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Exhibit R-2, RDT&E Budget Item Justification: PB 2014 Defense Health Program **DATE:** March 2013

APPROPRIATION/BUDGET ACTIVITY					R-1 ITEM NOMENCLATURE							
0130: <i>Defense Health Program</i> BA 2: <i>RDT&E</i>					PE 0604110HP: <i>Medical Products Support and Advanced Concept Development</i>							
COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 [#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
Total Program Element	-	191.536	144.403	132.430	-	132.430	146.610	116.973	133.255	139.115	Continuing	Continuing
374A: <i>GDF-Medical Products Support and Advanced Concept Development</i>	-	159.890	144.403	132.430	-	132.430	146.610	116.973	133.255	139.115	Continuing	Continuing
400Z: <i>CSI - Congressional Special Interests</i>	-	27.750	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
434A: <i>AF-Medical Products Support and Advanced Concept Development</i>	-	3.896	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

[#] FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

^{##} The FY 2014 OCO Request will be submitted at a later date

A. Mission Description and Budget Item Justification

Guidance for Development of the Force (GDF) - Medical Products Support And Advanced Concept Development: funding is for product support and advanced concept development of medical products that are regulated by the US Food and Drug Administration (FDA); the accelerated transition of FDA-licensed and unregulated products and medical practice guidelines to the military operational user, through clinical and field validation studies; prototyping, risk reduction and product transition efforts for medical information technology applications; and medical training systems' technologies.

The resulting advanced development portfolio is designed to address the following: areas of interest to the Secretary of Defense regarding Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System and the strategy and initiatives described in the Quadrennial Defense Review. Program development and execution is peer-reviewed and fully coordinated with all of the Military Services, appropriate Defense Agencies or Activities and other federal agencies, to include the Department of Veterans Affairs, the Department of Health and Human Services, and the Department of Homeland Security. This coordination occurs through the planning and execution activities of the Joint Program Committees, established for the Defense Health Program Research, Development, Test and Evaluation funding. Research supported by this program element includes accelerated transition of medical training and health information sciences, to include efforts at the Pacific Based Joint Information Technology Center, advanced development of rapid pathogen detection in fresh whole blood, field assessment of intervention tools for post traumatic stress disorder (PTSD), and clinical trials on biomarkers for traumatic brain injury (TBI) and spinal cord injury, combat casualty care advanced product development and rehabilitative medicine clinical trials.

The Army Medical Command received DHP Congressional Special Interest (CSI) research funding focused on Peer-Reviewed Traumatic Brain Injury and Psychological Health Research, and Peer-Reviewed Joint Warfighter Medical Research. Because of the CSI annual structure, out-year funding is not programmed.

PE 0604110HP: *Medical Products Support and Advanced Concept Deve...*
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APPROPRIATION/BUDGET ACTIVITY 0130: <i>Defense Health Program</i> BA 2: <i>RDT&E</i>	R-1 ITEM NOMENCLATURE PE 0604110HP: <i>Medical Products Support and Advanced Concept Development</i>
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B. Program Change Summary (\$ in Millions)	FY 2012	FY 2013	FY 2014 Base	FY 2014 OCO	FY 2014 Total
Previous President's Budget	189.844	144.403	132.430	-	132.430
Current President's Budget	191.536	144.403	132.430	-	132.430
Total Adjustments	1.692	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-2.308	-			
• Reprogramming - Rapid Product Integration and Transition (AF)	4.000	-	-	-	-

Congressional Add Details (\$ in Millions, and Includes General Reductions)

Project: 400Z: *CSI - Congressional Special Interests*

Congressional Add: 427A - *Traumatic Brain Injury/ Psychological Health*

Congressional Add: 441A - *Joint Warfighter Medical Research Program*

Congressional Add Subtotals for Project: 400Z

Congressional Add Totals for all Projects

FY 2012	FY 2013
17.750	-
10.000	-
27.750	0.000
27.750	0.000

Change Summary Explanation

FY 2012: Restore FY 2013 President's Budget decrease to Congressional Special Interest from DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) Program (-\$0.694 million) to DHP RDT&E, PE 0604110- Medical Products Support and Advanced Concept Development (+\$0.694 million).

Realignment from DHP RDT&E, PE 0604110-Medical Products Support and Advanced Concept Development (-\$3.002 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) Program (+\$3.002 million).

Prior Approval Reprogramming (FY 12-18 PA) from DHP O&M, Budget Activity Group: Private Sector Care (-\$4.000 million) to DHP RDT&E, PE 0604110-Medical Products Support and Advanced Concept Development (+\$4.000 million) for Rapid Product Integration and Transition (AF).

FY 2013: No Change

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Defense Health Program										DATE: March 2013		
APPROPRIATION/BUDGET ACTIVITY 0130: Defense Health Program BA 2: RDT&E					R-1 ITEM NOMENCLATURE PE 0604110HP: Medical Products Support and Advanced Concept Development				PROJECT 374A: GDF-Medical Products Support and Advanced Concept Development			
COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 [#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
374A: GDF-Medical Products Support and Advanced Concept Development	-	159.890	144.403	132.430	-	132.430	146.610	116.973	133.255	139.115	Continuing	Continuing
[#] FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012												
^{##} The FY 2014 OCO Request will be submitted at a later date												
A. Mission Description and Budget Item Justification												
Guidance for Development of the Force (GDF)-Medical Products Support and Advanced Concept Development: Advanced development efforts are intended to support clinical trials of promising technologies that may provide solutions for the most pressing medical needs of the Warfighter, acceleration of the transition of those technologies to the operators in the field, and promulgation of new, evidence-based approaches to the practice of medicine as clinical practice guidelines. Research will be conducted in four specific areas: trials for accelerated transition of modeling and simulation technology for medical training/education/treatment; trials for accelerated transition of medical technology, practice guidelines, and standards; advanced component development of medical products; and medical information technology development. Within the research areas of health informatics, research efforts will include force health protection and readiness, medical resourcing, healthcare services, and enterprise information management. Future efforts will provide long term efficiencies by defining processes to grow and improve the electronic healthcare record and other medical related systems, and to implement new trends and advancements in technology. The efforts will help improve healthcare access, availability, continuity, cost effectiveness, and quality. Initial candidates will be selected from those funded by other medical research sponsors in the Department, and from external sources such as academia and industry, including efforts funded with prior year Congressional special interest funding. Research supported by this program element includes medical simulation and training, health informatics, advanced development of rapid pathogen detection in fresh whole blood, field assessment of intervention tools for PTSD, and clinical trials on biomarkers for TBI and spinal cord injury, combat casualty care advanced product development and rehabilitative medicine clinical trials.												
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2012	FY 2013	FY 2014	
Title: GDF – Medical Product Support and Advanced Concept Development									159.890	144.403	132.430	
Description: Product support and advanced concept development of medical products that are regulated by the US Food and Drug Administration (FDA); the accelerated transition of FDA-licensed and unregulated products and medical practice guidelines to the military operational user, through clinical and field validation studies; prototyping, risk reduction and product transition efforts for medical information technology applications; and medical training systems' technologies.												
FY 2012 Accomplishments: Medical training and health information sciences (MTHIS) research has identified multiple prototypes and strategic project areas that support force health protection & readiness, medical resourcing, healthcare services, and enterprise infrastructure management. Defined processes to develop and integrate capabilities into the Defense Medical Research and Development												

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APPROPRIATION/BUDGET ACTIVITY 0130: <i>Defense Health Program</i> BA 2: <i>RDT&E</i>	R-1 ITEM NOMENCLATURE PE 0604110HP: <i>Medical Products Support and Advanced Concept Development</i>	PROJECT 374A: <i>GDF-Medical Products Support and Advanced Concept Development</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013
Program through projects to improve healthcare access, availability, continuity, cost-effectiveness, and quality. MTHIS has supported efforts to study military healthcare provider skill degradation following prolonged absence from their usual specialty practice (i.e., deployment) with the goal to reestablish provider specialty skills as soon as possible. Research in cross-functional areas such as open source physiology research platforms and virtual characters are underway through the Developer Tools for Medical Education Initiative. These efforts enable simulation technologies to be used by a much broader group and promote simulation training technology. Preliminary results from the Combat Casualty Training Consortium are beginning to identify gaps in the comparative research between using live-tissue versus simulation system training. The Medical Practice Initiative is researching technology based training flow processes to improve curricula and identify common training metrics for all services. Effective in FY12, the Pacific Joint Information Technology Center (JITC) is managed by the MTHIS program. FY12 accomplishments include continuing the following programs/projects: MSAT, Web-based Equipment Resources and Training, Theater Blood Management and Integration (3 phase project), Standardization of Legacy MHS platforms to the new EHR architecture, Pacific JITC Innovation Center Services and the new National Integrated Catastrophic Health Event Preparedness and Response prototype. High priority, critical Warfighter requirements were processed through the validation and prioritization committees (Theater Functional Work Group and Force Health Protection Council) in order to continually gather and re-evaluate the priority assigned to potential projects. The military infectious diseases research focused on the development of FDA-approved clinical assays for pathogen detection in the area of rapid screening of fresh whole blood. The product will be a multiplexed test device for the detection of antibody to Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV) and Hepatitis B Virus (HBV) Core Antigen (Anti-HBc total) and Hepatitis B Surface Antigen(HBsAg), which meets the requirement for FDA-cleared tests for prescreening deployed military forces for Transfusion Transmitted Diseases (TTDs) in emergency blood collection operations (no currently FDA-licensed tests available). The Materiel Development Decision was approved in the first quarter of FY12, and a Milestone B (a formal acquisition designation) is anticipated in FY13-FY14. Military operational medicine efforts initiated clinical trials for data analyses of a telephone training and intervention tool for PTSD; women's post-deployment intervention designed to address family re-integration coping skills; optimum interventions to mitigate or control the effects of PTSD; conduct field assessments of the long-term effects of non-pharmacological therapy for the treatment of PTSD; and bio-feedback therapy for the treatment of heart-rate variability as an intervention for PTSD. Also initiated was an integration of physiologic status monitoring capability into Spartan Sensor Network (SPARNET) system to demonstrate 2-way voice messaging capabilities that allows for constant monitoring of the physiological status of Soldiers across the spectrum of field operations. Clinical trials were initiated to determine if an antioxidant can protect against noise-induced hearing loss during weapons training; study the neurobiological mechanism (genetics, brain function) of PTSD in Operation Enduring Freedom/			

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013
Military operational medicine efforts are determining a time-course for antioxidant delivery after steady-state noise or impulse-noise to provide Warfighters with the best method to prevent hearing loss. Efforts are enhancing medical monitoring and alerting capabilities of the Spartan Sensor Network (SPARNET) system; continuing clinical trials for improved pharmacotherapy for deployment-related PTSD, evaluating the efficacy of prolonged exposure therapy plus sertraline or hydrocortisone (antidepressants) for OEF/OIF veterans with PTSD, conducting focus groups to evaluate an online mental health assessment tool, and evaluating factors that may mediate or moderate responses to brief interventions to reduce alcohol use and associated problems. Combat casualty care is continuing development efforts initiated in FY11 and FY12 to include further development of spray-dried plasma, smooth-pursuit eye tracking to diagnose concussions, a system that kills infectious organisms in whole blood, studies using infrared goggles in the treatment of severe trauma, clinical trials on the pre-hospital use of plasma, and a clinical trial for a drug to treat concussions. Clinical and rehabilitative medicine is advancing the clinical studies initiated in FY12 in the area of pain management, regenerative medicine, and sensory system restoration and rehabilitation after traumatic injury. Additional studies are beginning in FY13 for the areas of regenerative medicine and sensory system restoration and rehabilitation after traumatic injury to support the development and clinical evaluation of restoration and rehabilitation strategies and medical products. Specific focus areas include: regenerative medicine-based approaches for limb and digit salvage, craniomaxillofacial (skull, face and jaw) reconstruction, scarless wound healing, burn repair, genitourinary restoration and addressing compartment syndrome (muscle, nerve and vascular damage due to swelling post-injury), and restoration and rehabilitation of sensory system injury, including vision, hearing and balance injury and dysfunction. FY 2014 Plans: Medical Training and Health Information Sciences (MTHIS) will further its research in the Medical Simulation and Training portfolio through continued emphasis on the modular manikin core technology as well as anticipated release of a solicitation for low, mid, and high fidelity peripherals that connect with and communicate to the core manikin system. Anticipate a research announcement for methods to promote pre-deployment psychological resilience training. Efforts are planned to increase the presence of virtual standardized patients (avatars) into a National collaboration to accelerate research, development, validation, and verification of this promising technology. MTHIS's Health Informatics & Information Technology, in coordination with Pacific JITC, will conduct research on risk reduction within the Military Health System and identify IT needs of the Warfighter. MTHIS will identify ways to reduce potential near- and long-term risk of IT technology development and legacy systems, as well as the transition to the joint Department of Veterans Affairs and Department of Defense integrated Electronic Health Record.			

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2012	FY 2013	FY 2014
Military infectious diseases efforts will continue in the areas of Diagnostic Systems for Infectious Diseases to support field testing of diagnostic capabilities and systems across operational echelons (a request for proposal will be executed in FY14 to support the requirement, and continue multi-year efforts for the development of FDA-cleared tests to be used in prescreening deployed military forces for Transfusion Transmitted Diseases (TTDs) in emergency blood collection operations within the task entitled Rapid Screening of Fresh Whole Blood. Military operational medicine advanced development efforts will continue to support clinical trials for the validation of improved psychotherapies, improved pharmaceuticals for the treatment of PTSD, development and integration of the physiologic status monitor, trials on alcohol and substance abuse, suicide prevention, and nutrition and dietary supplement studies. Combat casualty care will continue development efforts initiated in FY11 and FY12 to include further development of spray-dried plasma, smooth-pursuit eye tracking to diagnose concussions, a system that kills infectious organisms in whole blood, clinical trials on the pre-hospital use of plasma, and a clinical trial for a drug to treat concussions. Advanced development on a system that can bring advanced intensive care capabilities to frontline medics and medical treatment facilities will be initiated. The Clinical and Rehabilitative Medicine Research Program will continue clinical studies in the areas of pain management, regenerative medicine, and sensory system restoration and rehabilitation after traumatic injury. New clinical trials will start for battlefield pain management and regenerative medicine-based approaches for limb and digit (fingers and toes) salvage, craniomaxillofacial (skull, face and jaw) reconstruction, scarless wound healing, burn repair, genitourinary restoration and addressing compartment syndrome (muscle, nerve and vascular damage due to swelling post-injury).					
Accomplishments/Planned Programs Subtotals			159.890	144.403	132.430
C. Other Program Funding Summary (\$ in Millions)					
N/A					
Remarks					
D. Acquisition Strategy					
Test and evaluate medical device prototypes, medical procedures, and drug and vaccine candidates in government-managed Phase 1/2 clinical trials to gather data required for military and regulatory requirements prior to production and fielding, to include FDA licensure and Environmental Protection Agency registration.					
E. Performance Metrics					
Principal Investigators will participate in In-Progress Reviews, high-level DHP-sponsored Review & Analysis meetings, submit quarterly and annual status reports, and are subjected to Program Office or Program Sponsor Representatives progress reviews to ensure that Decision Gate milestones are being met and deliverables will					

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COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 [#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
400Z: CSI - Congressional Special Interests	-	27.750	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
[#] FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012												
^{##} The FY 2014 OCO Request will be submitted at a later date												
A. Mission Description and Budget Item Justification												
The FY12 DHP Congressional Special Interests (CSI) funded peer-reviewed directed research for Traumatic Brain Injury and Psychological Health, and Joint Warfighter Medical Research. Because of the CSI annual structure, out-year funding is not programmed.												
B. Accomplishments/Planned Programs (\$ in Millions)								FY 2012	FY 2013			
Congressional Add: 427A - Traumatic Brain Injury/ Psychological Health								17.750	-			
FY 2012 Accomplishments: The Traumatic Brain Injury and Psychological Health (TBI/PH) CSI project funding was divided into applied research, technology development and concept development efforts. The project aims to prevent, mitigate, and treat the effects of combat-relevant traumatic stress and TBI on function, wellness, and overall quality of life, including interventions across the deployment lifecycle for warriors, Veterans, family members, caregivers, and communities. For TBI concept development efforts, researchers performed clinical trials that utilize smooth-pursuit eye tracking technology to diagnose concussions and pursued proposals to develop a burr-hole training device to aid in training non-neurosurgeons to do cranial decompression procedures and two clinical trials, one to test the use of low-dose methamphetamine for the treatment of TBI and the other to test Magnesium coupled with polyethylene glycol (a water soluble compound commonly used in medicine) for the treatment of spinal cord injury.												
Congressional Add: 441A - Joint Warfighter Medical Research Program								10.000	-			
FY 2012 Accomplishments: The Joint Warfighter Medical Research Program Congressional Special Interest (CSI) is intended to provide continuing support for promising previously funded CSI projects, and to augment and accelerate high priority DoD and Service medical requirements that are close to achieving their objectives and yielding a benefit to military medicine. Project funding is divided into technology development and concept development efforts. The concept development projects are to advance device development, clinical trial support, and other meritorious projects to be selected. Through an iterative process of recommendations, several prior years of CSI-funded projects nominated by the Services, CSI managers, and execution activities were invited to submit augmented preproposals through the US Army Medical Research and Materiel Command Broad Agency Announcement. Based on these preproposals a programmatic review committee prioritized												

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		PROJECT 400Z: <i>CSI - Congressional Special Interests</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013
the research initiatives and the prioritization was approved by DoD Health Affairs in early September. Full proposals were received through the Broad Agency Announcement in late September and peer reviewed by the contracting officer representative and then evaluated through a second tier review and approved for funding in early November in accordance with the prioritization plan. Contract awards will be completed during the latter part of the first quarter and the second quarter of FY 13.			
Congressional Adds Subtotals		27.750	0.000
C. Other Program Funding Summary (\$ in Millions) N/A			
Remarks			
D. Acquisition Strategy Work under this PE will be solicited by traditional Program Announcements resulting in contracts or other transactions.			
E. Performance Metrics N/A			

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COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 [#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
434A: AF-Medical Products Support and Advanced Concept Development	-	3.896	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
[#] FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012 ^{##} The FY 2014 OCO Request will be submitted at a later date												
A. Mission Description and Budget Item Justification												
Air Force Medical Products Support and Advanced Concept Development efforts are focused on achieving rapid transition of promising, high TRL commercially-available off-the-shelf products through minor modifications and/or enhancements to address the most pressing medical needs of the Warfighter, accelerating of the transition of those technologies to the operators in the field. Development, Modification and Enhancement projects will emphasize technologies supporting Expeditionary Medicine, Enroute Care, Force Health Protection, Operational Medicine and Human Performance.												
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2012	FY 2013	FY 2014	
Title: Air Force Medical Products Support and Advanced Concept Development									3.896	0.000	0.000	
Description: Rapidly transition key COTS and near-COTS based technology solutions to the warfighter through assessment/evaluation and minor modification or enhancement of solutions to address threshold operational requirements and associated key performance parameters.												
FY 2012 Accomplishments: Transition of non-invasive Patient Warming and Cooling technology to operational use in expeditionary medical and enroute care settings; Transition of expanded pathogen detection, identification and quantification (DIQ) technology to operational use on existing COTS gas chromatograph, mass spectrometer platforms to address harmful and potentially harmful microbial volatile organic compounds (MVOC) and improve Force Health Protection. Transition of expanded multi-lingual voice translation COTS capability to operational use in beyond line of site / comm-out settings requiring on-board hardware based rapid translation capability. Transition of sensor integration platform and situational awareness/decision analytics algorithms and visualization tools needed to aggregate and integrate data from numerous field sensor platforms performing DIQ of air, water, soil, confined space sample analysis data streams throughout an AoR into decision quality information for leadership and enhanced force health protection.												
FY 2013 Plans: Continue transition efforts begun with FY12 funding received September 2012.												
FY 2014 Plans:												

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013
Complete transition efforts begun with FY12 funding received September 2012.			
Accomplishments/Planned Programs Subtotals		3.896	0.000
C. Other Program Funding Summary (\$ in Millions) N/A			
Remarks			
D. Acquisition Strategy Partnership with the US Navy in an inter-agency agreement and use (award of delivery orders and task assignments) to a engineering and manufacturing development IDIQ vehicle awarded under SBIR phase III provisions			
E. Performance Metrics Achievement of required TRL for each advanced concept development/product support project and fulfillment of established KPPs for same.			