

**UNCLASSIFIED**

<b>ARMY RDT&amp;E BUDGET ITEM JUSTIFICATION (R-2 Exhibit)</b>									DATE <b>February 1999</b>	
<b>BUDGET ACTIVITY</b> <b>3 - Advanced Technology Development</b>				<b>PE NUMBER AND TITLE</b> <b>0603002A Medical Advanced Technology</b>						
<i>COST (In Thousands)</i>	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
Total Program Element (PE) Cost	202504	229325	10539	12591	13566	14957	19391	20858	Continuing	Continuing
D800 Telemedicine Testbed	0	0	0	1866	1669	0	2948	3433	Continuing	Continuing
D804 Prostate Cancer Research	0	49669	0	0	0	0	0	0	0	49669
D806 Breast Cancer Research	126469	134107	0	0	0	0	0	0	0	260576
D810 Industrial Base/Infectious Disease Vaccines and Drugs	7752	8480	7932	8096	8678	9147	9703	10216	Continuing	Continuing
D815 National Medical Testbed	7495	7947	0	0	0	0	0	0	0	15442
D818 Advanced Cancer Detection Center	3270	0	0	0	0	0	0	0	0	3270
D819 Field Medical Protection and Human Performance Enhancement Non-Systems - Advanced Development	0	0	200	194	557	576	618	647	Continuing	Continuing
D840 Combat Injury Management	3252	2450	2407	2435	2662	5234	6122	6562	Continuing	Continuing
D922 Emergency Telemedicine	2343	0	0	0	0	0	0	0	0	2343
D923 Prostate Diagnostic Imaging	4683	7450	0	0	0	0	0	0	0	12133
D924 Advanced Trauma Care	2810	0	0	0	0	0	0	0	0	2810
D929 Artificial Lung Technology	1405	845	0	0	0	0	0	0	0	2250
D930 Cooperative Teleradiology	2810	0	0	0	0	0	0	0	0	2810
D932 Periscopic Minimally Invasive Surgery	16000	0	0	0	0	0	0	0	0	16000
D933 Proton Beam Therapy	4000	0	0	0	0	0	0	0	0	4000

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COST <i>(In Thousands)</i>	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
D934 Volume Angiocat	3747	3974	0	0	0	0	0	0	0	7721
D937 Nervous System Studies	4468	0	0	0	0	0	0	0	0	4468
D938 Tissue Engineering	3500	0	0	0	0	0	0	0	0	3500
D939 Medical Imaging	3500	0	0	0	0	0	0	0	0	3500
D940 Epidermolysis Bullosa	1000	0	0	0	0	0	0	0	0	1000
D941 Diabetes Research	4000	4470	0	0	0	0	0	0	0	8470
D954 Digital X-Ray	0	3973	0	0	0	0	0	0	0	3973
D955 Assistive Technology	0	5960	0	0	0	0	0	0	0	5960

**A. Mission Description and Budget Item Justification:** This program element funds advanced technology development for the DoD core Vaccine and Drug Program, field medical protective devices, and combat injury management. These last two projects focus on diagnostic imaging devices, clinical studies of combat casualty care treatment modalities, and nutrition and soldier performance enhancement. The DoD core Vaccine and Drug Program provides, in accordance with Food and Drug Administration (FDA) regulations, drugs and vaccines for development that are effective protectants, treatments, and antidotes against military disease threats. Pilot and standard lots of candidate pharmaceutical-grade drugs, antidotes and vaccines are produced. The primary goal of this program is to provide, with minimum adverse effects, maximum soldier survivability and sustainability on the integrated battlefield as well as in military operations other than war. The work in this program element is consistent with the Army Science and Technology Master Plan, the Army Modernization Plan, and Project Reliance. This program is managed primarily by the U.S. Army Medical Research and Materiel Command. This program element also serves to track funds for Congressionally directed medical research in projects 806, 815, 818, 922, 923, 924, 929, 930, 932, 933, 934, 937, 938, 939, 940, 954, and 955.

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<b>B. Program Change Summary</b>	<u>FY 1998</u>	<u>FY 1999</u>	<u>FY 2000</u>	<u>FY 2001</u>
Previous President's Budget (FY 1999 PB)	176737	11012	10788	10977
Appropriated Value	190177	230862		
Adjustments to Appropriated Value				
a. Congressional General Reductions	-5471	-1537		
b. SBIR / STTR	-4305			
c. Omnibus or Other Above Threshold Adjustments	+22103			
d. Below Threshold Reprogramming				
e. Rescissions				
Adjustments to Budget Years Since FY 1999 PB			-249	1614
Current Budget Submit (FY 2000 / 2001 PB)	202504	229325	10539	12591

Change Summary Explanation: FY1998 Appropriated Value - Funding increased for new Congressionally directed projects. Funding was also affected by several reprogrammings of Congressional special interest funds for proper program execution. FY 2001 funding increase (+1614) for telemedicine ACTD (Project 800).

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COST <i>(In Thousands)</i>	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
D800 Telemedicine Testbed	0	0	0	1866	1669	0	2948	3433	Continuing	Continuing

**Mission Description and Justification:** This project funds development, evaluation, and demonstration of prototypes of advanced technologies that will incorporate health awareness into battlespace awareness, provide force protection, reduce time to critical intervention for injured personnel, improve the skills and proficiency of medical personnel, and improve the quality of emergency and surgical care throughout the battlespace. Key objectives are to demonstrate capabilities for real-time monitoring and assessment of soldiers, remote identification of injured personnel, simulations for training of medical personnel, and decision support and remote intervention for medical personnel.

**FY 1998 Accomplishments:** Project not funded in FY 1998.

**FY 1999 Planned Program:** Project not funded in FY 1999.

**FY 2000 Planned Program:** Project not funded in FY 2000.

**FY 2001 Planned Program:**

- 1866 Develop and test a seamless telemedicine network that connects health care providers in the front lines with tertiary medical treatment centers through the Joint Medical Operations - Telemedicine Advanced Concept Technology Demonstration.

Total 1866

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BUDGET ACTIVITY <b>3 - Advanced Technology Development</b>				PE NUMBER AND TITLE <b>0603002A Medical Advanced Technology</b>				PROJECT <b>D804</b>		
COST <i>(In Thousands)</i>	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
D804 Prostate Cancer Research	0	49669	0	0	0	0	0	0	0	49669
<p><b><u>Mission Description and Justification:</u></b> By Congressional direction, the purpose of this project is to continue the peer-reviewed Prostate Cancer Research Program.</p> <p><b>FY 1998 Accomplishments:</b> Project not funded in this PE in FY 1998.</p> <p><b>FY 1999 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 48353 Published a Program Announcement in December 1998. Conduct scientific peer review and programmatic review for training grants by April 1999 and make initial awards by May 1999. For Prostate Cancer Center grants, conduct scientific peer review by September 1999. Conduct programmatic review in October 1999 and make initial awards by December 1999. For idea grants, conduct scientific peer review and programmatic review by August 1999 and make initial awards by September 1999. All awards will be finalized by 30 September 2000.</li> <li>• 1316 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs</li> </ul> <p>Total 49669</p> <p><b>FY 2000 Planned Program:</b> Project not funded in FY 2000.</p> <p><b>FY 2001 Planned Program:</b> Project not funded in FY 2001.</p>										
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BUDGET ACTIVITY <b>3 - Advanced Technology Development</b>					PE NUMBER AND TITLE <b>0603002A Medical Advanced Technology</b>				PROJECT <b>D806</b>	
COST <i>(In Thousands)</i>	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
D806 Breast Cancer Research	126469	134107	0	0	0	0	0	0	0	260576
<p><b><u>Mission Description and Justification:</u></b> By Congressional direction, the purpose of this project is to continue the peer-reviewed Breast Cancer Research Program.</p> <p><b>FY 1998 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>• 126469 Published a Program Announcement in March 1998. Conducted scientific peer review and programmatic review by December 1998 and make initial awards in January 1999. Complete awards no later than 30 September 1999.</li> </ul> <p>Total 126469</p> <p><b>FY 1999 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 130555 Publish a Program Announcement in March 1999. Conduct scientific peer review and programmatic review by November 1999 and make initial awards in December 1999. All awards will be completed by 30 September 2000.</li> <li>• 3552 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs</li> </ul> <p>Total 134107</p> <p><b>FY 2000 Planned Program:</b> Project not funded in FY 2000.</p> <p><b>FY 2001 Planned Program:</b> Project not funded in FY 2001.</p>										
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<b>BUDGET ACTIVITY</b> <b>3 - Advanced Technology Development</b>	<b>PE NUMBER AND TITLE</b> <b>0603002A Medical Advanced Technology</b>	<b>PROJECT</b> <b>D810</b>
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COST ( <i>In Thousands</i> )	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
D810 Industrial Base/Infectious Disease Vaccines and Drugs	7752	8480	7932	8096	8678	9147	9703	10216	Continuing	Continuing

**Mission Description and Justification:** This project funds development of medical countermeasures for naturally occurring diseases that are militarily significant due to their potential impact on military operations. Development of medical countermeasures will protect the force from infection and sustain operations by preventing hospitalization and evacuations from the theater of operations. Major contractors are the University of California, San Francisco, CA; SRI, Inc., Menlo Park, CA; Starks Associates, Inc., Buffalo, NY; ASH Stevens, Inc., Detroit, MI; and Research Triangle Associates, Research Triangle Park, NC.

**FY 1998 Accomplishments:**

- 1660
Began study of “prime-boost” (prime immune system using a DNA vaccine and boost the immune system with a protein vaccine) vaccine system in Rhesus monkeys to attempt to enhance the poor antibody response typically seen with DNA vaccines, necessary study for selecting the best vaccine strategy. Began preclinical studies of *P. falciparum* TRAP immunogen combined with RTS,S vaccine in attempt to enhance vaccine-induced immune response to include phases of the parasite life cycle. In developing a *Plasmodium knowlesi* (Pk)/Rhesus monkey model for testing a DNA vaccine, sequenced, constructed and injected into monkeys four Pk genes, necessary for demonstrating safety and immunogenicity and for defining details of dosing, schedule, route, adjuvants, and vaccine delivery of a DNA vaccine. Immunogenicity and protection studies are ongoing. Tested 10 DNA vaccine candidates for *P. falciparum* in mice, *Aotus* and Rhesus monkeys for their ability to induce antibodies against blood-stage forms of the malaria parasite, necessary for finalizing the blood-stage DNA vaccine “cocktail.” Completed the first Phase 1 clinical trial of a *P. falciparum* DNA vaccine candidate, demonstrating vaccine safety and the ability to induce T cell immune responses, necessary clinical study for continued development and evaluation of DNA vaccines. Began a Phase 1/2a clinical trial of a five-gene DNA vaccine for prevention of malaria caused by *P. falciparum*, necessary clinical study for continued development and evaluation of DNA vaccines. Conducted epidemiological studies of *P. falciparum* malaria among Thai military forces on the Thai-Burmese border, necessary for continued disease risk assessment and for preparation for vaccine and drug studies. Developed clinical trial site for malaria vaccine trials in Kenya. Demonstrated significant genetic heterogeneity in the TRAP and CS genes among clinical *P. falciparum* isolates in Kenya, which suggests that a vaccine based on the current TRAP protein may be less effective in protecting individuals from malaria parasites in Kenya. This is important for designing and developing an effective malaria vaccine. Identified and characterized four potential field sites for malaria vaccine testing in Peru, necessary preparation for future malaria vaccine field trials. Identified a field site for malaria vaccine and drug trials in Indonesia consisting of nonimmune transmigrants, necessary for establishing comparative efficacy of malaria vaccines between persons who have never been exposed (nonimmune) versus those with a history of previous infection (“immune”).
- 2029
Identified and analyzed four metabolites of artemisinin acid metabolism in humans and produced three of them in sufficient quantity and purity for assessment of activity and toxicity, studies necessary for a complete assessment of the metabolism and toxicity of this candidate antimalarial drug prior to submission of a New Drug Application (NDA). Demonstrated that the presence of active infection with malaria does not alter the pharmacology or antimalarial activity of arteether or dihydroqinghaosu, necessary to understand the potential for toxicity or loss of drug activity that

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<p><b>FY 1998 Accomplishments: (continued)</b></p> <p>may occur due to effects of infection on drug metabolism. Identified new field sites in Thailand for clinical testing of candidate antimalarial drugs. Collected 70 new clinical pediatric malaria isolates for use in drug susceptibility screening, necessary for ongoing surveillance of drug resistance and disease risk assessment. Established laboratory capacity for polymerase chain reaction (PCR) analysis of malaria isolates for markers of drug resistance, necessary for ongoing studies of the dynamics of drug resistance as a part of new drug development. Completed a clinical trial of WR6026, a candidate drug for treatment of systemic leishmaniasis. Demonstrated limited efficacy and the occurrence of kidney toxicity in three patients, which may limit further development of WR6026.</p> <ul style="list-style-type: none"> <li>• 384 Studied safety and immunogenicity of human administration of <i>S. flexneri</i> 2a SC602 candidate vaccine to 33 subjects in an outpatient, Phase 1 clinical trial. Demonstrated safety in all volunteers with only 6 subjects (18%) experiencing fever or diarrhea and seroconversion in 60% of subjects, a necessary study for transition of candidate vaccine to advanced development.</li> <li>• 413 Using current Good Manufacturing Practice (cGMP), produced 100 master seed vials and 100 production seed vials of enterotoxigenic <i>Escherichia coli</i> (ETEC) strains B7A and H10407 for challenge studies, necessary for future clinical studies of ETEC vaccines. Developed clinically relevant ETEC challenge model using ETEC strains B7A and H10407 at a dose of 10<sup>10</sup> colony forming units/dose, necessary for future clinical studies of candidate ETEC vaccines. Established radiolabeled polynucleotide hybridization probe assay in Peru for detection of ETEC toxins in stool samples for support of surveillance and epidemiological studies and in support of future ETEC vaccine trials. Evaluated over 500 stool samples from diarrhea patients in Peru for the presence of ETEC; detected ETEC in 12%. This demonstrated a significant prevalence of ETEC in the community and contributed to ongoing surveillance and disease risk assessment. Conducted epidemiological studies of ETEC infection in Egypt. Documented 1.43 episodes of ETEC infection per person per year, studies necessary for clinical field site development for future ETEC vaccine trials.</li> <li>• 433 Developed an experimental model of human <i>C. jejuni</i> infection, necessary for future studies of immune response and protection induced by candidate vaccines for <i>Campylobacter jejuni</i>. Conducted testing on 250 stool samples obtained from soldiers and marines with diarrhea incurred during deployment to Thailand. Demonstrated 10% of cases to be associated with <i>Campylobacter</i> infection. These efforts were necessary for continued surveillance and disease risk assessment. Conducted clinical evaluation of "E-Test strips" for diagnosis of <i>Campylobacter</i> antibiotic resistance among soldiers and marines deployed to Thailand. Demonstrated comparable performance compared to traditional, time-consuming methods. This method may be adaptable to facilitate surveillance and disease risk assessment. Conducted surveillance and natural history study of <i>Campylobacter</i> enteritis among soldiers and marines deployed to Thailand. In 156 cases of diarrhea, there were 26 isolates of <i>Campylobacter</i>, 35 of ETEC, 34 of enteropathogenic <i>E. coli</i> (EPEC), and 42 of <i>Salmonella</i> species. All <i>Campylobacter</i> isolates were ciprofloxacin resistant. These studies were necessary for disease risk assessment and for preparation for vaccine trials in this population.</li> <li>• 283 Completed initial field evaluation of a commercially produced hand-held dengue diagnostic assay in concept evaluation phase (CEP). Tests on 80 documented positive and 17 documented negative patients in Indonesia showed that the hand-held assay exceeded sensitivity and specificity of the current reference laboratory diagnostic method. Completed initial field CEP evaluation of one commercially produced hand-held malaria diagnostic assay on patients in Indonesia with initial results showing very high sensitivity. Completed a limited field trial in Peru to evaluate the sensitivity of two commercially produced hand-held malaria diagnostic assays in detecting <i>P. vivax</i>. Enrolled over 3,000 volunteers in Peru and Thailand and completed 80% of testing in an expanded comparison of the malarial diagnostic assay candidates to demonstrate performance characteristics on different types of malaria worldwide. This comparison is critical to ensure that we will be able to detect malaria infection in our servicemembers despite parasite variability throughout the world.</li> </ul>		
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<p><b>FY 1998 Accomplishments: (continued)</b></p> <ul style="list-style-type: none"> <li>• 796 Evaluated protective efficacy of a recombinant vaccine against dengue type 2 in a cynomolgous monkey model. Results suggested that this vaccine is immunogenic but protection could not be determined from this model. An alternate species of monkey was proposed for future studies. Evaluated safety, immunogenicity, and protective efficacy of a DNA vaccine against dengue type 1 in Rhesus and Owl monkey models, comparing intradermal and intramuscular vaccine delivery with and without vaccine boosts. Both of these monkey models were very effective. These trials provide the first evidence of feasibility of DNA vaccines to protect against dengue infection and demonstrated that the vaccine was well tolerated, stimulated substantially increased antibody production after boosts and with intradermal delivery and was 30% protective. Completed two Phase 1 safety and immunogenicity trials of a live tetravalent dengue vaccine (dengue types 1, 2, 3 and 4) in 4 and 32 volunteers, respectively. These preliminary data suggest that this live vaccine is safe and more than 50% immunogenic. The second trial compared vaccination boosts at 1 and 3 months and showed that a second dose at either time interval increased the immune response significantly and to a similar extent. These results provide initial feasibility to support the overall objective of protecting servicemembers against all four types of dengue virus with a single vaccine. Identified two suitable cohorts in Thailand, one possible cohort in Indonesia and two possible cohorts in Peru with suitable dengue infection rates to support future vaccine field trials. It is important to be able to conduct field vaccine trials at geographically diverse locations throughout the world to ensure protection against antigenically distinct forms of the virus.</li> <li>• 136 Completed 60% of a clinical study to determine the efficacy of the antiviral drug ribavirin to treat sandfly fever virus infection in human volunteers.</li> <li>• 62 Identified potential cohorts in Nepal with high hepatitis transmission rates suitable for Hepatitis E vaccine field trials, which are necessary to meet milestone 0 exit criteria.</li> <li>• 106 Conducted studies in Thailand to identify ecology of scrub typhus. Analysis of 1,433 rodents and over 30,000 chiggers resulted in the identification of a new ecological habitat of rice agricultural areas, for <i>Orientia tsutsugamushi</i>, the organism that causes this disease. Knowledge of high risk areas for infection is important in protecting deployed troops. Developed and tested an immunocytochemical method to detect <i>O. tsutsugamushi</i> in chigger vectors and found it to be useful and sensitive. Modified a commercially available <i>O. tsutsugamushi</i> diagnostic kit so that it would be capable of identifying wild mammalian reservoirs of this organism. This mammalian test will allow medical personnel to monitor troop areas and assess whether there is risk for human scrub typhus infection.</li> <li>• 56 Identified populations endemic for leishmaniasis in Brazil and Bolivia and set up field sites for evaluations of rapid leishmania diagnostic tests. Trained research scientists in those remote locations on reference diagnostic test procedures that will be necessary as a standard for comparison of the rapid tests. An additional potential field site was identified in Kenya.</li> <li>• 258 Prepared and characterized a second clinical lot of Native Outer Membrane Vesicle (NOMV) Group B Meningococcal intranasal vaccine. This second lot was reproducible to the first in all aspects except for a lower pH and resulting decreased solubility. This study resulted in a recommendation to modify the production procedure to include buffering agents. All vaccine characterization data were forwarded to the Food and Drug Administration (FDA) along with a copy of the approved clinical protocol as an amendment to the Investigational New Drug (IND) protocol #6993. Evaluated mucosal immune response to intranasal vaccination with NOMV Group B Meningococcal vaccine as part of a Phase 1 clinical trial and found that this vaccine and route of immunization stimulates both serum and mucosal antibodies. The possibility of stimulating mucosal immune response is</li> </ul>		
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<p><b>FY 1998 Accomplishments: (continued)</b></p> <p>attractive as it provides an additional tier of defense not afforded by traditional vaccination methods. In support of CEP vaccine candidate comparison, prepared and obtained approvals for clinical protocol for Phase 1 safety and immunogenicity study of a second Group B Meningococcal vaccine candidate consisting of outer membrane proteins and detoxified lipooligosaccharides (OMP-dLOS).</p> <ul style="list-style-type: none"> <li>• 229 Compared effectiveness of DEET repellency in men versus women. Found that DEET has a shorter duration of effectiveness in women, suggesting the need for a change in doctrine directing women to reapply repellent more often (every 6 hours versus every 8 hours for men). Measured the effect of battle dress uniform abrasion on DEET-treated skin. BDU rubbing on the skin reduced the protective efficacy of DEET from 10 hours to less than 3 hours. Resistance to uniform abrasion is a significant factor that needs to be considered in future repellent formulations.</li> <li>• 907 The Pilot Bioproduction Facility at Walter Reed Army Institute of Research produced under Good Manufacturing Practices (GMP) pilot lots of vaccines and other biologicals of sufficient quality for Phase 1 human trials, to include: Four lots of Japanese encephalitis purified-inactivated vaccine, two lots of dengue type-2 purified-inactivated vaccine, one lot of Shigella intranasal proteosome, one lot of Meningitis Group B proteosome, six lots of HIV skin test peptides, one lot of scrub typhus diagnostic antigens, and one lot of leishmania skin test antigen. This facility is a unique asset that provides the GMP-quality products that are critical for progression from basic research to advanced development.</li> </ul> <p>Total 7752</p> <p><b>FY 1999 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 1516 Refine methods to measure immune responses to <i>Plasmodium falciparum</i> RTS,S and TRAP proteins to support Phase 1 trials of new formulations of combined vaccines containing both of these antigens. Identify correlation between specific immune antibody and cellular responses and protection against malaria in human volunteers. Conduct Phase 1 trial of new <i>Plasmodium falciparum</i> MSP-1 vaccine candidate.</li> <li>• 2971 Complete all remaining studies on the leading antimalarial compound necessary to obtain FDA approval for an IND application that permits evaluation of a new and improved drug to prevent malaria in humans.</li> <li>• 486 Submit IND application to the FDA for trials of combined live, oral <i>Shigella flexneri</i> 2a and <i>Shigella sonnei</i> vaccines. Conduct Phase 1 dose selection testing of the combined <i>Shigella flexneri</i> 2a and <i>Shigella sonnei</i> vaccine. Perform a challenge trial of a <i>S. sonnei</i> vaccine. Perform field trials with the <i>Shigella</i> PCR diagnostic device.</li> <li>• 445 Conduct Phase 1 clinical trial of microencapsulated ETEC CS6 vaccine to confirm its safety and immunogenicity. Perform preclinical evaluation and general safety of ETEC CS6 vaccine. Produce second lot of microencapsulated ETEC CS6 vaccine under GMP conditions.</li> <li>• 437 Assess protection by candidate live-attenuated or carrier-based Campylobacter vaccines against homologous and heterologous challenge in animal models. Scale up production of a live-attenuated or carrier-based Campylobacter vaccine under GMP conditions.</li> <li>• 136 Complete field testing of malaria and Shigella diagnostic tests. Field test multiple specimen collection and processing systems to support development of a portable system for far-forward diagnosis of infectious diseases.</li> <li>• 670 Evaluate sensitivity and specificity of a rapid dengue antibody test for clinical use in future vaccine field trials.</li> <li>• 51 Complete assessment of effectiveness of an antiviral drug (ribavirin) against sandfly fever virus in humans. Provide data to the FDA for this new indication for ribavirin use.</li> </ul>		
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<p><b>FY 1999 Planned Program: (continued)</b></p> <ul style="list-style-type: none"> <li>• 72 Conduct safety and immunogenicity testing of candidate hepatitis E vaccine in humans. Determine infection and disease rates in selected field site for future evaluation of candidate hepatitis E virus vaccines.</li> <li>• 96 Assess significance of rickettsial infection as a threat to deployed warfighters. Evaluate scrub typhus rapid diagnostic device.</li> <li>• 251 Conduct Phase 1 studies of three candidate vaccine formulations for prevention of bacterial meningitis due to Group B <i>Neisseria meningitidis</i>.</li> <li>• 215 Demonstrate the effectiveness of Global Information Systems (GIS) in mapping, monitoring and predicting risk of vector-borne disease transmission. Field test device to detect any combination of dengue, <i>P. falciparum</i> and <i>P. vivax</i> in mosquitoes. Field test ELISA for identification of <i>Leishmania donovoni</i> in sand flies. Evaluate a prototype expert system for rapid assessment of vector borne diseases at the Army Medical Department (AMEDD) Center and School.</li> <li>• 905 Produce, purify and bottle 15-20 new vaccines at the vaccine pilot production facility under GMP conditions, applying the new technologies tested in FY98 research efforts. Conduct clinical trials of 10-15 vaccine candidates in volunteer recipients at the Clinical Trials Department of WRAIR.</li> <li>• 52 Evaluate safety of a hantavirus vaccine in humans.</li> <li>• 177 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs</li> </ul> <p>Total 8480</p> <p><b>FY 2000 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 1727 Analyze clinical samples from vaccine trials for specific humoral and cellular immune responses to component antigens. Produce <i>P. falciparum</i> sporozoites, and research grade recombinant antigens and synthetic peptides. Conduct preclinical studies of candidate vaccines to support sections 7 (Chemistry, Manufacturing and Control) and 8 (Pharmacology and Toxicology) of an IND application. Develop a method to perform CONUS-based <i>P. vivax</i> sporozoite challenge.</li> <li>• 2958 Maintain a drug repository to include acquisition, storage and distribution. Prepare gram and kilogram quantities of drug candidates under Good Laboratory Practice (GLP)/GMP. Perform pharmacokinetics, absorption, disposition, biotransformation and excretion studies of new drugs. Perform preclinical toxicology studies of new drugs. Perform quantitative analysis of drugs in biological fluids. Prepare drug delivery systems of compounds under GLP/GMP. Conduct a surveillance program for drug-sensitivity patterns of malaria from diverse geographic regions. Prepare Good Clinical Practice (GCP)-capable test sites for advanced testing of drug candidates.</li> <li>• 429 Evaluate immune responses generated by candidate <i>Shigella</i> vaccines. Develop, manufacture, and evaluate subcellular candidate vaccines. Develop and evaluate rapid and economical diagnostic techniques for use in <i>Shigella</i> vaccine trials. Conduct epidemiological evaluation of potential <i>Shigella</i> vaccine field trial sites.</li> <li>• 430 Characterize parameters of ETEC protection in humans. Conduct proof-of-concept testing of a microencapsulated, adherence factor-based vaccine in a human challenge model (6.2 and 6.3). Conduct proof-of-concept testing of a killed whole cell/recombinant B subunit vaccine in a human challenge model. Conduct in vitro and in vivo studies of mucosal adjuvants. Identify and develop field sites for testing ETEC vaccine candidates.</li> <li>• 510 Elucidate the components of a protective immune response in the human challenge model and in natural infection. Study the relative roles of cellular, humoral, and mucosal immunity in recovery from acute <i>C. jejuni</i> disease and in long-term protective immunity. Study the antigen-specific immune</li> </ul>		
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<p><b>FY 2000 Planned Program: (continued)</b></p> <p>responses to known and newly characterized antigens (e.g., rFla, PEB, CDT). Compare the immune response to natural infection with the characteristics of the immune response generated in persons given adjuvanted whole-cell vaccine and with the immune responses in immunized or infected animals that are protected against illness. Study the antigen-specific nature and persistence of the immune responses over longer periods of time after infection and its relationship to protection. Evaluate circulating and mucosal antibodies as well as markers of T-cell mediated immunity, including T-cell memory.</p> <ul style="list-style-type: none"> <li>• 189 Optimize unique gene amplification primers and probes. Identify multiple gene targets per agent. Develop field test sites and collect well-characterized clinical specimen collections.</li> <li>• 604 Prepare for/execute Phase 1 tests of “dead” and DNA vaccine candidates that retain potential for rapid (i.e., suitable for travelers) immunization. Refine human challenge model as tool for development of dengue vaccines. Conduct additional studies of WRAIR and PMC tetravalent live vaccines to assess their commercial potential. Characterize natural immune responses to dengue viruses that protect against severe disease upon heterologous challenge. Characterize vector role in determining outcome (no infection, infection, disease) and whether human challenge model is valid only when virus is inoculated by mosquito bite. Train cadre for vaccine studies CONUS and OCONUS. Identify sites/populations for Phase 1b evaluation of vaccine candidates among adults with well-characterized immunity to one or two dengue viruses, or yellow fever vaccine, or Japanese encephalitis (JE) vaccine.</li> <li>• 55 Investigate disease outbreaks to validate assays and obtain fresh field samples for viral isolation and antibody analysis. Develop testbeds for efficacy evaluations of candidate vaccines and protective strategies in human, at-risk populations.</li> <li>• 284 Perform family studies to assess importance of reinfection (infection with anamnestic antibody response), waning antibody levels in older adults, and the relevance of these phenomena to disease. Prepare for Phase 3 vaccine study in Nepal and to support Phase 2 vaccine studies elsewhere in Asia and Africa. Characterize determinants and pathophysiology of fulminant hepatitis E. Initiate Phase 1 study of combined hepatitis E and hepatitis A vaccine. Train cadre for vaccine studies in Nepal; maintain expertise in tropical hepatology.</li> <li>• 110 Prepare one or more potential vaccines candidates (e.g., recombinant, DNA) and evaluate their protective efficacy in mice against homologous challenge. If homologous efficacy is established, then evaluate the vaccines' efficacy against heterologous challenge.</li> <li>• 264 Produce preclinical lots vaccines using the three approaches: (1) native outer membrane vesicles (NOMV) presented as an intranasal vaccine; (2) purified OMP and LOS recombined as noncovalent complexes, in liposomes or as proteoliposomes presented as a parenteral vaccine; and (3) NOMV from an <i>htrB(-)</i> mutant that expresses a low toxicity LOS presented as a parenteral vaccine. Prepare and characterize cGMP lots of vaccine and conduct preclinical testing of the vaccines in animals. Prepare and submit clinical protocols and IND applications for FDA approval. Define more completely the optimal conditions or methods for production of the OMP-dLOS and/or NOMV vaccines to ensure reproducibility and optimal immunogenicity. Prepare a cGMP grade lot of vaccine using one of the new vaccine strains.</li> <li>• 297 Conduct risk assessment and identification of vectors. Evaluate the threat of tick and chigger-borne diseases to the U.S. military. Seek and test new repellent candidates that will outperform the current repellent (DEET) in durability, effectiveness, and user acceptability. Coordinate fielding of improved bednet by entering into the appropriate development process that will fund final testing for efficacy. Begin development of a dengue Vector Control System, an integrated system of tools and information that can be physically packaged for a Preventive Medicine Detachment (or service</li> </ul>		
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<p><b>FY 2000 Planned Program: (continued)</b></p> <p>equivalent): (1) Begin evaluation of existing devices for evaluating biting rate of these vectors; (2) begin development of handbook and accompanying software for identification of vectors, evaluation of pathogens in humans and vectors, and most appropriate control and surveillance techniques; and (3) establish requirements document and liaison with those who field equipment to MTOE units.</p> <ul style="list-style-type: none"> <li>• 21 Devise processes for manufacture of at least 10 new vaccine lots under cGMP compliance.</li> <li>• 54 Improve capability to rapidly identify, assess risk, and formulate control strategies for hantaviruses, including conduct of serosurveys of rodents or humans to detect hantaviruses. Publish a detailed assessment of the threat of hantaviruses to military operations.</li> </ul> <p>Total 7932</p> <p><b>FY 2001 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 1816 Conduct preclinical studies of a <i>P. vivax</i> vaccine. Validate the <i>P. vivax</i> experimental challenge model.</li> <li>• 3446 Transition to advanced development at least one new drug for oral treatment of multidrug-resistant malaria. Complete evaluation of prototype kits and other methodologies for determining with greater than 90% accuracy the degree of malaria parasites' resistance to therapeutic agents in both focal and broadly endemic geographic regions. Submit IND to the FDA for a drug that will effect radical cure of malaria.</li> <li>• 433 Transition to advanced development a <i>S. dysenteriae</i> candidate vaccine with potential to protect 80% of immunized personnel.</li> <li>• 434 Transition to advanced development an oral microencapsulated ETEC vaccine with potential to protect 80% of immunized personnel from traveler's diarrhea.</li> <li>• 510 Conduct animal studies to determine safety and immunogenicity of combined enteric (Campylobacter, Shigella and ETEC) vaccine formulations.</li> <li>• 181 Evaluate the nucleic acid analysis system platform to confirm broad application to multiple agents and sample sources. Integrate the reporting system into the nucleic acid system platform.</li> <li>• 621 Transition to advanced development a candidate polyvalent dengue virus vaccine with potential to protect 80 percent of immunized personnel from dengue fever caused by dengue virus types 1, 2, 3, and 4.</li> <li>• 351 Provide strategy for countering all viral hepatitis threats worldwide.</li> <li>• 54 Transition to advanced development a monovalent group B Meningococcal vaccine with the potential of reducing disease by over 70 percent in immunized personnel. Conduct Phase 1 studies of multivalent vaccine candidates for prevention of bacterial meningitis due to group B <i>Neisseria meningitidis</i>.</li> <li>• 250 Transition to advanced development insect repellent to replace DEET.</li> </ul> <p>Total 8096</p>		
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BUDGET ACTIVITY 3 - Advanced Technology Development				PE NUMBER AND TITLE 0603002A Medical Advanced Technology					PROJECT D815	
COST (In Thousands)	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
D815 National Medical Testbed	7495	7947	0	0	0	0	0	0	0	15442
<p><b>Mission Description and Justification:</b> By Congressional direction, the purpose of this project is to develop initial research models for national medical testbed which display measurable improvements in cost and effectiveness in many areas of health care delivery.</p> <p><b>FY 1998 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>• 7495 Awarded contract to Loma Linda Medical Center - National Medical Testbed.</li> </ul> <p>Total 7495</p> <p><b>FY 1999 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 7736 Support studies that will benefit civilian and military personnel with diagnostic and therapeutic modalities. Fields of interest include management of trauma and shock; chronic disorders; prevention of premature delivery and brain injury at birth; modalities that may improve the rate of tissue and bone healing as well as the regulation of growth, healing, and bone restructuring; prevention of hypoxic brain injury at birth and brain injury; and development and testing of new medical instrumentation.</li> <li>• 211 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs</li> </ul> <p>Total 7947</p> <p><b>FY 2000 Planned Program:</b> Project not funded in FY 2000.</p> <p><b>FY 2001 Planned Program:</b> Project not funded in FY 2001.</p>										
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<b>BUDGET ACTIVITY</b> <b>3 - Advanced Technology Development</b>	<b>PE NUMBER AND TITLE</b> <b>0603002A Medical Advanced Technology</b>	<b>PROJECT</b> <b>D818</b>
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COST ( <i>In Thousands</i> )	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
D818 Advanced Cancer Detection Center	3270	0	0	0	0	0	0	0	0	3270

**Mission Description and Justification:** By Congressional direction, the purpose of this project is to develop research models for an advanced cancer detection center for military personnel, dependents, and retired servicemembers, using a network including a military hospital or hospitals, a regional TRICARE provider, a Department of Veteran Affairs hospital or hospitals, and a medical facility with a focused cancer center, in order to conduct coordinated screening for early detection and treatment to train military cancer specialists, and to develop improved cancer detection equipment and technology.

**FY 1998 Accomplishments:**

- 3270 Army assumed management of the ongoing Navy research program, including evaluation of the project, and provision of supplemental funding to the University of South Florida Advanced Cancer Detection Center.
- Total 3270

**FY 1999 Planned Program:** Project not funded under this PE in FY 1999.

**FY 2000 Planned Program:** Project not funded in FY 2000.

**FY 2001 Planned Program:** Project not funded in FY 2001.

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ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)								DATE February 1999		
BUDGET ACTIVITY 3 - Advanced Technology Development				PE NUMBER AND TITLE 0603002A Medical Advanced Technology				PROJECT D819		
COST (In Thousands)	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
D819 Field Medical Protection and Human Performance Enhancement Non-Systems - Advanced Development	0	0	200	194	557	576	618	647	Continuing	Continuing
<p><b>Mission Description and Justification:</b> This project supports laboratory validation studies and field demonstrations focused on soldier protection, sustainment, and enhancement associated with soldiers operating, wearing, and consuming materiel systems in all climatic and operational conditions. Specific support includes medical development of laser eye protection technologies and laser bioeffects treatment, environmental health monitoring methods to link soldier physiological status with climatic and environmental conditions, methods to enhance sleep and alertness during continuous/sustained operational scenarios, nutritional strategies to enhance soldier mental and physiological performance, and medical protection from vibration and repeated shock hazards arising from the operation of combat vehicle and aircraft systems and rapid test kits for toxic industrial and agricultural chemicals.</p> <p><b>FY 1998 Accomplishments:</b> Project not funded in FY 1998.</p> <p><b>FY 1999 Planned Program:</b> Project not funded in FY 1999.</p> <p><b>FY 2000 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 200 Develop a rapid detection system for toxic industrial and agricultural chemicals that present acute neurotoxic risks (mediated through oxidant stress mechanisms) to deployed soldiers.</li> </ul> <p>Total 200</p> <p><b>FY 2001 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 194 Continue development of rapid detection system.</li> </ul> <p>Total 194</p>										
Project D819			Page 16 of 33 Pages				Exhibit R-2A (PE 0603002A)			

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BUDGET ACTIVITY <b>3 - Advanced Technology Development</b>	PE NUMBER AND TITLE <b>0603002A Medical Advanced Technology</b>	PROJECT <b>D840</b>
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COST ( <i>In Thousands</i> )	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
D840 Combat Injury Management	3252	2450	2407	2435	2662	5234	6122	6562	Continuing	Continuing

**Mission Description and Justification:** This project funds prototypes of nonsystem-specific medical materiel items for far-forward medical management of shock and trauma and for casualty resuscitation including preclinical testing of large standard lots of candidate compounds and equipment to obtain data necessary for Food and Drug Administration (FDA) approval for human use. A major contractor is the University of North Carolina, Chapel Hill, NC.

**FY 1998 Accomplishments:**

- 512 Transitioned Advanced Surgical Suite for Trauma Casualties (ASSTC) to advanced development.
  - 300 Developed breadboard prototype for all-electric dental field operating system.
  - 185 Completed laboratory validation of far-forward version of a microwave resuscitation fluid warmer.
  - 277 Tested landmine protective footwear in cadaver models.
  - 254 Established models for studies into blood loss and resuscitation.
  - 250 Tested receptor activating/blocking compounds in animal models to assess neuroprotective efficacy.
  - 400 Conducted preclinical studies to evaluate fibrin-based hemostatic bandage formulation for hemorrhage.
  - 202 Began to assess efficacy of fibrin foam as hemostatic agent in preclinical models of organ trauma.
  - 200 Began clinical testing of a frozen red blood cell washer.
  - 300 Began clinical testing of a 10-week red blood cell storage solution.
  - 172 Completed development of a digital dental radiographic imager to remove requirements for field film and film development equipment.
  - 200 Submitted Critical Care System for Trauma and Transport (CSTAT) for airworthiness certification.
- Total 3252

**FY 1999 Planned Program:**

- 50 Continue tests of microwave warming catheter in treating hypothermia.
- 225 Explore diagnostic imaging technologies for use in far-forward environments.
- 266 Evaluate treatments for wound repair (e.g., freeze-dried allografts, skin preparations).
- 100 Refine field-deployable all-electric dental operating system.
- 200 Perform research into infectious organisms' role in periodontal disease and other dental infections.
- 600 Continue testing neuroprotective drugs in animal models to assess efficacy.
- 300 Continue clinical testing of 10-week red blood cell storage solution to assess safety and efficacy.
- 100 Complete clinical testing of frozen red blood cell washer.

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BUDGET ACTIVITY <b>3 - Advanced Technology Development</b>	PE NUMBER AND TITLE <b>0603002A Medical Advanced Technology</b>	PROJECT <b>D840</b>
<b>FY 1999 Planned Program: (continued)</b>		
•	200 Evaluate formulations for extended liquid storage of platelets to enhance availability in far-forward locations.	
•	350 Continue evaluation of fibrin foam in preclinical models of organ trauma.	
•	59 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs	
Total	2450	
<b>FY 2000 Planned Program:</b>		
•	50 Complete tests of microwave warming catheter to treat hypothermia.	
•	200 Continue to explore diagnostic imaging technologies for use in far-forward environments.	
•	300 Continue to evaluate treatments for wound repair (e.g., freeze-dried allografts, skin preparations).	
•	100 Complete development of a field-deployable all-electric dental operating system.	
•	200 Investigate microencapsulated anti-inflammatory pulp-capping agents to enhance return to duty in far-forward locations.	
•	600 Continue testing neuroprotective drugs in animal models to assess efficacy.	
•	300 Complete clinical testing of 10-week red blood cell storage solution.	
•	400 Continue evaluation of fibrin foam in preclinical models of organ trauma.	
•	257 Test lead formulation for extended liquid storage of platelets in appropriate animal model.	
Total	2407	
<b>FY 2001 Planned Program:</b>		
•	500 Test commercial off-the-shelf oxygen carrier solutions in austere environments to assess suitability for military use.	
•	300 Develop advanced field dressing incorporating ease of use, air tight seal, and advanced materials.	
•	800 Develop and test miniaturized field oxygen concentrators to replace bottled oxygen.	
•	200 Transition 10-week red blood cell storage solution to advanced development.	
•	235 Transition fibrin foam to Phase 1 clinical trials.	
•	200 Begin preclinical trials of antisense DNA as a therapy against excess mucus secretion after smoke inhalation.	
•	200 Transition formulation for extended liquid storage of platelets to advanced development.	
Total	2435	

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ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)								DATE February 1999		
BUDGET ACTIVITY 3 - Advanced Technology Development				PE NUMBER AND TITLE 0603002A Medical Advanced Technology				PROJECT D922		
COST (In Thousands)	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
D922 Emergency Telemedicine	2343	0	0	0	0	0	0	0	0	2343
<p><b>Mission Description and Justification:</b> By Congressional direction, this program supports efforts to develop, facilitate, and improve the application of telemedicine technologies. This program develops engineering applications specific to emergency medicine including trauma, medical imaging, lab outreach and patient tracking.</p> <p><b>FY 1998 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>2343 Contracted with Mercy Health Care System to provide research related to diagnosis and treatment-based interventions through the application of telemedical and telecommunication-based technologies in order to improve medical outcomes. Findings from this research project will address accuracy of diagnosis; rapid initiation of treatment; and assist emergency medical specialists and rescue teams to more effectively address the needs of patients who are located in remote locations.</li> </ul> <p>Total 2343</p> <p><b>FY 1999 Planned Program:</b> Project not funded in FY 1999.</p> <p><b>FY 2000 Planned Program:</b> Project not funded in FY 2000.</p> <p><b>FY 2001 Planned Program:</b> Project not funded in FY 2001.</p>										
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BUDGET ACTIVITY <b>3 - Advanced Technology Development</b>					PE NUMBER AND TITLE <b>0603002A Medical Advanced Technology</b>				PROJECT <b>D923</b>	
COST <i>(In Thousands)</i>	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
D923 Prostate Diagnostic Imaging	4683	7450	0	0	0	0	0	0	0	12133
<p><b>Mission Description and Justification:</b> By Congressional direction, the purpose of this project is to develop initial research models for prostate cancer research to include studying prostate cancer diagnosis and treatment. The Army established a public/private research project with appropriate government agencies and private institutions to explore promising technologies for improvement of prostate diagnostic imaging and treatment technology.</p> <p><b>FY 1998 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>• 4683 Awarded contract to the Henry Jackson Foundation (which will co-manage this effort with Walter Reed Medical Center). Efforts will include developing an advanced electronic, thin-film x-ray imaging technology for improved diagnostic location of prostate cancer using implanted radio opaque seeds, and advance the application of an ultrasound scanning system used in the Transrectal sensor system. Improvements will be retrofitted to prototype I for early evaluation. Such enhancements in the Transrectal sensor system will be included in Prototype II as appropriate.</li> </ul> <p>Total 4683</p> <p><b>FY 1999 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 7253 Continue intramural research effort conducted by the Walter Reed Center for Prostate Disease Research in the area of prostate cancer detection and treatment.</li> <li>• 197 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs</li> </ul> <p>Total 7450</p> <p><b>FY 2000 Planned Program:</b> Project not funded in FY 2000.</p> <p><b>FY 2001 Planned Program:</b> Project not funded in FY 2001.</p>										
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BUDGET ACTIVITY <b>3 - Advanced Technology Development</b>				PE NUMBER AND TITLE <b>0603002A Medical Advanced Technology</b>				PROJECT <b>D924</b>		
COST <i>(In Thousands)</i>	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
D924 Advanced Trauma Care	2810	0	0	0	0	0	0	0	0	2810
<p><b><u>Mission Description and Justification:</u></b> By Congressional direction, this program funds the development of technology to promote real-time medical situational awareness through medical mentoring and consultation.</p> <p><b>FY 1998 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>• 2810 Awarded contract to Illinois Institute of Technology Research Institute (IITRI). Efforts will include: Research in telecommunications, medical informatics, and analog-to-digital conversion technologies for support of advanced trauma care. Support Department of Defense government-wide strategy to implement emergency medical response via a national telemedicine network.</li> </ul> <p>Total 2810</p> <p><b>FY 1999 Planned Program:</b> Project not funded in FY 1999.</p> <p><b>FY 2000 Planned Program:</b> Project not funded in FY 2000.</p> <p><b>FY 2001 Planned Program:</b> Project not funded in FY 2001.</p>										

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<i>COST (In Thousands)</i>	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
D929 Artificial Lung Technology	1405	845	0	0	0	0	0	0	0	2250
<p><b>Mission Description and Justification:</b> By Congressional direction, the purpose of this program is to develop an intravenous membrane-based oxygenator to enable oxygen delivery to patients with pulmonary insufficiency.</p> <p><b>FY 1998 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>• 1405 Solicited and evaluated proposals and made an award.</li> </ul> <p>Total 1405</p> <p><b>FY 1999 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 823 Complete initial acute and long-term (21 days) testing of intravenous membrane oxygenator patency and function in an animal model of pulmonary insufficiency.</li> <li>• 22 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs</li> </ul> <p>Total 845</p> <p><b>FY 2000 Planned Program:</b> Project not funded in FY 2000.</p> <p><b>FY 2001 Planned Program:</b> Project not funded in FY 2001.</p>										
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BUDGET ACTIVITY <b>3 - Advanced Technology Development</b>	PE NUMBER AND TITLE <b>0603002A Medical Advanced Technology</b>	PROJECT <b>D930</b>
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COST <i>(In Thousands)</i>	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
D930 Cooperative Teleradiology	2810	0	0	0	0	0	0	0	0	2810

**Mission Description and Justification:** By Congressional direction, this program funds the development of experimental technologies that will allow medical imaging to be deployed in remote and far-forward locations. Additionally, this program funds the research for the development of imaging networks that can deliver medical studies for interpretation.

**FY 1998 Accomplishments:**

- 2810 Awarded contract to University of South Florida (USF). This is a cooperative research effort between the Uniformed Services University of the Health Sciences (USUHS) and the USF.
- Total 2810

**FY 1999 Planned Program:** Project not funded in FY 1999.

**FY 2000 Planned Program:** Project not funded in FY 2000.

**FY 2001 Planned Program:** Project not funded in FY 2001.

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<b>ARMY RDT&amp;E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)</b>								DATE <b>February 1999</b>		
BUDGET ACTIVITY <b>3 - Advanced Technology Development</b>					PE NUMBER AND TITLE <b>0603002A Medical Advanced Technology</b>				PROJECT <b>D932</b>	
COST <i>(In Thousands)</i>	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
D932 Periscopic Minimally Invasive Surgery	16000	0	0	0	0	0	0	0	0	16000
<p><b><u>Mission Description and Justification:</u></b> By Congressional direction, this project funds research and development in minimally invasive back and spine surgery methods, protocol, and technologies to improve processes and outcomes.</p> <p><b>FY 1998 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>• 3000 Contract awarded to Georgetown Medical Center as a cooperative agreement to conduct research and development in Periscopic Minimally Invasive Surgery to improve protocols and outcomes of back/spine surgery.</li> <li>• 13000 Developed a program at Massachusettes General Hospital/Harvard University that will conduct collaborative research between industry, medical research institutions and DOD health care and research organizations to develop and evaluate new techniques utilizing non-invasinve and minimally invasive diagnostic and surgical techniques</li> </ul> <p>Total 16000</p> <p><b>FY 1999 Planned Program:</b> Project not funded in FY 1999.</p> <p><b>FY 2000 Planned Program:</b> Project not funded in FY 2000.</p> <p><b>FY 2001 Planned Program:</b> Project not funded in FY 2001.</p>										
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BUDGET ACTIVITY <b>3 - Advanced Technology Development</b>					PE NUMBER AND TITLE <b>0603002A Medical Advanced Technology</b>				PROJECT <b>D933</b>	
COST <i>(In Thousands)</i>	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
D933 Proton Beam Therapy	4000	0	0	0	0	0	0	0	0	4000
<p><b>Mission Description and Justification:</b> By Congressional direction, this project funds proton radiation therapy technology. Proton radiation therapy improves physicians' ability to treat cancer and some benign disorders with radiation; it responds to the need for improved control of beam delivery, enabling physicians to increase the likelihood of disease control while reducing treatment side effects.</p> <p><b>FY 1998 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>• 4000 Received research proposal. Contract awarded to Loma Linda to conduct research and development in proton radiation therapy, and the need for improved control of beam delivery.</li> </ul> <p>Total 4000</p> <p><b>FY 1999 Planned Program:</b> Project not funded in FY 1999.</p> <p><b>FY 2000 Planned Program:</b> Project not funded in FY 2000.</p> <p><b>FY 2001 Planned Program:</b> Project not funded in FY 2001.</p>										
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BUDGET ACTIVITY <b>3 - Advanced Technology Development</b>				PE NUMBER AND TITLE <b>0603002A Medical Advanced Technology</b>				PROJECT <b>D934</b>		
COST (In Thousands)	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
D934 Volume Angiocat	3747	3974	0	0	0	0	0	0	0	7721
<p><b>Mission Description and Justification:</b> By Congressional direction, this project will fund development of a multimodality platform integrated into a single device that will perform many aspects of diagnostic studies.</p> <p><b>FY 1998 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>• 3747 Awarded contract to MultiDimensional Imaging (MDI), Inc.</li> </ul> <p>Total 3747</p> <p><b>FY 1999 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 850 Develop sequential rapid slice or high speed computer tomography (HSCT) scanning to provide true real-time and true volume 4D imaging.</li> <li>• 750 Develop state-of-the-art CT spatial resolution, superior tissue contrast resolution, and improved signal-to-noise ratio with a photon flux rate 10X that of electron beam computer tomography (EBCT) or HSCT.</li> <li>• 650 Provide markedly superior temporal resolution with routine exposure times of 50-100 ms compared to about 1 sec in current state-of-the-art HSCT A.</li> <li>• 619 Create a single rapid diagnostic examination that will replace 2-4 examinations that are currently being performed.</li> <li>• 500 Integrate stereo fluorography and high resolution digital radiography into the 3D/4D volume imaging for combined digital angiography, mammography, or 3D fluoroscopic guidance of instrumentation.</li> <li>• 500 Allow for routine body scanning at 1.0-3.0 mm slice thickness interpolated down to 0.1mm and will scan at speeds over 100X the current EBCT or 400X that of spiral scanning technologies, in a given volume.</li> <li>• 105 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs</li> </ul> <p>Total 3974</p> <p><b>FY 2000 Planned Program:</b> Project not funded in FY 2000.</p> <p><b>FY 2001 Planned Program:</b> Project not funded in FY 2001.</p>										
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BUDGET ACTIVITY <b>3 - Advanced Technology Development</b>				PE NUMBER AND TITLE <b>0603002A Medical Advanced Technology</b>				PROJECT <b>D937</b>		
COST <i>(In Thousands)</i>	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
D937 Nervous System Studies	4468	0	0	0	0	0	0	0	0	4468
<p><b><u>Mission Description and Justification:</u></b> By Congressional direction, the purpose of this effort is to support continuing research programs related to the mechanisms and treatment of central nervous system injury (brain trauma, spinal cord injury, and/or stroke) and related cognitive dysfunction.</p> <p><b>FY 1998 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>• 4468 Received research proposal. Scientifically review full proposal; award contract (to be accomplished in FY1999).</li> </ul> <p>Total 4468</p> <p><b>FY 1999 Planned Program:</b> Project not funded in FY 1999.</p> <p><b>FY 2000 Planned Program:</b> Project not funded in FY 2000.</p> <p><b>FY 2001 Planned Program:</b> Project not funded in FY 2001.</p>										
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BUDGET ACTIVITY <b>3 - Advanced Technology Development</b>					PE NUMBER AND TITLE <b>0603002A Medical Advanced Technology</b>				PROJECT <b>D938</b>	
COST <i>(In Thousands)</i>	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
D938 Tissue Engineering	3500	0	0	0	0	0	0	0	0	3500
<p><b><u>Mission Description and Justification:</u></b> By Congressional direction, this project supports the development of tissue substitutes using biologic molecules deposited with a laser fusion technique. These tissues and methods lend themselves to far forward use on the battlefield and will serve to reduce the mortality and disability of severe trauma.</p> <p><b>FY 1998 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>• 3500 Phase 3 proposal received and reviewed. Contract award to be completed in FY1999.</li> </ul> <p>Total 3500</p> <p><b>FY 1999 Planned Program:</b> Project not funded in FY 1999.</p> <p><b>FY 2000 Planned Program:</b> Project not funded in FY 2000.</p> <p><b>FY 2001 Planned Program:</b> Project not funded in FY 2001.</p>										
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BUDGET ACTIVITY <b>3 - Advanced Technology Development</b>					PE NUMBER AND TITLE <b>0603002A Medical Advanced Technology</b>				PROJECT <b>D939</b>	
COST <i>(In Thousands)</i>	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
D939 Medical Imaging	3500	0	0	0	0	0	0	0	0	3500
<p><b><u>Mission Description and Justification:</u></b> By Congressional direction, the purpose of this project is to conduct research and development efforts in three-dimensional medical imaging (e.g., ultrasound).</p> <p><b>FY 1998 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>• 3500 Contracted with Cleveland Clinic to perform research and development in medical imaging.</li> </ul> <p>Total 3500</p> <p><b>FY 1999 Planned Program:</b> Project not funded in FY 1999.</p> <p><b>FY 2000 Planned Program:</b> Project not funded in FY 2000.</p> <p><b>FY 2001 Planned Program:</b> Project not funded in FY 2001.</p>										
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BUDGET ACTIVITY <b>3 - Advanced Technology Development</b>					PE NUMBER AND TITLE <b>0603002A Medical Advanced Technology</b>				PROJECT <b>D940</b>	
COST <i>(In Thousands)</i>	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
D940 Epidermolysis Bullosa	1000	0	0	0	0	0	0	0	0	1000
<p><b><u>Mission Description and Justification:</u></b> By Congressional direction, the purpose of this project is to investigate the pathophysiological similarities of sulfur mustard (SM) injuries to the naturally occurring disease Epidermolysis Bullosa (EB).</p> <p><b>FY 1998 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>• 1000 Received research proposals. (Award contract in FY1999.)</li> </ul> <p>Total 1000</p> <p><b>FY 1999 Planned Program:</b> Project not funded in FY 1999.</p> <p><b>FY 2000 Planned Program:</b> Project not funded in FY 2000.</p> <p><b>FY 2001 Planned Program:</b> Project not funded in FY 2001.</p>										
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BUDGET ACTIVITY <b>3 - Advanced Technology Development</b>				PE NUMBER AND TITLE <b>0603002A Medical Advanced Technology</b>					PROJECT <b>D941</b>	
COST <i>(In Thousands)</i>	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
D941 Diabetes Research	4000	4470	0	0	0	0	0	0	0	8470
<p><b><u>Mission Description and Justification:</u></b> By Congressional direction, the purpose of this project is to conduct diabetes research.</p> <p><b>FY 1998 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>• 2859 Contract awarded to Joslin Diabetes Center for research in improving methods of detection, prevention, and diagnosis of diabetes.</li> <li>• 570 Contract awarded to the Department of Veterans Affairs to assist in research in improving methods of detection, prevention, and diagnosis of diabetes.</li> <li>• 571 Contract awarded to Tripler Army Medical Center to assist in research in improving methods of detection, prevention, and diagnosis of diabetes.</li> </ul> <p>Total 4000</p> <p><b>FY 1999 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 3900 Continue FY 1998 program (digital capture of retinal images to detect, prevent, and diagnose Type II diabetes).</li> <li>• 451 Begin implementation of Phase 2 of program.</li> <li>• 119 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs</li> </ul> <p>Total 4470</p> <p><b>FY 2000 Planned Program:</b> Project not funded in FY 2000.</p> <p><b>FY 2001 Planned Program:</b> Project not funded in FY 2001.</p>										
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BUDGET ACTIVITY 3 - Advanced Technology Development				PE NUMBER AND TITLE 0603002A Medical Advanced Technology					PROJECT D954	
COST (In Thousands)	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
D954 Digital X-Ray	0	3973	0	0	0	0	0	0	0	3973
<p><b>Mission Description and Justification:</b> By Congressional direction, this program funds development of a prototype portable digital x-ray for field and fixed facility applications.</p> <p><b>FY 1998 Accomplishments:</b> Project not funded in FY 1998.</p> <p><b>FY 1999 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 3868 Develop, at the General Electric Center for Research and Development, prototype portable digital x-ray for field and fixed facility applications.</li> <li>• 105 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs</li> </ul> <p>Total 3973</p> <p><b>FY 2000 Planned Program:</b> Project not funded in FY 2000.</p> <p><b>FY 2001 Planned Program:</b> Project not funded in FY 2001.</p>										
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BUDGET ACTIVITY 3 - Advanced Technology Development				PE NUMBER AND TITLE 0603002A Medical Advanced Technology				PROJECT D955		
COST (In Thousands)	FY 1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	Cost to Complete	Total Cost
D955 Assistive Technology	0	5960	0	0	0	0	0	0	0	5960
<p><b>Mission Description and Justification:</b> By Congressional direction, this program funds the research, development, and evaluation of technologies (initially developed for military and space purposes) that can be used to improve the lives of Americans with disabilities.</p> <p><b>FY 1998 Accomplishments:</b> Project not funded in FY 1998.</p> <p><b>FY 1999 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 5802 Research, develop, and evaluate, at the National Rehabilitation Hospital Assistive Technology Center, technologies initially developed for military and space purposes that can be used to improve the lives of Americans with disabilities.</li> <li>• 158 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs</li> </ul> <p>Total 5960</p> <p><b>FY 2000 Planned Program:</b> Project not funded in FY 2000.</p> <p><b>FY 2001 Planned Program:</b> Project not funded in FY 2001.</p>										
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