change Summary Explanation:

Significant Changes: FY02 - Congressional Adds totalling $1000K (as noted below) added to this PE.

Project 832, Cartledge Infuser (+$1000)- The objective of this one year add is to develop and complete a peer review and begin development of a high-volume warmed-blood infuser.

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)

February 2002

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
5 - Engineering and manufacturing development	**0604807A - Medical Materiel/Medical Biological Defense Equipm**	**832**

COST (In Thousands)		FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
832	COMBAT MEDICAL MATL ED	2148	5001	8328	3543	3467	4038	4101	0	39117

A. Mission Description and Budget Item Justification: The project supports engineering and manufacturing development to field new and improved medical materiel essential for combat casualty care to reduce the logistical support requirements and minimize loss of life. The major contract is American Red Cross. This program supports the Legacy to Objective transition path of the Transformation Campaign Plan (TCP).

FY 2001 Accomplishments:

- 738 Completed some of the required animal efficacy trials for the Hemostatic Dressing (HD).
- 195 Completed an initial user evaluation of the initial version of Critical Care System for Trauma and Transport device (CSTAT). Conducted a MS B.
- 1215 Conducted testing of field medical treatment and treatment aid devices.
  - Conducted vibration tests, safety and in vitro tests for Thawed Blood Processing System (TBPS).
  - Evaluated commercial technologies for Dental Filmless Imaging System (DFIS).
  - Conducted tests and evaluation of the Dental Field Operating and Treatment System (DEFTOS).

Total 2148

FY 2002 Planned Program

- 2259 Conduct the Food and Drug Administration (FDA) mandated phase 1 safety trials for the HD.
- 60 Conduct evaluation of the CSTAT device and start pre-planned product improvement to meet Operational Requirements Document (ORD).
- 1682 Conduct testing and milestone IPRs for field medical treatment and treatment aid devices.
  - Conduct clinical trials and submit application for FDA clearance of TBPS.
  - Complete operational testing in the field of the DEFTOS and conduct MS B/C.

FY 2002 Planned Program (Continued)

- Conduct evaluation of pre-production prototypes for the One-Handed Tourniquet.

• 1000 Conduct peer review and begin development of warmed blood infuser

Total 5001

FY 2003 Planned Program

• 6609 Conduct elective surgery trials using informed consent for HD. Discuss military trauma indication with FDA. Conduct a MS B.

• 75 Redesign new devices into containerized modules and integrate a new CSTAT system. Conduct a MS C for CSTAT.

• 1332 Conduct testing and milestone IPRs for field medical treatment and treatment aid devices.

- Conduct MS C for TBPS.
- Complete detailed testing of the Pressure Swing Absorption Oxygen Generator (PSAOG).
- Obtain FDA approval for the Ceramic Oxygen Generator System (COGS).

• 312 Conduct tests and prepare for milestones for medical monitoring and imaging systems.

- Complete Warrior Medic System operational test and evaluation. Conduct MS B/C.

Total 8328

B. Other Program Funding Summary	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	To Compl	Total Cost
Not applicable.	0	0	0	0	0	0	0	0	0

C. Acquisition Strategy: Evaluate commercially developed materiel in government-managed trials.

D. Schedule Profile	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Critical Care System for Trauma & Transport (MS B); (MS C)	3Q		4Q				
Hemostatic Dressing (MS B); (MS C)			1Q		4Q		
Ceramic Oxygen Generator System (MS B/C)					4Q		
Pressure Swing Adsorption Oxygen Generator (MS B/C)				4Q			
Thawed Blood Processing System (MS C)			2Q				
Warrior Medic (MS B/C)			4Q				
Dental Field Treatment and Operating System (MS B/C)		4Q					

ARMY RDT&E COST ANALYSIS(R-3)

February 2002

BUDGET ACTIVITY
5 - Engineering and manufacturing development

PE NUMBER AND TITLE
0604807A - Medical Materiel/Medical Biological Defense Equipm

PROJECT
832

I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . Hemostatic Dressing		Red Cross, Charlotte, NC	0	738		2259		6609		0	9606	0
Subtotal:			0	738		2259		6609		0	9606	0

II. Support Cost	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . Not Applicable			0	0		0		0		0	0	0
Subtotal:			0	0		0		0		0	0	0

ARMY RDT&E COST ANALYSIS(R-3)

February 2002

BUDGET ACTIVITY
5 - Engineering and manufacturing development

PE NUMBER AND TITLE
0604807A - Medical Materiel/Medical Biological Defense Equipm

PROJECT
832

III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . 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 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than $1M individually			6199	1410		2742		1719		Continue	12070	0
Subtotal:			6199	1410		2742		1719		Continue	12070	0
Project Total Cost:			6199	2148		5001		8328		Continue	21676	0

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)

February 2002

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
5 - Engineering and manufacturing development	**0604807A - Medical Materiel/Medical Biological Defense Equipm**	**849**

COST (In Thousands)		FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
849	INFEC DIS DRUG/VACC ED	3134	3273	3479	3428	3430	1438	1539	Continuing	Continuing

A. Mission Description and Budget Item Justification: This project funds engineering and manufacturing development of sufficient candidate medical countermeasures to permit large-scale field testing and complete studies required for Food and Drug Administration (FDA) licensure and Environmental Protection Agency (EPA) registration. Work performed in laboratories and among troop populations is directed for prevention, diagnosis, and treatment of viral, bacterial, and parasitic diseases to prevent casualties, sustain operational performance, and minimize deaths and disability of armed forces during military operations. Preclinical trials, as well as phase 1, 2, and 3 trials, are performed as required for drug, vaccine, and device licensure by the FDA. This program supports the Legacy to Objective transition path of the Transformation Campaign Plan (TCP).

FY 2001 Accomplishments:

- 1983 Completed nonclinical carcinogenicity study of Tafenoquine. Completed one phase 3 trial and initiated another to evaluate the effectiveness of Tafenoquine as an antimalarial prophylactic drug.
- 686 Completed phase 3 studies in Egypt and Israel to evaluate effectiveness of enterotoxigenic Escherichia coli (ETEC) vaccine in preventing traveler's diarrhea.
- 465 Completed phase 1 safety and immunogenicity study for improved dose regimen of Campylobacter vaccine.

Total 3134

FY 2002 Planned Program

- 1176 Complete clinical trials and developmental testing of malarial/antimalarial vaccines, drugs, and diagnostics:
  - Conduct one phase 3 clinical trial to evaluate the effectiveness of Tafenoquine, an antimalarial prophylactic drug.
  - Complete developmental testing of a prototype Malaria Rapid Diagnostic Device (continued from PE/Project 0603807A/808, FY 2001). Conduct a Milestone (MS) B In Process Review (IPR). Prepare and submit a Pre-Market Approval application to the FDA.
- 2025 Conduct studies on diarrheal vaccines.
  - Conduct phase 2 dose ranging study of ETEC vaccine.

FY 2002 Planned Program (Continued)

- Conduct phase 2 challenge trial for new adjuvant lot of Campylobacter diarrheal vaccine.
- Conduct a MS B IPR on Shigella flexneri vaccine.

• 72 Conduct clinical study and trial, and appropriate reviews for Leishmaniasis vaccines:

- Begin 2-year phase 3 clinical trial to determine the effectiveness of paromomycin/gentamicin topical antileishmanial cream. Conduct a MS B IPR.

Total 3273

FY 2003 Planned Program

• 1060 Conduct clinical trial, and appropriate reviews for malarial/antimalarial vaccines, drugs and diagnostics:

- Complete the phase 3 clinical trial to evaluate the effectiveness of Tafenoquine started in FY02.
- Conduct a MS C IPR for Malaria Rapid Diagnostic Device.
- Plan and begin a multi-year phase 3 clinical trial for the RTS,S malaria vaccine. Conduct a MS B IPR.

• 1545 Conduct and/or continue appropriate trials and review of diarrheal vaccines:

- Prepare and submit a Biologics License Application for the ETEC vaccine for the prevention of traveler's diarrhea. Conduct a MS C IPR.
- Plan multi-year phase 3 pivotal trial for new adjuvant lot of Campylobacter vaccine. Conduct Campylobacter vaccine MS C.
- Begin 3-year phase 3 clinical trial to determine the effectiveness of Shigella flexneri vaccine to prevent traveler's diarrhea.

• 874 Continue clinical studies and trials of grouped vaccines, drugs, and diagnostics (Leishmaniasis, Paromomycin and Hepatitis E):

- Continue 2-year phase 3 clinical trial to determine the effectiveness of paromomycin/gentamicin topical antileishmanial.
- Produce three new production lots of Hepatitis E Virus Vaccine under good manufacturing practices.
- Conduct bridging study to compare new lots of Hepatitis E Virus Vaccine with old lots.
- Conduct phase 2 clinical study to determine the safety, sensitivity, and specificity of new Leishmania skin test components. Conduct a MS B IPR.

Total 3479

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)

February 2002

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
5 - Engineering and manufacturing development	**0604807A - Medical Materiel/Medical Biological Defense Equipm**	**849**

B. Other Program Funding Summary	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	To Compl	Total Cost
Not applicable.	0	0	0	0	0	0	0	0	0

C. Acquisition Strategy: Test and evaluate in-house and commercially developed products in government-managed trials to meet FDA requirements and EPA registration.

D. Schedule Profile	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
ETEC vaccine (MS C)			2Q				
Campylobacter vaccine (MS C)						1Q	
Tafenoquine antimalarial drug (MS C)				1Q			
Malaria Rapid Diagnostic Device (MS B); (MS C)		1Q	4Q				
Leishmania skin test (MS B); (MS C)			1Q		1Q		
Shigella flexneri (MS B); (MS C)		3Q				4Q	
Paromomycin/Gentamicin (MS B); (MS C)		3Q		3Q			
RTS,S malaria vaccine (MS B)			1Q				
Artelinic Acid (MS B)				1Q			
Shigella sonnei vaccine (MS B)				1Q			
Japanese encephalitis vaccine (improved) (MS B)				3Q			
Group B meningitis vaccine (MS B)					3Q		
Dengue tetravalent vaccine (MS B)						1Q	
Shigella dysenteriae vaccine (MS B)						3Q	

ARMY RDT&E COST ANALYSIS(R-3)

February 2002

BUDGET ACTIVITY
5 - Engineering and manufacturing development

PE NUMBER AND TITLE
0604807A - Medical Materiel/Medical Biological Defense Equipm

PROJECT
849

I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than $1M individually			1340	1312		1347		1495		Continue	5494	Continue
Subtotal:			1340	1312		1347		1495		Continue	5494	Continue

II. Support Cost	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than $1M individually			149	117		122		125		Continue	Continue	Continue
Subtotal:			149	117		122		125		Continue	Continue	Continue

ARMY RDT&E COST ANALYSIS(R-3)

February 2002

BUDGET ACTIVITY
5 - Engineering and manufacturing development

PE NUMBER AND TITLE
0604807A - Medical Materiel/Medical Biological Defense Equipm

PROJECT
849

III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than $1M individually			2190	1531		1623		1673		Continue	Continue	Continue
Subtotal:			2190	1531		1623		1673		Continue	Continue	Continue

IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than $1M individually			558	174		181		186		Continue	Continue	Continue
Subtotal:			558	174		181		186		Continue	Continue	Continue

Project Total Cost:			4237	3134		3273		3479		Continue	Continue	Continue