

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

June 2001

BUDGET ACTIVITY

5 - ENG MANUFACTURING DEV

PE NUMBER AND TITLE

0604807A - Med Material/Med Bio Def Equip ED

COST (In Thousands)	FY 2000 Actual	FY 2001 Estimate	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	9394	6261	8228	0	0	0	0	0	0	0
812 MIL HIV VAC&DRUG DEV	2290	151	0	0	0	0	0	0	0	0
832 COMBAT MEDICAL MATL ED	3280	2213	4041	0	0	0	0	0	0	0
834 SOLDIER SYS PROT-ED	662	681	887	0	0	0	0	0	0	0
849 INFEC DIS DRUG/VACC ED	3162	3216	3300	0	0	0	0	0	0	0

A. Mission Description and Budget Item Justification:

PLEASE NOTE: This administration has not addressed FY2003-2007 requirements. All FY 2003-2007 budget estimates included in this book are notional only and subject to change.

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 2002/2003 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.

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<u>B. Program Change Summary</u>	FY 2000	FY 2001	FY 2002	FY 2003
Previous President's Budget (FY2001 PB)	9636	6318	8971	0
Appropriated Value	9705	6318	0	
Adjustments to Appropriated Value	0	0	0	
a. Congressional General Reductions	0	0	0	
b. SBIR / STTR	-242	0	0	
c. Omnibus or Other Above Threshold Adjustments	-38	0	0	
d. Below Threshold Reprogramming	0	0	0	
e. Rescissions	-31	-57	0	
Adjustments to Budget Years Since FY2001 PB	0	0	-743	
Current Budget Submit (FY 2002/2003 PB)	9394	6261	8228	0

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BUDGET ACTIVITY 5 - ENG MANUFACTURING DEV				PE NUMBER AND TITLE 0604807A - Med Material/Med Bio Def Equip ED				PROJECT 832		
COST (In Thousands)	FY 2000 Actual	FY 2001 Estimate	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	3280	2213	4041	0	0	0	0	0	0	0
<p><u>A. Mission Description and Budget Item Justification:</u> 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. The major contract is United Defense Limited Partnership. This program supports the Legacy to Objective transition path of the Transformation Campaign Plan (TCP).</p> <p><u>FY 2000 Accomplishments</u></p> <ul style="list-style-type: none"> • 2811 Conducted tests and analysis of medical evacuation systems. <ul style="list-style-type: none"> - Received delivery of the engineering and manufacturing development vehicle for the Armored Medical Evacuation Vehicle (AMEV) and conducted limited user test. - Completed Critical Care System for Trauma and Transport device cost-benefit trade-off analysis. Completed health hazard assessment clinical and field testing. Gained positive user input through deployment in Kosovo. • 469 Conducted Milestone (MS) I In-Process Review (IPR) on potential Hemostatic Dressing formulations to determine the most effective formulation to control bleeding on the battlefield. <p>Total 3280</p> <p><u>FY 2001 Planned Program</u></p> <ul style="list-style-type: none"> • 734 Conduct testing and evaluations of medical evacuation systems. <ul style="list-style-type: none"> - Evaluate ability of Interim Armored Vehicle (IAV) to meet current operational requirements. Participate in Force Development Exercises of IAV to assess provision of medical care. - Complete an initial operational test and evaluation for initial version of Critical Care System for Trauma and Transport device. Conduct MS I/II. • 738 Start the Food and Drug Administration (FDA) mandated phase 1 safety trials for the Hemostatic Dressing. Complete animal efficacy trials under Good Laboratory Practice for the Hemostatic Dressing. 										

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PROJECT

832

FY 2001 Planned Program (Continued)

- 324 Conduct testing of field treatment/treatment aid devices.
 - Conduct sterility tests and in vitro tests; obtain FDA approval for Thawed Blood Processing System.
- 352 Conduct tests and prepare for milestones for medical monitoring and imaging systems.
 - Evaluate commercial technologies for Dental Filmless Digital Imaging System.
 - Conduct an initial operational test and evaluation for the Warrior Medic System.
- 65 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs.

Total 2213

FY 2002 Planned Program

- 553 Demonstrate and perform testing of medical evacuation systems.
 - Implement necessary medical modifications to IAV and support fielding.
 - Conduct a MS III IPR for the initial version of Critical Care System for Trauma and Transport device, and initiate pre-planned product improvement to meet Operational Requirements Document (ORD) requirements.
- 2144 Start elective surgery trials using informed consent for hemostatic dressing.
- 664 Monitor and test field treatment/treatment aid devices.
 - Conduct in vivo tests; submit application for FDA approval of Thawed Blood Processing System; conduct MS III.
 - Conduct MS I, and initiate operational testing in the field of the Dental Field Treatment and Operating System.
- 680 Conduct tests and prepare for milestones for medical monitoring and imaging systems.
 - Conduct a MS III IPR for Filmless Digital Imager - medical version.
 - Start an initial operational test and evaluation for the Warrior Medic System.
 - Conduct a market investigation and complete an analysis of alternatives for the Non-Contact Heart Rate Monitor.

Total 4041

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PROJECT

832

B. Other Program Funding Summary: Not applicable for this item.

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

D. Schedule Profile	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Critical Care System for Trauma & Transport (MS I/II); (MS III)	4Q		4Q	0	0	0	0	0
Hemostatic Dressing (MS I); (MS II); (MS III)	4Q			0	0	0	0	0
Ceramic Oxygen Generator System (MS I); (MS II)			4Q	0	0	0	0	0
Thawed Blood Processing System (MS III)			4Q	0	0	0	0	0
Interim Armored Vehicle - Medical (MS II)				0	0	0	0	0
Hemostatic Foam (MS I); (MS II)				0	0	0	0	0
Filmless Digital Imager System (Dental) (MS III)		4Q		0	0	0	0	0
Filmless Digital Imager System (Medical) (MS III)			4Q	0	0	0	0	0
Dental Field Treatment and Operating System (MS II/III)				0	0	0	0	0

ARMY RDT&E COST ANALYSIS(R-3)									June 2001			
BUDGET ACTIVITY 5 - ENG MANUFACTURING DEV					PE NUMBER AND TITLE 0604807A - Med Material/Med Bio Def Equip ED					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 . Armored Medical Evacuation Vehicle	MIPR	PM Bradley, Warren MI	5709	0		0		0	0	0	0	0
b . Hemostatic Dressing			0	590		1632		0	0	0	0	0
Subtotal:			5709	590		1632		0		0	0	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
Subtotal:			0	0		0		0		0	0	0
Remarks: No product/contract costs greater than \$1M individually.												

ARMY RDT&E COST ANALYSIS(R-3)									June 2001			
BUDGET ACTIVITY 5 - ENG MANUFACTURING DEV					PE NUMBER AND TITLE 0604807A - Med Material/Med Bio Def Equip ED					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
			0	0		0		0		0	0	0
Subtotal:												
Remarks: No product/contract costs greater than \$1M individually.												
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			2061	1623		2409		0	0	0	0	0
Subtotal:			2061	1623		2409		0		0	0	0
Project Total Cost:			7770	2213		4041		0		0	0	0

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BUDGET ACTIVITY 5 - ENG MANUFACTURING DEV				PE NUMBER AND TITLE 0604807A - Med Material/Med Bio Def Equip ED				PROJECT 849			
COST (In Thousands)		FY 2000 Actual	FY 2001 Estimate	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	3162	3216	3300	0	0	0	0	0	0	0
<p>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. 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).</p> <p>FY 2000 Accomplishments</p> <ul style="list-style-type: none"> 1086 Continued 2-year preclinical carcinogenicity study of Tafenoquine, and conducted field site preparation for three phase 3 clinical trials to evaluate the effectiveness of Tafenoquine as an antimalarial prophylactic drug. Milestone (MS) II In-Process Review (IPR). 1129 Continued phase 3 studies in Egypt and Israel to evaluate effectiveness of Enterotoxigenic Escherichia coli (ETEC) vaccine at preventing traveler's diarrhea. 908 Completed preclinical evaluation and phase 1 safety trial of new adjuvant lot of Campylobacter vaccine. Also conducted phase 2 efficacy study for improved dose regimen of adjuvant lot of Campylobacter vaccine. 39 Maintained supplies of investigational new drugs for the experimental treatment of deployed warfighters diagnosed with Korean Hemorrhagic Fever or cutaneous Leishmaniasis. <p>Total 3162</p>											

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PROJECT

849

FY 2001 Planned Program

- 1481 Complete preclinical carcinogenicity study of Tafenoquine, and conduct three phase 3 clinical trials to evaluate the effectiveness of Tafenoquine as an antimalarial prophylactic drug.
- 777 Complete phase 3 studies in Egypt and Israel to evaluate effectiveness of ETEC vaccine at preventing traveler's diarrhea.
- 876 Complete phase 2 efficacy study for improved dose regimen, and plan and start multi-year phase 3 pivotal trial for new adjuvant lot of Campylobacter vaccine.
- 82 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs.

Total 3216

FY 2002 Planned Program

- 1356 Complete clinical trials and developmental testing of malarial/antimalarial vaccines, drugs, and diagnostics:
 - Complete three multi-year phase 3 clinical trials to evaluate the effectiveness of Tafenoquine, and prepare and submit a New Drug Application for Tafenoquine, an antimalarial prophylactic drug.
 - Complete developmental testing of a prototype Malaria Rapid Diagnostic Device (continued from PE/Project 0603807A/808, FY01), and prepare and submit a Pre-Market Approval application. Conduct MS II IPR.
- 894 Start and conduct studies on diarrheal vaccines.
 - Start 3-year phase 3 clinical trial to determine the effectiveness of Shigella flexneri vaccine to prevent traveler's diarrhea. Conduct MS II IPR.
 - Conduct multi-year phase 3 pivotal trial for new adjuvant lot of Campylobacter diarrheal vaccine.
- 1050 Conduct clinical study and trial, and appropriate reviews for grouped infectious disease vaccines and drugs (ETEC and Leishmaniasis):
 - Prepare and submit a Biologics License Application for the ETEC vaccine for preventing traveler's diarrhea.
 - Conduct phase 2 clinical study to determine the safety, sensitivity, and specificity of new Leishmania skin test components. Conduct MS II IPR.
 - Start 2-year phase 3 clinical trial to determine the effectiveness of paromomycin/gentamicin topical antileishmanial cream. Conduct MS II IPR.

Total 3300

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PROJECT
849

B. Other Program Funding Summary: Not applicable for this item.

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

D. Schedule Profile	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
ETEC vaccine (MS III)				0	0	0	0	0
Campylobacter vaccine (MS III)				0	0	0	0	0
Tafenoquine antimalarial drug (MS II); (MS III)	4Q			0	0	0	0	0
Malaria Rapid Diagnostic Device (MS II); (MS III)			1Q	0	0	0	0	0
Leishmania skin test (MS II); (MS III)			1Q	0	0	0	0	0
Shigella flexneri (MS II); (MS III)			2Q	0	0	0	0	0
Paromomycin/Gentamicin (MS II); (MS III)			3Q	0	0	0	0	0
RTS,S malaria vaccine (MS II)				0	0	0	0	0
Artelinic Acid (MS II)				0	0	0	0	0
Shigella sonnei vaccine (MS II)				0	0	0	0	0
Japanese encephalitis vaccine (improved) (MS II)				0	0	0	0	0
Group B meningitis vaccine (MS II)				0	0	0	0	0
Dengue tetravalent vaccine (MS II)				0	0	0	0	0
Shigella dysenteriae vaccine (MS II)				0	0	0	0	0

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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			1394	1346		1374		0	0	0	0	0
Subtotal:			1394	1346		1374		0		0	0	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 . No product/contract costs greater than \$1M individually			149	120		122		0	0	0	0	0
Subtotal:			149	120		122		0		0	0	0

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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	1571		1623		0	0	0	0	0
Subtotal:			2190	1571		1623		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			558	179		181		0	0	0	0	0
Subtotal:			558	179		181		0		0	0	0
Project Total Cost:			4291	3216		3300		0		0	0	0