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ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2 Exhibit)								DATE February 1999		
BUDGET ACTIVITY 4 - Demonstration and Validation				PE NUMBER AND TITLE 0603807A Medical Systems - Advanced Development						
COST (In Thousands)	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
Total Program Element (PE) Cost	9181	11329	12723	12235	12768	13382	11729	12976	Continuing	Continuing
D808 DoD Drug and Vaccine-Advanced Development	2063	3684	5153	4653	4084	5107	5161	5179	Continuing	Continuing
D811 Military HIV Vaccine and Drug-Advanced Development	0	3238	2689	2690	2702	2663	1735	1928	Continuing	Continuing
D836 Combat Medical Materiel-Advanced Development	6332	3606	3996	4031	4210	4042	4024	4080	Continuing	Continuing
D837 Soldier System Protection-Advanced Development	786	801	885	861	1772	1570	809	1789	Continuing	Continuing
<p>A. <u>Mission Description and Budget Item Justification:</u> This program element (PE) funds the Advanced Development (AD) of medical materiel necessary to field an effective capability for infectious diseases. The PE funds AD of systems for medical protection against naturally occurring diseases and Human Immunodeficiency Virus (HIV). This includes development and initial human testing of vaccines, prophylactic and therapeutic drugs. Additionally, the PE supports AD of field medical equipment and drugs essential for combat casualty care on all battlefields and military operations other than war while reducing logistical support requirements. The PE also funds AD of systems that provide enhancement of or protection against physiological and psychological factors affecting cognitive and physical performance imposed by military systems, combat operations or the environment. This includes AD of vision corrective devices. Systems include resuscitators, blood substitutes, advanced sensors and diagnostic algorithms, field x-ray, field production of medical grade oxygen, intensive care delivery platforms and litters, and Advanced Surgical Suites for Trauma Care (ASSTC). This program is primarily managed by the U.S. Army Medical Research and Materiel Command.</p>										

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BUDGET ACTIVITY 4 - Demonstration and Validation	PE NUMBER AND TITLE 0603807A Medical Systems - Advanced Development
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Program Change Summary	<u>FY 1998</u>	<u>FY 1999</u>	<u>FY 2000</u>	<u>FY 2001</u>
Previous President's Budget (FY 1999 PB)	6555	11414	11073	11041
Appropriated Value	6765	11414		
Adjustments to Appropriated Value				
a. Congressional General Reductions	-210	-85		
b. SBIR / STTR	-163			
c. Omnibus or Other Above Threshold Adjustments	2844			
d. Below Threshold Reprogramming	-55			
e. Rescissions				
Adjustments to Budget Years Since <u>FY 1999</u> PB			1650	1194
Current Budget Submit (<u>FY 2000 / 2001</u> PB)	9181	11329	12723	12235

Change Summary Explanation: Funding: FY1998 – Congressional special interest funds internally reprogrammed by DoD to this PE (+2844) for proper program execution. FY2000/FY2001: Funding increased to begin the advanced development on far-forward medical diagnostic kits and accelerate the development of products used to prevent or treat militarily relevant infectious diseases.

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BUDGET ACTIVITY 4 - Demonstration and Validation				PE NUMBER AND TITLE 0603807A Medical Systems - Advanced Development				PROJECT D808		
COST (In Thousands)	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
D808 DoD Drug and Vaccine-Advanced Development	2063	3684	5153	4653	4084	5107	5161	5179	Continuing	Continuing
<p>A. <u>Mission Description and Justification:</u> This project funds program definition and risk reduction of candidate medical countermeasures such as vaccines and drugs through safety, immunogenicity, and small-scale efficacy testing in volunteers against naturally occurring infectious diseases of mission-aborting potential. Work performed in laboratories and among troop populations is directed to prevention, diagnosis and treatment of viral, bacterial and parasitic disease to prevent casualties, sustain operational performance and minimize deaths and disability of armed forces during military operations. Some major contractors are Southern Research Institute, Birmingham AL; South Florida Research Institute, Miami, FL; Institute of Biology for the Army, Rio de Janeiro, Brazil; and Kenya Medical Research Institute, Nairobi, Kenya.</p> <p>FY 1998 Accomplishments:</p> <ul style="list-style-type: none"> • 756 Conducted Phase 1 safety trial for RTS,S malaria vaccine. • 75 Reformulated leishmania skin test to a liquid product. • 257 Conducted first year of Phase 1/2 safety and immunogenicity studies for <i>Shigella flexneri</i> vaccine. • 75 Continued Phase 2 efficacy studies for antimalarial drug WR238605. • 265 Conducted first year of disease incidence survey and site preparation for testing antimalarial drug WR238605 in Kenya. • 517 Conducted first year of multiple dose study with antimalarial drug WR238605 in Ghana. • 61 Conducted first year of carcinogenicity study in rats of antimalarial drug WR238605. • 19 Completed Phase 2 safety and efficacy study in Brazil with Paromomycin. • 38 Conducted first year of Paromomycin Phase 2 safety and efficacy study in Colombia. <p>Total 2063</p> <p>FY 1999 Planned Program:</p> <ul style="list-style-type: none"> • 1377 Conduct first year of Phase 2 field trials with RTS,S malaria vaccine. • 136 Conduct first year of Phase 2 study on Leishmania Skin Test Antigen. • 44 Conduct first year of testing of insect repellent camouflage face paint. • 70 Conduct first year of Phase 1 testing of artelinic acid for the treatment of malaria. • 780 Conduct first year of Phase 2 safety and efficacy trial for <i>Shigella flexneri</i> vaccine. • 145 Conduct first year of program for Malaria Rapid Diagnostic Device. 										
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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
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<p>FY 1999 Planned Program: (continued)</p> <ul style="list-style-type: none"> • 70 Complete Phase 1/2 safety and immunogenicity studies for <i>Shigella flexneri</i> vaccine. • 78 Conduct market survey for co-development partner for Paromomycin. • 8 Complete Paromomycin Phase 2 safety and efficacy study in Colombia. • 18 Complete Phase 2 efficacy studies for antimalarial drug WR238605. • 18 Complete disease incidence survey and site preparation for testing antimalarial drug WR238605 in Kenya. • 18 Complete multiple dose study with antimalarial drug WR238605 in Ghana. • 855 Continue carcinogenicity study in rats for antimalarial drug WR238605. • 67 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs <p>Total 3684</p> <p>FY 2000 Planned Program:</p> <ul style="list-style-type: none"> • 522 Continue Phase 2 studies on RTS,S Malaria vaccine. • 325 Conduct Phase 2 field trials for Malaria Rapid Diagnostic Device. • 312 Continue testing of insect repellent camouflage face paint. • 546 Complete Phase 1 testing of artelinic acid for the treatment of malaria. • 132 Conduct first year of Phase 2 clinical trials of artelinic acid. • 405 Complete Phase 2 safety and efficacy trial for <i>Shigella flexneri</i> vaccine. • 249 Continue carcinogenicity study in rats for antimalarial drug WR238605. • 72 Continue Phase 2 study on Leishmania Skin Test Antigen. • 339 Conduct first year of program for dengue rapid diagnostic device. • 110 Conduct first year of program for shigella rapid diagnostic device. • 338 Conduct first year of program for scrub typhus kit. • 328 Conduct first year of pilot lot manufacture and testing of Japanese encephalitis vaccine (improved). • 611 Conduct first year of Phase 2 trials for malaria DNA vaccine. • 864 Conduct first year of Phase 2 field trials for hepatitis E vaccine. <p>Total 5153</p> <p>FY 2001 Planned Program:</p> <ul style="list-style-type: none"> • 300 Complete testing on insect repellent camouflage paint. • 216 Continue Phase 2 study on leishmania skin test antigen. 		
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BUDGET ACTIVITY 4 - Demonstration and Validation	PE NUMBER AND TITLE 0603807A Medical Systems - Advanced Development	PROJECT D808
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FY 2001 Planned Program: (continued)

- 438 Continue Phase 2 clinical trials of artelinic acid.
 - 671 Continue Phase 2 trials for malaria DNA vaccine.
 - 486 Complete Phase 2 studies on RTS,S malaria vaccine.
 - 200 Develop planning for pivotal Phase 3 study for *Shigella flexneri* vaccine.
 - 300 Complete Phase 1 and initiate Phase 2 testing of Japanese Encephalitis Vaccine (improved).
 - 621 Continue Phase 2 field trials for Hepatitis E vaccine.
 - 879 Conduct first year of Phase 2 field trials for dengue tetravalent vaccine.
 - 216 Continue program for dengue rapid diagnostic device.
 - 110 Continue program for shigella rapid diagnostic device.
 - 216 Continue program for scrub typhus kit.
- Total 4653

B. Other Program Funding Summary: Not applicable.

C. Acquisition Strategy: Test and evaluate in-house and commercially developed products in extensive government-managed clinical trials to gather data required for Food and Drug Administration licensure.

D. Schedule Profile	<u>FY 1996</u>	<u>FY 1997</u>	<u>FY 1998</u>	<u>FY 1999</u>	<u>FY 2000</u>	<u>FY 2001</u>	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
RTS,S malaria vaccine - MS II							2Q02			
Leishmania skin test - MS II					1Q00					
Camouflage face paint - MS I and MS II				4Q99		3Q01				
Artelinic acid - MS I and MS II				2Q99		2Q01				
Shigella flexneri - MS II							2Q02			
Paromomycin - MS II						1Q01				
WR238605 antimalarial - MS II				2Q99						
Dengue rapid diagnostic device - MS I and MS II					1Q00		1Q02			
Malaria DNA vaccine - MS I and MS II					1Q00				1Q04	
Hepatitis E vaccine - MS I and MS II					1Q00				1Q04	
Dengue tetravalent vaccine - MS I and MS II						4Q01			1Q04	
Malaria Rapid Diagnostic Device						1Q01				

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ARMY RDT&E COST ANALYSIS (R-3)

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BUDGET ACTIVITY
4 - Demonstration and Validation

PE NUMBER AND TITLE
0603807A Medical Systems - Advanced Development

PROJECT
D808

I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a. No product/contract costs greater than \$1M individually			204	295		412		373		Continue	Continue	
b. Subtotal Product Development:			204	295		412		373		Continue	Continue	

II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a. No product/contract costs greater than \$1M individually			103	185		259		233		Continue	Continue	
b. Subtotal Support Costs:			103	185		259		233		Continue	Continue	

III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a. No product/contract costs greater than \$1M individually			1278	2320		3246		2931		Continue	Continue	
b. Subtotal Test and Evaluation:			1278	2320		3246		2931		Continue	Continue	

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ARMY RDT&E COST ANALYSIS (R-3)	DATE February 1999
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BUDGET ACTIVITY 4 - Demonstration and Validation	PE NUMBER AND TITLE 0603807A Medical Systems - Advanced Development	PROJECT D808
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IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a. No product/contract costs greater than \$1M individually			478	884		1236		1116		Continue	Continue	
b. Subtotal Management Services:			478	884		1236		1116		Continue	Continue	
Project Total Cost:			2063	3684		5153		4653				

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ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)								DATE February 1999		
BUDGET ACTIVITY 4 - Demonstration and Validation				PE NUMBER AND TITLE 0603807A Medical Systems - Advanced Development				PROJECT D811		
COST <i>(In Thousands)</i>	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
D811 Military HIV Vaccine and Drug-Advanced Development	0	3238	2689	2690	2702	2663	1735	1928	Continuing	Continuing
<p>A. <u>Mission Description and Justification:</u> This project funds Congressionally mandated, militarily relevant Human Immunodeficiency Virus (HIV) research for demonstration and validation of candidate vaccines and drugs through safety, immunogenicity and small-scale efficacy testing and behavioral intervention in volunteers. Efforts are directed to answer militarily unique needs affecting manning, mobilization and deployment.</p> <p>FY 1998 Accomplishments: Project not funded in FY 1998.</p> <p>FY 1999 Planned Program:</p> <ul style="list-style-type: none"> • 3152 Conduct Phase 2/3 efficacy field trials for GP120 recombinant protein HIV vaccine. • 86 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs <p>Total 3238</p> <p>FY 2000 Planned Program:</p> <ul style="list-style-type: none"> • 2689 Conduct first year of Phase 2/3 efficacy field trials for avipox HIV vaccine. <p>Total 2689</p> <p>FY 2001 Planned Program:</p> <ul style="list-style-type: none"> • 2690 Continue Phase 2/3 efficacy field trials for avipox HIV vaccine. <p>Total 2690</p> <p>B. <u>Other Program Funding Summary:</u> Not applicable.</p> <p>C. <u>Acquisition Strategy:</u> Test and evaluate commercially developed vaccine candidates in government-managed trials.</p>										
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BUDGET ACTIVITY 4 - Demonstration and Validation	PE NUMBER AND TITLE 0603807A Medical Systems - Advanced Development	PROJECT D811
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D. Schedule Profile	<u>FY 1996</u>	<u>FY 1997</u>	<u>FY 1998</u>	<u>FY 1999</u>	<u>FY 2000</u>	<u>FY 2001</u>	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
GP 120 recombinant protein HIV vaccine - MSI				1Q99						
GP 120 recombinant protein HIV vaccine - MSII					1Q00					
Avipox HIV vaccine - MSI and MSII					1Q00		1Q02			
Combined HIV Vaccine - MSI								1Q03		

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BUDGET ACTIVITY 4 - Demonstration and Validation					PE NUMBER AND TITLE 0603807A Medical Systems - Advanced Development					PROJECT D811		
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a. Product Development		WRAIR/AFRIMS		3238		2689		2690		Continue	Continue	
b. Subtotal Product Development:				3238		2689		2690		Continue	Continue	
II. Support Costs: Not applicable												
III. Test and Evaluation: Not applicable												
IV. Management Services: Not applicable												
Project Total Cost:				3238		2689		2690		Continue	Continue	
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PE NUMBER AND TITLE
0603807A Medical Systems - Advanced Development

COST (In Thousands)	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
D836 Combat Medical Materiel-Advanced Development	6332	3606	3996	4031	4210	4042	4024	4080	Continuing	Continuing

A. Mission Description and Justification: The project supports Advanced Development of new and improved systems essential for battlefield casualty care, patient transport and evacuation, and return to duty in support of special contingency and conventional force operations. Primary civilian contractors are University of Illinois, Chicago, IL and United Defense Limited Partnership, San Jose, CA.

FY 1998 Accomplishments:

- 1990 Completed an Analysis of Alternatives for Armored Medical Evacuation Vehicle (AMEV), initial prototype constructed and delivered to 4th Infantry Division for initial user evaluation.
 - 350 Completed Operational Requirements Document and market investigation for Life Support for Trauma and Transport (LSTAT); conducted electromagnetic emissions testing, submitted data to the Food and Drug Administration (FDA), and received FDA approval for initial model of LSTAT medical device.
 - 745 Developed Analysis of Alternatives and manufacturing process for production and demonstration of efficacy of fibrin bandage.
 - 300 Completed initial development of glycerolization portion of thawed blood processing system to extend shelf life of thawed blood products from 24 hours to 2 weeks.
 - 200 Initiated evaluation of ceramic oxygen generator system to replace currently used oxygen cylinders in medical evacuation.
 - 23 Completed standardization of field triage light.
 - 2724 Developed plan to conduct cost-benefit trade-offs, overcome technological barriers and integrate solutions into next generation LSTAT.
- Total 6332

FY 1999 Planned Program:

- 1013 Evaluate AMEV in National Training Center Rotation 99-05 and conduct concept evaluation phase (CEP) test.
- 316 Develop prototype Warrior Medic variant system and test effectiveness in Land Warrior.
- 69 Transition Warrior Medic program to advanced development [Milestone O/I In-process Review (IPR)].
- 130 Conduct first year of clinical testing and FDA approval process of thawed blood processing device while continuing development of glycerolization device.
- 303 Develop quality control assays for fibrin bandage and prepare to conduct a Milestone I/II for fibrin bandage in order to move into clinical trials in humans.

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<ul style="list-style-type: none"> • 28 Continue evaluation of ceramic oxygen generator system. 		
FY 1999 Planned Program: (continued)		
<ul style="list-style-type: none"> • 842 Develop next generation jet injector for administration of vaccines to large numbers of troops without cross-contamination. 		
<ul style="list-style-type: none"> • 136 Continue development and refinement of LSTAT device to include air worthiness certification and preparation of FDA submission. 		
<ul style="list-style-type: none"> • 275 Design and construct lightweight litter using advanced composite materials. 		
<ul style="list-style-type: none"> • 425 Conduct market survey and evaluation of candidate technologies for microbiological assay and sample preparation for the Drinking Water microbiological assay system. 		
<ul style="list-style-type: none"> • 69 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs 		
<p>Total 3606</p>		
FY 2000 Planned Program:		
<ul style="list-style-type: none"> • 1704 Complete evaluation and conduct a Milestone I/II and production qualification test (PQT) for AMEV. 		
<ul style="list-style-type: none"> • 62 Conduct technology cost-benefit trade-off analysis and initiate formal acquisition program for upgraded LSTAT device. 		
<ul style="list-style-type: none"> • 573 Complete Warrior Medic variant design and qualification testing. 		
<ul style="list-style-type: none"> • 100 Conduct clinical trials for efficacy and safety of fibrin bandage. 		
<ul style="list-style-type: none"> • 970 Conduct clinical trials and continue development of FDA submission of thawed blood processing system. 		
<ul style="list-style-type: none"> • 587 Prepare documentation for FDA approval to conduct bioequivalence testing of next generation jet injector. 		
<p>Total 3996</p>		
FY 2001 Planned Program:		
<ul style="list-style-type: none"> • 100 Conduct clinical trials for the fibrin bandage program and prepare the Product License Application (PLA) and Establishment License Application (ELA). 		
<ul style="list-style-type: none"> • 125 Prepare IOT&E and conduct Milestone II/III IPR for Warrior Medic program. 		
<ul style="list-style-type: none"> • 700 Finalize development of the platelet processing system for thawed blood processing system. 		
<ul style="list-style-type: none"> • 1700 Begin low rate initial production (LRIP) and conduct production verification test (PVT) for AMEV. 		
<ul style="list-style-type: none"> • 1406 Develop and conduct field for testing of the improved Advanced Surgical Suites for Trauma Casualties (ASSTC). 		
<p>Total 4031</p>		
B. <u>Other Program Funding Summary:</u> Not applicable.		
C. <u>Acquisition Strategy:</u> Evaluate commercially developed materiel in government-managed tests for hardening or other modification.		
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D. Schedule Profile	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005
Warrior Medic				MS0/I 4QTR		MS III 4QTR				
LSTAT						4QTR				
Fibrin Bandage				MSI 3QTR	3QTR					
AMEV					MS I/II 4QTR					
Ceramic Oxygen Generator System				4QTR						
Jet Injector					MS I/II 4QTR					
Thawed Blood System					MS I/II 4QTR					

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I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a. AMEV	MIPR	PM Bradley, Warren, MI	1990	1010	Nov 98	1404	Nov 98	1700	Nov 98	Continue	Continue	
b. LSTAT	TBD	TBD	2724							Continue	Continue	
c. ASSTC								1410		Continue	Continue	
Subtotal Product Development:			4714	1010		1404		3110				

II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a. No product/contract costs greater than \$1M individually												
Subtotal Support Costs:												

III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a. No product/contract costs greater than \$1M individually												
Subtotal Test and Evaluation:												

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IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a. No product/contract costs greater than \$1M individually			1618	2596		2592		921		Continue	Continue	
Subtotal Management Services:			1618	2596		2592		921				
Project Total Cost:			6332	3606		3996		4031				

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ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)								DATE February 1999		
BUDGET ACTIVITY 4 - Demonstration and Validation				PE NUMBER AND TITLE 0603807A Medical Systems - Advanced Development				PROJECT D837		
COST (In Thousands)	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
D837 Soldier System Protection-Advanced Development	786	801	885	861	1772	1570	809	1789	Continuing	Continuing
<p>A. <u>Mission Description and Justification:</u> This project supports demonstration and validation 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. Focus is on reduction in the incidence 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>FY 1998 Accomplishments:</p> <ul style="list-style-type: none"> • 32 Provided consultation on the warfighter physiological status monitor. • 192 Integrated databases of the Medical Situational Awareness and Control System (MSAC) into databases of Combat Service and Support Control System (CSSCS). • 191 Developed software links to port all of MSAC into CSSCS. • 62 Developed organizational structure for Medical Communications for Combat Casualty Care (MC4) program management office. • 124 Integrated MC4 functional requirements into Theatre Medical Information Program (TMIP) requirements documentation. • 185 Provided system engineering support to Army Medical Department (AMEDD) integrated process and product development. <p>Total 786</p> <p>FY 1999 Planned Program:</p> <ul style="list-style-type: none"> • 45 Provide consultation on the warfighter physiological status monitor. • 588 Develop prototype warrior medic variant system and test effectiveness in Land Warrior initial operational test and evaluation (IOT&E). • 147 Provide system engineering support for system integration with Force XXI Battle Command – Brigade and Below (FBCB2) and Global Combat Support System (GCSS). • 21 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs <p>Total 801</p> <p>FY 2000 Planned Program:</p> <ul style="list-style-type: none"> • 31 Provide consultation on the warfighter physiological status monitor. • 41 Prepare acquisition documents for Milestone 0 In-process Review (IPR) for warfighter physiological status monitor. 										
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FY 2000 Planned Program: (continued)

- 715 Initiate contract funding for required Investigational New Drug (IND) application sections and manufacturing of leishmania skin test antigen (LSTA) kits.
 - 49 Initiate program for second indication for modafinil as short-term measure to sustain performance in continuous operations (counter fatigue).
 - 49 Initiate program for caffeine formulations to counter fatigue.
- Total 885

FY 2001 Planned Program:

- 31 Provide consultation on the warfighter physiological status monitor.
 - 700 Provide for manufacture of LSTA kits for Phase 1 dose ranging safety and sensitivity clinical trial.
 - 91 Continue to investigate caffeine formulation as short-term measure to sustain performance in continuous operations.
 - 39 Initiate program for melatonin formulations to counter warfighter fatigue.
- Total 861

B. Other Program Funding Summary: Not applicable.

C. Acquisition Strategy: Test and evaluate materiel in government-managed trials to meet fielding requirements.

D. Schedule Profile	<u>FY 1996</u>	<u>FY 1997</u>	<u>FY 1998</u>	<u>FY 1999</u>	<u>FY 2000</u>	<u>FY 2001</u>	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Leishmania Skin Test Antigen - MS II						4Q01				
Modafinil - MS 0 and MS I/II				1Q99	3Q00					
Caffeine - MS 0 and MS I				1Q99	4Q00					
Melatonin - MS 0 and MS I				4Q99		4Q01				
Warfighter Physiological Status Monitor - MS 0					4Q00					

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ARMY RDT&E COST ANALYSIS (R-3)										DATE February 1999		
BUDGET ACTIVITY 4 - Demonstration and Validation					PE NUMBER AND TITLE 0603807A Medical Systems - Advanced Development					PROJECT D837		
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a. No product/contract costs greater than \$1M individually				520		715		700		Continue	Continue	
Subtotal Product Development:				520		715		700		Continue	Continue	
II. Support Costs: Not applicable												
III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a. No product/contract costs greater than \$1M individually								52		Continue	Continue	
Subtotal Test and Evaluation:								52		Continue	Continue	
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a. No product/contract costs greater than \$1M individually				281		170		109		Continue	Continue	
Subtotal Management Services:				281		170		109		Continue	Continue	
Project Total Cost:				801		885		861		Continue	Continue	