Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program	Date: February 2015
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*

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
Total Program Element	352.253	296.634	150.822	103.443	-	103.443	129.137	140.826	146.781	149.354	Continuing	Continuing
374A: *GDF-Medical Products Support and Advanced Concept Development*	280.424	244.621	97.614	99.443	-	99.443	125.137	136.826	142.781	145.354	Continuing	Continuing
400Z: *CSI - Congressional Special Interests*	67.933	49.000	53.208	-	-	-	-	-	-	-	Continuing	Continuing
434A: *Medical Products Support and Advanced Concept Development (AF)*	3.896	3.013	-	4.000	-	4.000	4.000	4.000	4.000	4.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force (GDF) - Medical Products Support and Advanced Concept Development: Funding supports (1) advanced concept development of medical products that are regulated by the US Food and Drug Administration (FDA), (2) clinical and field validation studies supporting the transition of FDA-licensed and unregulated products and medical practice guidelines to the military operational user,(3) prototyping, (4) 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 (5) medical simulation and training system technologies. This portfolio is designed to address areas of interest to the Secretary of Defense related to Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and the sustainment of priority investments in science, technology, research, and development, as stated 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 such as the Department of Veterans Affairs, the Department of Health and Human Services, and the Department of Homeland Security. Coordination occurs through the planning and execution activities of the Defense Health Agency's Joint Program Committees (JPC), which were established to manage research, development, test and evaluation for Defense Health Program (DHP) sponsored research. Research within this program element encompasses Medical Simulation and Information Sciences (through JPC-1), Military Infectious Disease (through JPC-2), Military Operational Medicine (through JPC-5), Combat Casualty Care (through JPC-6), and Clinical and Rehabilitative Medicine (through JPC-8). As the research efforts mature, the most promising efforts will transition to medical products and support systems development funding, Program Element 0605145.

For the Air Force Medical Service, funding in this program element supports technology development for the rapid transition of medical products and capabilities from Air Force laboratories, and the ability to perform modifications /enhancements required to integrate commercial off-the-shelf (COTS) and near-COTS products into the military operating environment. Ability to enhance or modify existing COTS is a cost effective technique we should maximize where possible, ensuring warfighters have appropriate technology at hand to care for wounded at the point of injury through definitive care and on to rehabilitation and reintegration at the most efficient cost and schedule possible. Significant benefits can be obtained from rapid insertion of high value / impact technologies into healthcare operations to address capabilities that enter the acquisition life-cycle at high TRL levels that can readily be implemented with significant upside potential. Cannot ensure viability of S&T and translational research efforts with a materiel component without correctly programmed funding for logical progression and transition of those activities in the product development

lifecycle. Ensures viability of S&T and translational research efforts with a materiel component by providing programmed funding for logical progression and transition of those activities in the product development lifecycle.

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

B. Program Change Summary ($ in Millions)	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Previous President's Budget	132.430	97.787	95.815	-	95.815
Current President's Budget	296.634	150.822	103.443	-	103.443
Total Adjustments	164.204	53.035	7.628	-	7.628
• Congressional General Reductions	-0.124	-0.173			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	49.000	53.208			
• Congressional Directed Transfers	-	-			
• Reprogrammings	126.369	-			
• SBIR/STTR Transfer	-11.041	-			
• Program Realignment - Project 374A	-	-	3.628	-	3.628
• Program Realignment - Project 434A	-	-	4.000	-	4.000

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2014	FY 2015
Project: 400Z: *CSI - Congressional Special Interests*		
Congressional Add: *427A - Traumatic Brain Injury/ Psychological Health*	10.000	20.000
Congressional Add: *441A - Joint Warfighter Medical Research Program*	35.000	20.000
Congressional Add: *455A - Therapeutic Service Dog Training Program (USUHS)*	4.000	3.000
Congressional Add: *464A – Program Increase: Restore Core Research Funding Reduction (GDF)*	-	10.208
Congressional Add Subtotals for Project: 400Z	49.000	53.208
Congressional Add Totals for all Projects	49.000	53.208

Change Summary Explanation

FY 2014: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0604110-Medical Products Support and Advanced Concept Development (-$11.041 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) Program (+$11.041 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: Federally Funded Research and Development Center Reduction, PE 0604110-Medical Products Support and Advanced Concept Development (-$0.124 million).

FY 2015: Federally Funded Research and Development Center Reduction, PE 0604110-Medical Products Support and Advanced Concept Development (-$0.173 million).

FY 2015: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0604110-Medical Products Support and Advanced Concept Development (+ $53.208 million).

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0603115-Medical Technology Development (-$4.000 million) to DHP RDT&E PE 0604110-Medical Products Support and Advanced Concept Development (+$4.000 million).

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0605145-Medical Products and Support System Development (-$3.628 million) to DHP RDT&E PE 0604110-Medical Products Support and Advanced Concept Development (+$3.628 million).

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program			Date: February 2015
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 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
374A: *GDF-Medical Products Support and Advanced Concept Development*	280.424	244.621	97.614	99.443	-	99.443	125.137	136.826	142.781	145.354	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force (GDF)-Medical Products Support and Advanced Concept Development: This funding supports (1) clinical trials of promising technologies that may provide solutions for the most pressing medical needs of the Warfighter, (2) accelerated transition of promising technologies to the field, and (3) promulgation of new, evidence-based approaches to the practice of medicine as clinical practice guidelines. Research will be conducted in the following areas: (1) Medical Simulation and Information Sciences/JPC-1. This JPC seeks to promote long-term efficiencies by defining processes improving the electronic healthcare record/other medical related systems, and the implementation of new trends and advancements in technology to 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 CSI funding; (2) Military Infectious Disease/JPC-2. This JPC supports the advanced development of systems to rapidly detect pathogens (infectious agents)in fresh whole blood, as well as efforts related to the prevention and management of wound infections and the development of antimicrobial countermeasures and infectious disease-related diagnostic systems; (3) Military Operational Medicine/JPC-5. This JPC supports clinical assessments related to interventions for post-traumatic stress disorder (PTSD), nutrition and dietary supplementation to promote health and resilience, the development of mitigation strategies to prevent hearing loss, the development of techniques to enhance military family and community health and resilience, validation trials for enhanced suicide prevention, and the accomplishment of related field studies with end users; (4) Combat Casualty Care/JPC-6. This JPC supports clinical trials such as those assessing biomarkers (biological indicators) for traumatic brain injury (TBI) and spinal cord injury, product development related to forward surgical/intensive critical care, enroute care, hemorrhage and resuscitation, and treatments for tissue injury; (5) Clinical and Rehabilitative Medicine/JPC-8. Advanced development efforts in this JPC involve clinical trials related to pain management and regenerative medicine.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Title: GDF – Medical Product Support and Advanced Concept Development	244.621	97.614	99.443
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 2014 Accomplishments: Medical Simulation and Information Sciences conducted research in two primary research portfolios -- Medical Simulation and Training, and Health Informatics and Information Technology. Under the Medical Simulation and Training portfolio, development began on the core (torso) portion (Phase 1) of the Advanced Modular Manikin. This platform will be used in the training of medical intervention procedures. Under the Health Informatics and Information Technology portfolio, coordination continued on electronic			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
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*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
medical information technology research to support care for the Warfighter, and to mitigate program risk for the Military Health System. Identified options to reduce potential near- and long-term risks associated with information technology development and legacy systems, and prepared for the transition to the Department of Defense modernized Electronic Health Record. Research continued on closing gaps related to mobile health and personal health management, and advancing the ability to capture data from the point of injury to the point of definitive care. This effort involves data transmission initiatives, new clinical decision support algorithms, and patient identification issues incorporating patient consent, privacy, and security. Military Infectious Diseases completed down-selection on a Next Generation Diagnostic System for the Combat Support Hospital. Initiated advanced development on three polymerase chain reaction-based assays (malaria, dengue, and chikungunya) to be used on the Next Generation Diagnostic System (NGDS). Military Operational Medicine completed clinical trials on the use of improved psychotherapies (psychological treatment of mental disorders) for the treatment of PTSD in Operation Iraqi Freedom/Operation Enduring Freedom returnees. These studies provided evidence for the efficacy of delivering PTSD treatment in-home, and supported delivery of PTSD treatment in a shortened period of time. In collaboration with the Veterans Administration, clinical trials were initiated examining the use of pharmaceuticals for the treatment of deployment-related symptoms of PTSD (e.g., improving sleep and reducing nightmares). Clinical trials continued on alcohol and substance abuse and suicide prevention interventions. Development was completed on actionable algorithms for integration into physiological health status monitoring systems. Field studies were conducted with end users. Continued initiatives developing mitigation strategies for prevention of hearing loss, and on safety and efficacy studies related to clinical nutrition and dietary supplements. Combat Casualty Care conducted research in Hemorrhage and Resuscitation, Neurotrauma, Traumatic Tissue Injury, Forward Surgical Intensive Critical Care, and joint Enroute Care. Under Hemorrhage and Resuscitation: Initiated a Phase 2 clinical trial in humans on a spray dried plasma product in support of a FDA Biologic License Application. Initiated Phase 2 and Phase 3 clinical trials on a device to kill infectious organisms in fresh whole blood collected on the battlefield for transfusion. Conducted clinical trials on the pre-hospital use of plasma. Under Neurotrauma: Conducted a DoD-Veteran's Administration multi-site collaborative study assessing the effectiveness of commonly prescribed off-label treatments for combat-related PTSD. Continued study assessing the effectiveness of non-invasive diagnostic/assessment tools for Traumatic Brain Injury (TBI), and the assessment of TBI biomarkers in patients with concussive injuries. Conducted clinical trials on a drug to treat concussions. Continued validation studies on a smooth-pursuit eye tracking system to diagnose concussions. Under Forward Surgical Intensive Critical Care and joint Enroute Care: Initiated advanced development on a system bringing advanced intensive care capabilities to frontline medics and medical treatment facilities.			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
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*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Clinical and Rehabilitative Medicine sponsored advanced clinical studies within the areas of pain management, and regenerative and rehabilitative therapies after traumatic injury. Continued clinical research and clinical trials for regenerative medicine-based approaches for restoration of 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 (reproductive and urinary organs). Continued composite tissue allotransplantation (hand and face transplantation) efforts and associated immune system modulation technologies. Initiated clinical research and new clinical trials for pain management.			
FY 2015 Plans: Medical Simulation and Information Sciences conduct research in two primary research portfolios -- Medical Simulation and Training, and Health Informatics and Information Technology. Under the Medical Simulation and Training portfolio, the Advanced Modular Manikin Phase 1 effort continues developing a core (torso) portion for use in the training of medical intervention procedures. Efforts are underway to assess the value of stress inoculation simulation training methodologies, technologies, and techniques in better protecting Warfighters from deployment related psychological stresses and trauma. Under the Health Informatics portfolio, efforts continue towards filling theater information technology research gaps such as the capturing and transmission of point of injury data, the incorporation of theater health information into DoD and Veteran's Administration health systems, and technology issues related to a theater environment. Military Infectious Disease continue advanced development on polymerase chain reaction-based assays for malaria, dengue, and chikungunya to be used on the Next Generation Diagnostic System (NGDS) for Combat Support Hospitals. Efforts begin on an antimicrobial countermeasures study supporting the development of an antibacterial drug effective against multiple drug resistant bacteria. A clinical study on wound infection prevention and management begins. Military Operational Medicine is applying the results of clinical trials to the development of clinical practice guidelines for improved psychotherapies (psychological treatment of mental disorders) for the treatment of PTSD. Continue Veterans Administration-DoD clinical trials studying the use of pharmaceuticals for the treatment of deployment-related symptoms of PTSD (e.g., improving sleep and reducing nightmares). Complete clinical trials on alcohol and substance abuse and suicide prevention interventions, and begin to apply results to the development of clinical practice guidelines. Continue integration of actionable algorithms into physiologic status monitoring systems based on end user feedback. Validate data from human studies on nutrition and dietary supplements. Combat Casualty Care conducts research in Hemorrhage and Resuscitation, Neurotrauma, Traumatic Tissue Injury, Forward Surgical Intensive Critical Care, and joint Enroute Care. Under Hemorrhage and Resuscitation: Continue Phase 2 and initiate Phase 3 clinical trials supporting FDA Biologic License Application for a spray-dried plasma product. Complete clinical trials on a device killing infectious organisms in fresh whole blood collected on the battlefield for transfusion. Under Neurotrauma: Continue			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
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*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
a DoD-Veteran's Affairs multi-site collaborative study assessing the effectiveness of commonly prescribed off-label treatments for combat-related PTSD. Continue studying the effectiveness of non-invasive diagnostic tools for TBI and the assessment of TBI biomarkers in patients with concussive injuries. Evaluate and validate two TBI biomarker point-of-care devices in conjunction with a biomarker-specific diagnostic assay system. Continue to develop the Biomarker Assessment for Neurotrauma Diagnosis and Improved Triage System (BANDITS) diagnostic. Validate pivotal clinical trial results from the Portable Neuromodulation Stimulator (PONS) as a treatment for TBI balance disorders. Under Forward Surgical Intensive Care and joint Enroute Care: Continue the advanced development of a system to provide advanced intensive care capabilities to first responders and frontline Military Treatment Facilities. Clinical and Rehabilitative Medicine continues to maximize the opportunity to transition current efforts to fielding, private industry, or medical systems development. Continue clinical studies in the areas of pain management, and regenerative and rehabilitative therapies for traumatic injury. Continue clinical trials for regenerative medicine-based approaches for restoration of 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, and genitourinary system (reproductive and urinary organs). Continue composite tissue allotransplantation (hand and face transplantation) efforts and associated immune system modulation technologies. Transition product for battlefield pain management to late-phase FDA regulated clinical trials. For the tri-service translational research at Military Treatment Facilities, collaborative efforts are underway to solicit and make awards. Applications are to focus on advanced concept development efforts in combat casualty care, operational medicine, infectious diseases, and/or clinical and rehabilitative medicine. These include clinical trials for validation of improved psychotherapies (psychological treatment of mental disorders), improved pharmaceuticals (medications) and devices for the treatment of TBI/PH. ***FY 2016 Plans:*** Medical Simulation and Information Sciences will conduct research in two primary research portfolios -- Medical Simulation and Training, and Health Informatics and Information Technology. Under the Medical Simulation and Training portfolio, Phase 1 of the Advanced Modular Manikin project will end with platform downselect and one award for a standardized manikin core (torso) platform. Advanced Modular Manikin, Phase 2 will begin the development of task specific peripherals (i.e., arm, legs, and head) for integration onto the core platform selected from Phase 1. Advanced development efforts will continue on a stress inoculation simulation system to better protect Warfighters from the deployment related psychological stresses and trauma. Testing will continue on next generation mobile technologies for more effective advanced distributed learning applications, and on systems development for improved mobile health technologies, visualization of health related data, and medical provider decision support algorithms.			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
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*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Military Infectious Diseases will initiate advanced development on one infectious disease polymerase chain reaction-based assay to be used on the Next Generation Diagnostic System (NGDS). Clinical studies will continue on the development of an antibacterial drug effective against multiple drug resistant bacteria, and on wound infection prevention and management. Military Operational Medicine will continue the development of clinical practice guidelines for improved psychotherapies (psychological treatment of mental disorders) for PTSD, for the use of pharmaceuticals for the treatment of deployment-related symptoms of PTSD (e.g., improving sleep and reducing nightmares), and on alcohol and substance abuse and suicide prevention interventions. Continue validation studies on clinical nutrition and dietary supplement safety and efficacy. Develop gender-specific and gender-neutral standards that apply across garrison and combat operations to reduce injuries in the total force. Continue efforts within the area of environmental health and protection to refine algorithms to reliably predict core body temperature from non-invasive measurements (e.g., skin temperature and heart rate) for a physiological health status monitoring system. Initiate studies assessing the use of a physiological health monitoring system to determine the prevalence and severity of pulmonary disease in pre-deployed and returned service members. Combat Casualty Care conducted research in Hemorrhage and Resuscitation, Neurotrauma, Traumatic Tissue Injury, Forward Surgical Intensive Critical Care, and joint Enroute Care. Under Hemorrhage and Resuscitation: Complete Phase 2 and Phase 3 clinical trials supporting FDA Biologic License Application for a spray-dried plasma product. Complete clinical trials on a device that kills infectious organisms in fresh whole blood. Initiate clinical trials on an intracavitary hemostatic product and a low-volume resuscitation drug. Under Neurotrauma: Continue clinical trials on a point-of-care diagnostic tool for traumatic brain injury. Continue studies advancing the development of TBI biomarker devices. Validate results of a multi-site collaborative TBI endpoints study to improve clinical trial design. Continue the advanced development of novel diagnostics for traumatic brain injury. Under Traumatic Tissue Injury: Continue the development of technologies transitioned from the Peer Reviewed Orthopedic Research Program. Under Forward Surgical Intensive Critical Care and joint Enroute Care: Continue advanced development of a system to provide advanced intensive care capabilities to first responders, frontline Military Treatment Facilities, and data collection systems for battlefield point of injury Clinical and Rehabilitative medicine will continue to transition current efforts to fielding or private industry for products/solutions/ guidelines. Complete late phase FDA regulated clinical trials for battlefield pain management products and submit a New Drug Application with the US FDA. Continue the development of regenerative and rehabilitative therapies for traumatic injury. Progress clinical trials for regenerative medicine-based approaches for restoration of 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, and genitourinary system (reproductive and urinary organs). Improve non-invasive clinical monitoring of composite tissue allotransplantation (hand and face transplantation) and continue support for associated immune system modulation technologies.			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
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*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Initiate clinical trials on methods to reconstruct facial features (such as lips and eyelids), test nerve allograft materials, and enhance muscle regeneration. The Tri-service translational research Military Treatment Facility-based studies recommended for funding in FY15 will recruit, screen, and enroll patients and will begin to collect data for advanced concept development efforts in combat casualty care, operational medicine, infectious diseases, and clinical and rehabilitative medicine. Examples of initiatives within this area include clinical trials to validate improved psychotherapies (psychological treatment of mental disorders), and efforts to improve pharmaceuticals (medications) and devices for the treatment of TBI/PH).			
Accomplishments/Planned Programs Subtotals	244.621	97.614	99.443

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.

E. Performance Metrics

Research will be evaluated through In-Progress Reviews, high-level DHP-sponsored review and analysis meetings, quarterly and annual status reports, and will be subject 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.

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program			Date: February 2015
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 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
400Z: *CSI - Congressional Special Interests*	67.933	49.000	53.208	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

The FY14 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 2014	FY 2015
Congressional Add: 427A - Traumatic Brain Injury/ Psychological Health	10.000	20.000

FY 2014 Accomplishments: The Traumatic Brain Injury and Psychological Health (TBI/PH) Congressional Special Interest research program 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. Key priorities of the FY14 TBI/PH research program were to support projects aligned with the National Research Action Plan, address Congressional intent, enable significant research collaborations, and complement ongoing Department of Defense (DoD) efforts to ensure the mental health and readiness of our military forces by promoting a better standard of care for PH and TBI in the areas of prevention, detection, diagnosis, treatment, and rehabilitation. In addition to service-requested nominations, individual Broad Agency Announcement applications, and promising ongoing studies, four program announcements (PAs) were released to solicit applications that address these priorities. The Psychological Health Research Award PA is intended to support both applied (preclinical) research and clinical trials within specific topic areas addressing the prevention and treatment of military-relevant psychological health issues. The Neurosensory and Rehabilitation Research Award PA Supports both applied (preclinical) research and clinical trials addressing TBI within specific focus areas of pain management, hearing loss/dysfunction, balance disorders, tinnitus, vision, or physical rehabilitation associated with TBI. The Investigative Treatments for TBI and PTSD Clinical Trial Award PA responds to Section 704 of the National Defense Authorization Act for Fiscal Year 2014 and supports investigational treatments (including diagnostic testing) of TBI and PTSD received by members of the Armed Forces in health care facilities other than military treatment facilities. The Community Partners in Mental Health Research Award PA responds to Section 706 of the National Defense Authorization Act for Fiscal Year 2013 by supporting research on the causes, development, and innovative treatment of mental health, substance use disorders, TBI, and suicide prevention in members of the National Guard and Reserves, their family members, and their caregivers. Application submission deadlines for the PAs are in November 2014, January 2015, and February 2015. Scientific peer

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
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*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015
reviews will be held in January and March 2015 followed by programmatic reviews in March and May 2015. Awards will be made by September 2015. ***FY 2015 Plans:*** This Congressional Special Interest research initiative is for Traumatic Brain Injury/ Psychological Health.		
Congressional Add: 441A - Joint Warfighter Medical Research Program ***FY 2014 Accomplishments:*** The Joint Warfighter Medical Research Program (JWMRP) provides continuing support for promising research previously funded under Congressional Special Interest programs. 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 health information sciences, and clinical and rehabilitative medicine. Through an iterative process of recommendations, prior year CSI-funded projects were nominated for consideration by the Services, Joint Program Committees, and Execution Management Agency 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. The scientific peer review was completed in late June. The programmatic review was completed in August with the recommended funding list for 16 projects forwarded to the Director of Research and Development, Defense Health Agency for approval. Award negotiations will be complete by September 2015. ***FY 2015 Plans:*** This Congressional Special Interest research initiative is for Joint Warfighter Medical Research Program.	35.000	20.000
Congressional Add: 455A - Therapeutic Service Dog Training Program (USUHS) ***FY 2014 Accomplishments:*** This Congressional Special Interest project will support Therapeutics Service Dog Training research. ***FY 2015 Plans:*** This Congressional Special Interest research initiative is for Therapeutic Service Dog Training Program (USUHS).	4.000	3.000
Congressional Add: 464A – Program Increase: Restore Core Research Funding Reduction (GDF)	-	10.208

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
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*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015
FY 2014 Accomplishments: No funding programmed. This is an FY 2015 DHP Congressional Special Interest (CSI) spending item. ***FY 2015 Plans:*** FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in the Medical Products Support and Advanced Concept Development Program Element (PE) - 0604110.		
Congressional Adds Subtotals	49.000	53.208

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

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program			Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110HP / *Medical Products Support and Advanced Concept Development*	**Project (Number/Name)** 434A / *Medical Products Support and Advanced Concept Development (AF)*	

COST ($ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
434A: *Medical Products Support and Advanced Concept Development (AF)*	3.896	3.013	-	4.000	-	4.000	4.000	4.000	4.000	4.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Air Force Medical Products Support and Advanced Concept Development & Prototyping 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. Ensure Healthcare delivery remains current and relevant. Provide critical capability to make and act on material solution investment decisions in an annual cycle. Derive benefits from rapid insertion of high value / impact technologies into healthcare operations with programmed funding to address capabilities that enter the acquisition life-cycle at high TRL levels that can readily be implemented with significant upside potential. Ensure viability of S&T and translational research efforts with a materiel component without programmed funding for logical progression and transition of those activities in the product development lifecycle.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Title: Medical Products Support and Advanced Concept Development (AF)	3.013	-	4.000

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.Provide core capability to rapidly transition key, high value and impact technologies to operational use Provide core capability to logically progress initiatives and concepts in the S&T and translational/knowledge-focused programs (6.1-6.3) into material solutions and conduct the advanced development and transition activities needed to ensure those products are fielded in an effective, timely and efficient manner.

FY 2014 Accomplishments:

Completed transition of non-invasive Patient Warming & Cooling technology to Program of Record; 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. Completed 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. Prepare and issue solicitation for award of an advanced technology development effort to refine and transition the Cardiovascular Sonospectrographic Analyzer (CSA) pursuant to the approved FY14 Omnibus Reprogramming action.

FY 2015 Plans:

Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program		Date: February 2015
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110HP / *Medical Products Support and Advanced Concept Development*	**Project (Number/Name)** 434A / *Medical Products Support and Advanced Concept Development (AF)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Award effort to refine and commercialize the Cardiovascular Sonospectrographic Analyzer (CSA). Conduct developmental engineering activities to ready the device for inclusion in advanced clinical trials and guiding it to the FDA regulatory approval pathway. Award effort to develop a next generation multi-channel infusion pump via a modified-COTS approach to rapidly and safely deliver drugs and therapeutics to DoD wounded, ill and injured personnel in the field, in the air and while awaiting evacuation to definitive care. ***FY 2016 Plans:*** Evaluate the Cardiovascular Sonospectrographic Analyzer (CSA), technology through clinical trials by improving sensitivity and specificity and form factor enhancements to device that can process sound signatures of turbulent blood through partially occluded arteries - target level of sensitivity is CT angiography--include device in ongoing and planned clinical trials for submission of the 510K predicate device application to the FDA. Continue efforts to develop a next generation multi-channel and prepare for predicate device submission to the FDA for transition of the technology.			
Accomplishments/Planned Programs Subtotals	3.013	-	4.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Partnership with the US Navy, AFRL and the Department of the Interior in inter-agency agreements and use (award of delivery orders and task assignments) to engineering and manfacturing development IDIQ vehicles awarded under SBIR phase III provisions. Utilization of Small Business Innovative Research program direct awards for Phase III transition efforts and a Cooperative Agreement structure through Foundations supporting military medical research and development programs.

E. Performance Metrics

Achievement of required TRL for each advanced concept development/product support project and fulfillment of estabilshed KPPs for same.