

UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2015 Defense Health Program **Date:** March 2014

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>					R-1 Program Element (Number/Name) PE 0604110HP <i>I Medical Products Support and Advanced Concept Development</i>							
COST (\$ in Millions)	Prior Years	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO #	FY 2015 Total	FY 2016	FY 2017	FY 2018	FY 2019	Cost To Complete	Total Cost
Total Program Element	191.536	160.717	177.601	97.787	-	97.787	95.815	120.502	136.540	151.921	Continuing	Continuing
374A: <i>GDF-Medical Products Support and Advanced Concept Development</i>	159.890	120.534	128.601	97.787	-	97.787	95.815	120.502	136.540	151.921	Continuing	Continuing
400Z: <i>CSI - Congressional Special Interests</i>	27.750	40.183	49.000	-	-	-	-	-	-	-	Continuing	Continuing
434A: <i>AF-Medical Products Support and Advanced Concept Development</i>	3.896	-	-	-	-	-	-	-	-	-	Continuing	Continuing

The FY 2015 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 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, such as coordination with the Program Execution Office for possible integration into the Military Health System; and medical simulation and training system 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 Defense Medical Research and Development Program's Joint Program Committees, established to manage research, development, test and evaluation for the Defense Health Program (DHP). Research supported by this program element includes transition of medical training and health information sciences; advanced development of rapid pathogen (infectious agent) detection in fresh whole blood; field assessment of intervention tools for post traumatic stress disorder (PTSD); and clinical trials on biomarkers (biological indicators) for traumatic brain injury (TBI) and spinal cord injury, combat casualty care advanced product development, and rehabilitative medicine. As the research efforts mature, the most promising efforts will transition to medical products and support systems development funding, Program Element 0605145.

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 Development*
Defense Health Program

UNCLASSIFIED

UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2015 Defense Health Program	Date: March 2014
---	-------------------------

Appropriation/Budget Activity 0130: Defense Health Program I BA 2: RDT&E	R-1 Program Element (Number/Name) PE 0604110HP I Medical Products Support and Advanced Concept Development
--	--

B. Program Change Summary (\$ in Millions)	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO	FY 2015 Total
Previous President's Budget	144.403	132.430	146.610	-	146.610
Current President's Budget	160.717	177.601	97.787	-	97.787
Total Adjustments	16.314	45.171	-48.823	-	-48.823
• Congressional General Reductions	-0.259	-0.124			
• Congressional Directed Reductions	-15.897	-			
• Congressional Rescissions	-	-			
• Congressional Adds	43.712	49.000			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-2.864	-			
• SBIR/STTR Transfer	-8.378	-3.705			
• Reductions related to Departmental Efficiencies - Project 374A	-	-	-48.823	-	-48.823

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: 455A - Therapeutics Service Dog Training Program

Congressional Add Subtotals for Project: 400Z

Congressional Add Totals for all Projects

FY 2013	FY 2014
28.493	10.000
11.690	35.000
-	4.000
40.183	49.000
40.183	49.000

Change Summary Explanation

FY 2013: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0604110-Medical Products Support and Advanced Concept Development (-\$8.378 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) Program (+\$8.378 million).

FY 2013: Congressional Special Interest (CSI) additions to DHP RDT&E, PE 0604110-Medical Products Support and Advanced Concept Development (+ \$43.712 million).

FY 2013: General Congressional Reductions to DHP RDT&E, PE 0604110-Medical Products Support and Advanced Concept Development (-\$0.259 million).

FY 2013: Congressional Directed Reductions (Sequestration) to DHP RDT&E, PE 0604110-Medical Products Support and Advanced Concept Development (- \$15.897 million).

UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2015 Defense Health Program		Date: March 2014
Appropriation/Budget Activity	R-1 Program Element (Number/Name)	
0130: <i>Defense Health Program I BA 2: RDT&E</i>	PE 0604110HP <i>I Medical Products Support and Advanced Concept Development</i>	
FY 2013: Below Threshold Reprogramming (BTR) from DHP RDT&E PE, 0604110-Medical Products Support and Advanced Concept Development (-\$0.124 million) to DHP RDT&E PE, 0603002-Advanced Technology (AFRRI) (+\$0.124 million).		
FY 2013: Below Threshold Reprogramming (BTR) from DHP RDT&E PE, 0604110-Medical Products Support and Advanced Concept Development (-\$2.740 million) to DHP RDT&E PE, 0606105-Medical Program-Wide Activities (+\$2.740 million).		
FY 2014: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0604110-Medical Products Support and Advanced Concept Development (+ \$49.000 million).		
FY 2014: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0604110-Medical Products Support and Advanced Concept Development (-\$3.705 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) Program (+\$3.705 million).		
FY 2015: Reduces non-combat injury research funding in order to focus and continue the pace of progress in critical and high priority research areas for DHP RDT&E, PE 0604110-Medical Products Support and Advanced Concept Development (\$-48.823 million).		

PE 0604110HP: *Medical Products Support and Advanced Concept
Deve...*
Defense Health Program

UNCLASSIFIED

Page 3 of 13

R-1 Line #7

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program										Date: March 2014		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0604110HP / Medical Products Support and Advanced Concept Development				Project (Number/Name) 374A / GDF-Medical Products Support and Advanced Concept Development			
COST (\$ in Millions)	Prior Years	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO #	FY 2015 Total	FY 2016	FY 2017	FY 2018	FY 2019	Cost To Complete	Total Cost
374A: GDF-Medical Products Support and Advanced Concept Development	159.890	120.534	128.601	97.787	-	97.787	95.815	120.502	136.540	151.921	Continuing	Continuing

The FY 2015 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 transition of modeling and simulation technology for medical training/education/treatment; trials for transition of medical technology, practice guidelines, and standards; advanced component development of medical products; and medical information technology development. Within the areas of medical simulation and training the research areas concentrate in Combat Casualty Training Initiative (CCTI), Medical Practice Initiative (MPI), Health Focus Initiative (HFI), and Tools for Medical Education Initiative (TMEI). 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. Within military infectious diseases, research efforts include advanced development of rapid pathogen (infectious agent) detection in fresh whole blood, wound infection prevention and management, antimicrobial countermeasures, and diagnostic systems for infectious diseases. Within operational medicine, advanced development efforts include field assessment of intervention tools for post traumatic stress disorder (PTSD), nutrition and dietary supplements, advancement of the physiologic status monitor, pharmaceuticals for the treatment of PTSD, development of military family and community health and resilience diagnoses and treatment, and validation trials for enhanced suicide prevention. For combat casualty care advanced product development, efforts include clinical trials on biomarkers (biological indicators) for traumatic brain injury (TBI) and spinal cord injury; forward surgical/intensive critical care; control, resuscitation and blood products, craniomaxillofacial injury, lung injury and burns; and enroute care. For rehabilitative medicine, efforts include pain management and regenerative medicine clinical trials.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2013	FY 2014	FY 2015
Title: GDF – Medical Product Support and Advanced Concept Development	120.534	128.601	97.787
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.			

PE 0604110HP: *Medical Products Support and Advanced Concept Deve...*
Defense Health Program

UNCLASSIFIED

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program		Date: March 2014	
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0604110HP / <i>Medical Products Support and Advanced Concept Development</i>	Project (Number/Name) 374A / <i>GDF-Medical Products Support and Advanced Concept Development</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2013	FY 2014
<p><i>FY 2013 Accomplishments:</i></p> <p>For medical training and health information sciences (MTHIS), a combat casualty training initiative improved the ability of simulation systems to minimize live tissue usage. Solicitation and initial funding selections were made for Phase 1 of an advanced modular manikin core technology to which future peripheral modules can attach and interact to provide a breadth of training capabilities. Research continued on medical practice initiatives started within the fiscal year, which will result in materiel or knowledge products that support the MTHIS mission. MTHIS and Pacific Joint Information Technology Center (P-JITC) coordinated with the functional end-users and the Program Offices to map proposed and current research initiatives critical to the Warfighter. Research efforts explored emerging technologies that mitigate enterprise risk within health informatics, force health protection and readiness, medical resourcing, healthcare services, and enterprise infrastructure management with a focus on projects advancing data management, more sophisticated analytics, and promoting the advancement of novel user interfaces and data presentation for better information display. Specific efforts focused on theater data capture and management, information sharing and interoperability, identity management, clinical decision support, mobile devices, and novel information displays. Additionally, MTHIS and P-JITC worked with the Integrated Electronic Health Record way-ahead offices of the Department of Defense Military Health System and Veteran's Affairs for requirements identification and collaboration/coordination with the new Development and Test Center in Richmond, Virginia and the Telemedicine and Advanced Technology Research Center Test Lab at Fort Detrick, Maryland. P-JITC also maintained the test and evaluation lab (Independent Verification and Validation Center) for testing and integration of departmental/Warfighter projects in the Sensitive Compartment Information Facility lab in Hawaii.</p> <p>Military infectious diseases research continued support for field testing diagnostic capabilities and systems across operational echelons, as well as continued multi-year efforts for the development of FDA-cleared tests to be used in the prescreening of deployed military forces for transfusion transmitted diseases in emergency blood collection operations within the task for Rapid Screening of Fresh Whole Blood. The Acquisition Decision Memorandum for this effort was signed and the project transitioned to Advanced Development. Research efforts continued on products enabling the DoD to better diagnose and respond to future disease outbreaks as directed in the Quadrennial Defense Review.</p> <p>Military operational medicine efforts included a time-course determination for antioxidant delivery after steady-state noise or impulse-noise to assess the best method to prevent hearing loss, began studies focused on enhancing medical monitoring and alerting capabilities of the Spartan Sensor Network (SPARNET) system, continued clinical trials assessing the use of drugs as a treatment for deployment-related post traumatic stress disorder (PTSD) and evaluation of the effectiveness of prolonged exposure therapy plus antidepressants for OEF/OIF veterans with PTSD, conducted focus groups to evaluate an online mental health assessment tool, and evaluated factors that may mediate or moderate responses to brief interventions to reduce alcohol use and associated problems.</p>			

PE 0604110HP: *Medical Products Support and Advanced Concept Deve...*
 Defense Health Program

UNCLASSIFIED

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program		Date: March 2014		
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0604110HP / <i>Medical Products Support and Advanced Concept Development</i>	Project (Number/Name) 374A / <i>GDF-Medical Products Support and Advanced Concept Development</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2013	FY 2014	FY 2015
<p>Combat casualty care continued efforts initiated in FY11 and FY12 to develop a spray-dried plasma product, a smooth-pursuit eye tracking monitor to diagnose concussions, and a device to screen and kill infectious organisms in whole blood. Received Food and Drug Administration (FDA) 501(k) clearance for a decision support system to manage fluid resuscitation in severely burned patients. Supported studies involving the use of infrared goggles to treat severe trauma, and clinical trials on the pre-hospital use of plasma and a drug to treat concussions. This candidate drug responds to the Joint Capabilities Integration Development System requirement for a drug treatment for traumatic brain injury as well as the Quadrennial Defense Review requirement to increase research and treatment for traumatic brain injuries. Finalized agreement with the Veteran's Administration (VA) enabling initiation of a co-sponsored multi-site clinical study assessing the effectiveness of commonly prescribed off-label treatments for combat-related post-traumatic stress disorder (PTSD).</p> <p>Clinical and rehabilitative medicine continued clinical research started in FY12 within the areas of pain management, regenerative medicine, and sensory system restoration and rehabilitation after traumatic injury. Additional clinical studies were initiated within the focus areas of regenerative medicine-based approaches for limb (arms and legs) and digit (fingers, thumbs and toes) salvage, craniomaxillofacial (skull, face and jaw) reconstruction, scarless wound healing, burn repair, and genitourinary (system of the reproductive and urinary organs) restoration.</p> <p>FY 2014 Plans:</p> <p>Medical training and health information sciences (MTHIS) research is beginning on the core portion (Phase 1) of the advanced modular manikin within the Medical Simulation and Training portfolio. Medical Simulation and Training continues efforts to develop products that employ the use of simulation technologies in Warfighter medical training. MTHIS's Health Informatics & Information Technology, coordinates research to mitigate program risk for the Military Health System information program. The primary focus is on medical information technology and informatics needs to support the Warfighter. MTHIS continues to identify ways to reduce potential near- and long-term risks associated with information technology development and legacy systems, and to prepare for the transition to the Department of Defense modernized Electronic Health Record. Research solicitations focus on gaps such as mobile health and personal health management, advancement of advance data capture from Point of Injury to CONUS care, to include data transmission initiatives, new clinical decision support efforts, and patient identification issues that incorporate patient consent, privacy, and security.</p> <p>Military infectious diseases research is advancing development of a multiplexed infectious disease pathogen Nucleic Acid based diagnostic testing system for the rapid screening of donor-derived fresh whole blood. Three infectious disease assays being added this year.</p> <p>Military operational medicine advances development efforts through clinical trials to validate the use of improved psychotherapies (psychological treatment of mental disorders) and pharmaceuticals for the treatment of PTSD, as well as clinical trials studying</p>				

PE 0604110HP: *Medical Products Support and Advanced Concept Deve...*

Defense Health Program

UNCLASSIFIED

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program		Date: March 2014	
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0604110HP / <i>Medical Products Support and Advanced Concept Development</i>	Project (Number/Name) 374A / <i>GDF-Medical Products Support and Advanced Concept Development</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2013	FY 2014
<p>alcohol and substance abuse, and suicide prevention. Research is also supporting the development and integration of a physiologic status monitor, and clinical nutrition and dietary supplement studies.</p> <p>Combat casualty care is initiating Phase 2 and Phase 3 clinical trials to support an FDA Biologic License Application for a spray dried plasma product. Conduct a DoD-VA multi-site collaborative study assessing the effectiveness of commonly prescribed off-label treatments for combat-related PTSD. Continue validation of a smooth-pursuit eye tracking system to diagnose concussions and clinical trials on the pre-hospital use of plasma and a drug to treat concussions. Initiate Phase 2 and Phase 3 clinical trials for a device that kills infectious organisms in whole blood. Begin advanced development on a system bringing advanced intensive care capabilities to frontline medics and medical treatment facilities.</p> <p>Clinical and rehabilitative medicine is continuing clinical studies within the areas of pain management, regenerative medicine, and sensory system restoration and rehabilitation after traumatic injury. Clinical research is continuing, and new clinical trials are starting within the focus areas of regenerative medicine-based approaches for limb (arms and legs) and digit (fingers, thumbs and toes) salvage, craniomaxillofacial (skull, face and jaw) reconstruction, scarless wound healing, burn repair, and genitourinary (system of the reproductive and urinary organs) restoration. Clinical research is continuing, and new clinical trials are starting within the focus area of pain management.</p> <p>FY 2015 Plans:</p> <p>Medical training and health information sciences (MTHIS) within the medical simulation and training portfolio will build on the efforts of the Advanced Modular Manikin Phase 1 by down selecting to one partner for Phase 2. Upon completion of Phase 2, a manikin core will be complete in which task specific peripherals (i.e., arm, legs, head) can be attached for training. This will allow for a standardized core platform for which the future peripherals may attach and interact. Efforts will begin to explore technologies and techniques to better protect Warfighters from the psychological stresses and trauma experienced during deployment through the development of stress inoculation simulation systems. Medical simulation and training will develop methods in which virtual environments and serious gaming can be used to prepare service members for combat scenarios. MTHIS's health informatics portfolio will focus efforts on theater information technology research gaps such as point of injury data capture and transmission, incorporation of theater health information into DoD and VA health systems, and technology issues related to a theater environment.</p> <p>Military infectious diseases research will continue to develop diagnostic systems for infectious diseases by funding a combat support hospital-based polymerase chain reaction (PCR) system for detection of infectious diseases at a rate of up to three infectious disease assays per year added to the next generation system. Funds will be allocated to support one antimicrobial countermeasures human clinical study for the development of an antibacterial drug effective against multiple drug resistant bacteria, to support one wound infection prevention and management clinical study to advance our knowledge of clinical</p>			

PE 0604110HP: *Medical Products Support and Advanced Concept Deve...*

Defense Health Program

UNCLASSIFIED

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program		Date: March 2014	
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0604110HP / <i>Medical Products Support and Advanced Concept Development</i>	Project (Number/Name) 374A / <i>GDF-Medical Products Support and Advanced Concept Development</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2013	FY 2014
management of infected wounds with a clinical practice guideline being the deliverable, and to support rapid screening of fresh whole blood clinical development via a Nucleic Acid Testing platform, which will transition to medical products development, Program Element 0605145.			
Military operational medicine will support advanced development efforts initiated in FY14 programs: clinical practice guidelines for improved psychotherapies (psychological treatment of mental disorders) for PTSD; clinical trials to enhance pharmaceutical (medications) treatment of PTSD; clinical practice guidelines for the prevention of alcohol and substance abuse; and clinical practice guidelines for suicide prevention. Research will develop and integrate the physiologic status monitor, and will conduct human studies on validation of nutrition and dietary supplements.			
Combat casualty care will complete Phase 2 and Phase 3 clinical trials to support FDA Biologic License Application for a spray-dried plasma product. Continue DoD-VA multi-site collaborative study assessing the effectiveness of commonly prescribed off-label treatments for combat-related PTSD. Complete clinical trials on a device that kills infectious organisms in whole blood. Will continue advanced development of a system to provide advanced intensive care capabilities to first responders and frontline medical treatment facilities. These products will increase survival on the battlefield and enhance survival and improve outcomes of casualties at medical treatment facilities in theater.			
Clinical and rehabilitative medicine will transition current efforts to fielding, private industry, or medical systems development, PE 0605145, for products/solutions/guidelines, and continue clinical studies in the areas of pain management, regenerative medicine, and rehabilitation after traumatic injury. Clinical trials will begin for regenerative medicine-based approaches, which include approaches for limb (arms and legs) and digit (fingers, thumbs and toes) salvage, craniomaxillofacial (skull, face and jaw) reconstruction, scarless wound healing, repair of skin injury resulting from burns, composite tissue allotransplantation (hand and face transplantation) and associated immune system modulation technologies, and genitourinary (system of the reproductive and urinary organs) restoration. Products for battlefield pain management will transition to late phase FDA regulated clinical trials.			
Accomplishments/Planned Programs Subtotals		120.534	128.601
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 2 clinical trials to gather data required for military and regulatory requirements prior to production and fielding, to include FDA approval and Environmental Protection Agency registration.			

PE 0604110HP: *Medical Products Support and Advanced Concept Deve...*

Defense Health Program

UNCLASSIFIED

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program		Date: March 2014
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0604110HP / <i>Medical Products Support and Advanced Concept Development</i>	Project (Number/Name) 374A / <i>GDF-Medical Products Support and Advanced Concept Development</i>
E. Performance Metrics <p>Principal Investigators will participate in In-Progress Reviews, high-level DHP-sponsored review and 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 be transitioned on schedule. In addition, Integrated Product Teams, if established for a therapy or device, will monitor progress in accordance with DoD Regulation 5000 series. The benchmark performance metric for transition of research supported in this PE will be the attainment of a maturity level that is typical of Technology Readiness Level (TRL) 7.</p>		

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program										Date: March 2014		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0604110HP / Medical Products Support and Advanced Concept Development				Project (Number/Name) 400Z / CSI - Congressional Special Interests			
COST (\$ in Millions)	Prior Years	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO #	FY 2015 Total	FY 2016	FY 2017	FY 2018	FY 2019	Cost To Complete	Total Cost
400Z: CSI - Congressional Special Interests	27.750	40.183	49.000	-	-	-	-	-	-	-	Continuing	Continuing
# The FY 2015 OCO Request will be submitted at a later date.												
A. Mission Description and Budget Item Justification												
The FY13 DHP Congressional Special Interest (CSI) funding supported 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 2013	FY 2014			
Congressional Add: 427A - Traumatic Brain Injury/ Psychological Health								28.493	10.000			
FY 2013 Accomplishments: The Traumatic Brain Injury and Psychological Health (TBI/PH) Congressional Special Interest 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. Project funding was divided into basic research, applied research, technology development and advanced concept development efforts. For TBI concept development efforts, researchers continued clinical trials utilizing smooth-pursuit eye tracking technology to diagnose concussions, began development of a burr-hole (round hole surgically cut in the skull) training device to aid in training non-neurosurgeons to do cranial decompression procedures, and began two clinical trials: one to test the use of low-dose methamphetamine for the treatment of TBI and the other to assess a novel treatment for spinal cord injury. For psychological health, researchers performed clinical trials on rapid trauma management therapy for intensive treatment of post-traumatic stress disorder (PTSD).												
FY 2014 Plans: This Congressional Special Interest project will support Traumatic Brain Injury/ Psychological Health research.												
Congressional Add: 441A - Joint Warfighter Medical Research Program								11.690	35.000			
FY 2013 Accomplishments: The Joint Warfighter Medical Research Program (JWMRP) is intended to provide continuing support for promising previously funded Congressional Special Interest projects. The focus is 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 engineering and manufacturing development efforts. The JWMRP directly supports military medical research in military infectious diseases, combat casualty care, military operational medicine, medical training and												

PE 0604110HP: *Medical Products Support and Advanced Concept Deve...*

Defense Health Program

UNCLASSIFIED

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program		Date: March 2014												
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0604110HP / <i>Medical Products Support and Advanced Concept Development</i>	Project (Number/Name) 400Z / <i>CSI - Congressional Special Interests</i>												
B. Accomplishments/Planned Programs (\$ in Millions) <table border="1"> <thead> <tr> <th></th> <th>FY 2013</th> <th>FY 2014</th> </tr> </thead> <tbody> <tr> <td>health information sciences, and clinical and rehabilitative medicine to include pain management, regenerative medicine, and sensory system (hearing and sight) rehabilitation and restoration. Through an iterative process of recommendations, prior year CSI-funded projects were nominated for consideration by the Services, Joint Program Committee Chairs, and execution management activities. Those projects deemed by the Joint Program Committees to have the highest priority to fill critical research or materiel gaps and those projects close to developing a product were invited to submit a full proposal for the next level of effort. A technical review of the full proposals was completed. A Programmatic Review Board recommended 17 projects in the technology development area and 7 projects in the advanced concept development area for funding. The office of the Assistant Secretary of Defense (Health Affairs) approved the recommended funding prioritization list. Projects selected for funding are in the initial stages of the contracting process. Award negotiations will be completed by the end of the third quarter of FY14.</td> <td></td> <td></td> </tr> <tr> <td> FY 2014 Plans: This Congressional Special Interest project will support the Joint Warfighter Medical Research Program. Congressional Add: 455A - Therapeutics Service Dog Training Program FY 2013 Accomplishments: None. FY 2014 Plans: This Congressional Special Interest project will support Therapeutics Service Dog Training research. </td> <td>-</td> <td>4.000</td> </tr> <tr> <td>Congressional Adds Subtotals</td> <td>40.183</td> <td>49.000</td> </tr> </tbody> </table>				FY 2013	FY 2014	health information sciences, and clinical and rehabilitative medicine to include pain management, regenerative medicine, and sensory system (hearing and sight) rehabilitation and restoration. Through an iterative process of recommendations, prior year CSI-funded projects were nominated for consideration by the Services, Joint Program Committee Chairs, and execution management activities. Those projects deemed by the Joint Program Committees to have the highest priority to fill critical research or materiel gaps and those projects close to developing a product were invited to submit a full proposal for the next level of effort. A technical review of the full proposals was completed. A Programmatic Review Board recommended 17 projects in the technology development area and 7 projects in the advanced concept development area for funding. The office of the Assistant Secretary of Defense (Health Affairs) approved the recommended funding prioritization list. Projects selected for funding are in the initial stages of the contracting process. Award negotiations will be completed by the end of the third quarter of FY14.			FY 2014 Plans: This Congressional Special Interest project will support the Joint Warfighter Medical Research Program. Congressional Add: 455A - Therapeutics Service Dog Training Program FY 2013 Accomplishments: None. FY 2014 Plans: This Congressional Special Interest project will support Therapeutics Service Dog Training research.	-	4.000	Congressional Adds Subtotals	40.183	49.000
	FY 2013	FY 2014												
health information sciences, and clinical and rehabilitative medicine to include pain management, regenerative medicine, and sensory system (hearing and sight) rehabilitation and restoration. Through an iterative process of recommendations, prior year CSI-funded projects were nominated for consideration by the Services, Joint Program Committee Chairs, and execution management activities. Those projects deemed by the Joint Program Committees to have the highest priority to fill critical research or materiel gaps and those projects close to developing a product were invited to submit a full proposal for the next level of effort. A technical review of the full proposals was completed. A Programmatic Review Board recommended 17 projects in the technology development area and 7 projects in the advanced concept development area for funding. The office of the Assistant Secretary of Defense (Health Affairs) approved the recommended funding prioritization list. Projects selected for funding are in the initial stages of the contracting process. Award negotiations will be completed by the end of the third quarter of FY14.														
FY 2014 Plans: This Congressional Special Interest project will support the Joint Warfighter Medical Research Program. Congressional Add: 455A - Therapeutics Service Dog Training Program FY 2013 Accomplishments: None. FY 2014 Plans: This Congressional Special Interest project will support Therapeutics Service Dog Training research.	-	4.000												
Congressional Adds Subtotals	40.183	49.000												
C. Other Program Funding Summary (\$ in Millions) N/A Remarks D. Acquisition Strategy Prior year CSI funded research will be assessed for developmental maturity and qualification for initial or continued advanced development funding. If advanced development criteria are met, follow-on development will be solicited through a peer-reviewed process. E. Performance Metrics N/A														

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program										Date: March 2014																														
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0604110HP / <i>Medical Products Support and Advanced Concept Development</i>				Project (Number/Name) 434A / <i>AF-Medical Products Support and Advanced Concept Development</i>																															
COST (\$ in Millions)	Prior Years	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO #	FY 2015 Total	FY 2016	FY 2017	FY 2018	FY 2019	Cost To Complete	Total Cost																												
434A: <i>AF-Medical Products Support and Advanced Concept Development</i>	3.896	-	-	-	-	-	-	-	-	-	Continuing	Continuing																												
<p># The FY 2015 OCO Request will be submitted at a later date.</p> <p>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.</p> <p>B. Accomplishments/Planned Programs (\$ in Millions)</p> <table border="1"> <thead> <tr> <th></th> <th>FY 2013</th> <th>FY 2014</th> <th>FY 2015</th> </tr> </thead> <tbody> <tr> <td>Title: Air Force Medical Products Support and Advanced Concept Development</td> <td>-</td> <td>-</td> <td>-</td> </tr> <tr> <td>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.</td> <td></td> <td></td> <td></td> </tr> <tr> <td>FY 2013 Accomplishments: Continue transition efforts begun with FY12 funding received September 2012.</td> <td></td> <td></td> <td></td> </tr> <tr> <td>FY 2014 Plans: Complete transition efforts begun with FY12 funding received September 2012.</td> <td></td> <td></td> <td></td> </tr> <tr> <td>FY 2015 Plans: No funding programmed. Program transfered to USUHS starting in FY 2015.</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Accomplishments/Planned Programs Subtotals</td> <td>-</td> <td>-</td> <td>-</td> </tr> </tbody> </table> <p>C. Other Program Funding Summary (\$ in Millions) N/A</p> <p>Remarks</p>														FY 2013	FY 2014	FY 2015	Title: Air Force Medical Products Support and Advanced Concept Development	-	-	-	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 2013 Accomplishments: Continue transition efforts begun with FY12 funding received September 2012.				FY 2014 Plans: Complete transition efforts begun with FY12 funding received September 2012.				FY 2015 Plans: No funding programmed. Program transfered to USUHS starting in FY 2015.				Accomplishments/Planned Programs Subtotals	-	-	-
	FY 2013	FY 2014	FY 2015																																					
Title: Air Force Medical Products Support and Advanced Concept Development	-	-	-																																					
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 2013 Accomplishments: Continue transition efforts begun with FY12 funding received September 2012.																																								
FY 2014 Plans: Complete transition efforts begun with FY12 funding received September 2012.																																								
FY 2015 Plans: No funding programmed. Program transfered to USUHS starting in FY 2015.																																								
Accomplishments/Planned Programs Subtotals	-	-	-																																					

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program		Date: March 2014
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0604110HP / Medical Products Support and Advanced Concept Development	Project (Number/Name) 434A / AF-Medical Products Support and Advanced Concept Development
<p>D. Acquisition Strategy</p> <p>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</p>		
<p>E. Performance Metrics</p> <p>Achievement of required TRL for each advanced concept development/product support project and fulfillment of established KPPs for same.</p>		