Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0604110DHA *I Medical Products Support and Advanced Concept Development*

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
Total Program Element	648.887	146.411	175.518	96.602	-	96.602	114.382	131.866	143.793	148.111	Continuing	Continuing
374A: *GDF-Medical Products Support and Advanced Concept Development*	525.045	85.628	99.443	92.602	-	92.602	110.382	127.866	139.793	144.031	Continuing	Continuing
400Z: *CSI - Congressional Special Interests*	116.933	60.783	72.075	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
434A: *Medical Products Support and Advanced Concept Development (AF)*	6.909	0.000	4.000	4.000	-	4.000	4.000	4.000	4.000	4.080	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force (GDF) - Medical Products Support and Advanced Concept Development: This program element (PE) provides funding to support: 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. Research in this PE is designed to address areas of interest to the Secretary of Defense regarding Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and sustainment of DoD and multi-agency priority investments in science, technology, research, and development. Medical research, development, test, and evaluation priorities for the Defense Health Program (DHP) are guided by, and will support, the Quadrennial Defense Review, the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service Members, and Military Families, the National Strategy for Combating Antibiotic Resistance, and the National Strategy for Biosurveillance. Research will support efforts such as the Precision Medicine Initiative, translational research focused on protection against emerging infectious disease threats, the advancement of state of the art regenerative medicine manufacturing technologies consistent with the National Strategic Plan for Advanced Manufacturing, the advancement of global health engagement and capitalization of complementary research and technology capabilities, and the strengthening of the scientific basis for decision-making in patient safety and quality performance in the Military Health System. The program also supports the Interagency Strategic Plan for Research and Development of Blood Products and Related Technologies for Trauma Care and Emergency Preparedness. Program development and execution is peer-reviewed and 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. Coordination occurs through the planning and execution activities of the Joint Program Committees (JPCs), established to manage research, development, test and evaluation for DHP-sponsored research. The JPCs supported by this PE include medical simulation and information sciences, military infectious diseases, military operational medicine, combat casualty care, and clinical and rehabilitative medicine. As the research efforts mature, the most promising will transition to medical products and support systems development funding, PE 0605145.

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

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

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. The viability of S&T and translational research with a materiel component cannot be ensured without correctly programmed funding for logical progression and transition of those activities in the product development lifecycle. This PE 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.

B. Program Change Summary ($ in Millions)	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total
Previous President's Budget	97.787	103.443	129.137	-	129.137
Current President's Budget	146.411	175.518	96.602	-	96.602
Total Adjustments	48.624	72.075	-32.535	-	-32.535
• Congressional General Reductions	-0.173	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	60.783	72.075			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-3.463	-			
• SBIR/STTR Transfer	-8.523	-			
• Rebalance Joint Program Committees	-	-	-13.403	-	-13.403
• DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care	-	-	-9.738	-	-9.738
• Health Information Technology Optimization Reduction	-	-	-7.000	-	-7.000
• Restore USUHS Breast, GYN, and Prostate Cancer Centers of Excellence	-	-	-2.394	-	-2.394

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2015	FY 2016
Project: 400Z: *CSI - Congressional Special Interests*		
Congressional Add: *427A - Traumatic Brain Injury / Psychological Health*	20.000	21.375

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency	Date: February 2016
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0604110DHA *I Medical Products Support and Advanced Concept Development*

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2015	FY 2016
Congressional Add: *441A - Joint Warfighter Medical Research Program*	20.000	20.000
Congressional Add: *455A - Therapeutic Service Dog Training Program (USUHS)*	3.000	0.000
Congressional Add: *464A – Program Increase: Restore Core Research Funding Reduction (GDF)*	17.783	30.700
Congressional Add Subtotals for Project: 400Z	60.783	72.075
Congressional Add Totals for all Projects	60.783	72.075

Change Summary Explanation

FY 2015: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0604110-Medical Products Support and Advanced Concept Development (-$8.523 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$8.523 million).

FY 2015: Federally Funded Research and Development Center (FFRDC) Reduction (FFRDC), 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 (+ $60.783 million).

FY 2016: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0604110-Medical Products Support and Advanced Concept Development (+ $72.075 million).

FY 2017: Realignment from DHP RDTE PE 0604110-Medical Products Support and Advanced Concept Development (-$13.403 million) to DHP RDTE PE 0603115-Medical Technology Development for the rebalancing of the Joint Program Committees (+$13.403 million).

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0604110-Medical Products Support and Advanced Concept Development (-$9.738 million) to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care (+$9.738 million).

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FY 2017: Realignment from DHP RDTE PE 0604110-Medical Products Support and Advanced Concept Development (-$7.000 million) as a result of DoD CIO Health Information Technology Optimization review.

FY 2017: Realignment from DHP RDTE PE 0604110-Medical Products Support and Advanced Concept Development (-$2.394 million) to DHP RDTE PE 0603115-Medical Technology Development for Breast, Gynecological and Prostate Cancer Centers of Excellence (+2.394 million).

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110DHA / *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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
374A: *GDF-Medical Products Support and Advanced Concept Development*	525.045	85.628	99.443	92.602	-	92.602	110.382	127.866	139.793	144.031	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. Medical products advanced concept development is managed by the Joint Program Committees (JPCs) in the following areas: 1- Medical simulation and information sciences. 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, quality, and patient safety through improved decision making via training, education, and informatics. Initial candidates will be selected from those funded by medical research sponsors in the Department of Defense, and from external sources such as academia and industry, including efforts funded with prior year Congressional Special Interest funding. 2- Military infectious diseases. This JPC supports the advanced development of systems to rapidly detect pathogens (infectious agents), 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. This JPC supports clinical assessments related to interventions for post-traumatic stress disorder, nutrition and dietary supplementation to promote health and resilience, real-time physiological status monitoring, interventions for hearing loss and tinnitus, enhancement of military family and community health and resilience techniques, validation trials for suicide prevention, and the accomplishment of related field studies with end users. 4- Combat casualty care. This JPC supports clinical trials such as those assessing biomarkers (biological indicators) for traumatic brain injury, and advanced product development related to hemorrhage, extremity trauma, prehospital combat casualty care, and enroute care. 5- Clinical and rehabilitative medicine supports clinical trials related to pain management and regenerative medicine.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: GDF – Medical Product Support and Advanced Concept Development	85.628	99.443	92.602
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 2015 Accomplishments: Medical simulation and information sciences conducted research in two primary research tasks -- medical simulation and health information technology (IT). Under the medical simulation task: Began development on Phase 1 of the Advanced Modular Manikin, a training platform for medical intervention procedures. Phase 1 consists of the development of a core (torso) portion,			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110DHA / *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 2015	FY 2016	FY 2017
which will be used in identifying the mechanical requirements for future peripheral development. In addition, developed a direct observation and automated assessment tool for multiple-casualty scenarios that augments human observations with other measurable parameters. Under the health IT task: Continued coordination on electronic medical information technology research to Warfighter care and mitigate program risk for the Military Health System. Identified options to reduce potential near- and long-term risks associated with IT 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 involved data transmission initiatives, new clinical decision support algorithms, and patient identification issues incorporating patient consent, privacy, and security. Military infectious diseases performed initial optimization of polymerase chain reaction-based assays for malaria, dengue, and chikungunya to be used on the Next Generation Diagnostic System for Combat Support Hospitals. Supported clinical study on skin and soft tissue infection in military trainees at Fort Benning, Georgia. Military operational medicine applied the results of clinical trials to the development of clinical practice guidelines for improved psychotherapies (psychological treatment of mental disorders) for the treatment of post-traumatic stress disorder (PTSD). Continued Veterans Affairs-DoD clinical trials studying the use of pharmaceuticals for the treatment of deployment-related symptoms of PTSD (e.g., improving sleep, reducing nightmares). Continued clinical trials examining the efficacy of a program designed to support families throughout the deployment lifecycle and promote positive behavioral health outcomes. Continued development of an objective, blood-based biomarker assay for PTSD screening. Initiated a multi-service clinical trial for validation of daily psychotherapy sessions for (compressed schedule) PTSD treatment, preliminary to knowledge product dissemination. Validated data from human studies on nutrition and dietary supplements. Continued integration of actionable algorithms into physiologic status monitoring systems based on end-user feedback from field studies. Completed a phase II clinical trial of a potential pharmaceutical intervention for hearing loss and tinnitus in a military training environment. Completed development of a new active and passive hearing protection device that increases situational awareness while reducing risk of injury from impulse noise. Combat casualty care. Hemorrhage: Continued safety study in humans that supported FDA Biologic License Application for a spray-dried plasma product. Supported studies on the prehospital use of plasma for treating patients with traumatic hemorrhage. Initiated clinical studies on the use of tranexamic acid, a drug to help control severe bleeding. Supported clinical trials on a device killing infectious organisms in fresh whole blood collected on the battlefield for transfusion. Neurotrauma: Completed assessment of a Burr Hole Trainer prototype instruct on the proper technique for drilling a cranial burr to relieve intracranial pressure. Assessed the effectiveness of non-invasive neuroassessment devices/tools for detecting mild TBI. Evaluated two			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110DHA / *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 2015	FY 2016	FY 2017

traumatic brain injury (TBI) biomarker point-of-care devices in conjunction with a biomarker-specific diagnostic assay system. Continued to develop the Biomarker Assessment for Neurotrauma Diagnosis and Improved Triage System) diagnostic. Supported clinical trials on the Portable Neuromodulation Stimulator as a treatment for mild TBI-associated balance disorders. Continued testing/validation and system refinement of the smooth pursuit eye tracking device for the detection of mild TBI. Continued safety, effectiveness, and dose studies of NNZ-2566 in patients with moderate to severe TBI and began enrollment of mildly affected subjects. Pre-hospital and Enroute Care: Advanced the development of a communication/ data transfer system to provide advanced intensive care capabilities to first responders and frontline Military Treatment Facilities.

Clinical and rehabilitative medicine continued clinical trials for regenerative medicine-based approaches for restoration of limb (arms and legs) and digit (fingers, thumbs and toes) salvage. Transitioned management of Sufentanil Nanotab, a battlefield pain management product, to the Advanced Developer to initiate Phase 3 FDA-regulated clinical trials.

Solicited applications for tri-Service translational research at Military Treatment Facilities with awards pending. Applications were requested to focus on advanced concept development efforts in combat casualty care, operational medicine, infectious diseases, clinical and rehabilitative medicine, and/or health services research including health care informatics, and interventional studies regarding access to care and health care disparities.

FY 2016 Plans:

Medical simulation and information sciences conducts research in two primary research tasks -- medical simulation and health information technology (IT). Under the medical simulation task: Continue the Advanced Modular Manikin Phase 1 development effort, a core (torso) portion for use in the training of medical intervention procedures. In addition, assess the value of stress inoculation simulation training methodologies, technologies, and techniques to protect Warfighters from deployment related psychological stresses and trauma. Conduct a preliminary assessment of a 3-D printer and/or fabricating synthetic material fibers to simulate ophthalmic tissues. Under the health IT task: Continue efforts towards filling theater information technology research gaps such as capturing and transmitting point of injury data, transitioning theater health information into Department of Defense and Veterans Affairs health systems, and resolving technology issues related to a theater environment.

Military infectious diseases continue optimization on the malaria, dengue, and chikungunya infectious disease polymerase chain reaction-based assay panel to be used on the Next Generation Diagnostic System. Continue to support skin and soft tissue infection clinical study in military trainees at Fort Benning, Georgia. These studies are in alignment with National Strategy for Combating Antibiotic Resistance.

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Military operational medicine continues the development and validation of lower extremity injury risk prediction models targeted towards quantifying fitness for duty in military training and operational populations, the evaluation of biofeedback sensors as tools to validate injury models, and mobile technology designed to reduce lower back pain in the military. Collaborate with Defense Center of Excellence (DCoE) to develop clinical practice guidelines for improved psychotherapies (psychological treatment of mental disorders) for post-traumatic stress disorder (PTSD), for the use of pharmaceuticals for the treatment of deployment-related symptoms of PTSD (e.g., improving sleep and reducing nightmares), and interventions related to alcohol and substance abuse and suicide prevention. Complete a study evaluating the efficacy of an intervention designed to support families and Service members throughout the deployment lifecycle. Continue development of an objective, blood-based PTSD biomarker assay through Advanced Development. Continue advanced development of pharmaceutical interventions for hearing loss and tinnitus. Continue studies to validate clinical protocols for the use of nutritional strategies and dietary supplements and confirm safety and efficacy. Develop gender-specific and gender-neutral standards that apply across garrison and combat operations to reduce injuries in the total force. Support the refinement of algorithms to reliably predict core body temperature and estimate physiological work strain from real-time non-invasive measurements (e.g., skin temperature and heart rate) into a physiological health status monitoring system for the end user. Combat casualty care. Hemorrhage: Complete safety study in humans that support FDA Biologic License Application for a spray-dried plasma product and initiate preparation for a larger safety and effectiveness study. Continue clinical studies on the pre-hospital use of plasma for treatment of patients with traumatic hemorrhage. Continue clinical studies on the use of tranexamic acid, a drug to help control severe bleeding. Continue clinical trials and analyze data on a device killing infectious organisms in fresh whole collected on the battlefield for transfusion. Begin clinical trials on an intracavitary hemostatic product to control bleeding (Wound Stasis System). Transition valproic acid, a drug that has demonstrated the potential to prolong patient survival following severe hemorrhage, from the Navy science and technology program into advanced development; ; ; continue initial safety studies in normal volunteers and begin effectiveness studies in patients. Transition Ethinyl Estradiol 3 Sulfate, a drug for low-volume resuscitation of patients with hemorrhagic shock following severe bleeding after trauma, from the Defense Advanced Research Projects Agency (DARPA) into advanced development and begin preparation for clinical trials. Start clinical studies in the use of extended shelf life platelets for transfusion.. Neurotrauma: Continue studies advancing the development novel TBI diagnostics. Continue the advanced development of novel diagnostics for mild TBI; begin clinical trials on a point-of-care tool for diagnosing TBI in conjunction with the validation of a biomarker specific assay system. Validate pivotal clinical trial results from the Portable Neuromodulation Stimulator (PONS) as a treatment for mild TBI-associated balance disorders. Perform interim data analysis of the smooth pursuit eye tracking device for the detection of mild TBI and continue to recruit subjects. Finish recruitment and patient follow-up of safety, effectiveness, and dose studies of NNZ-2566 in patients with moderate to severe TBI, analyze data, and prepare final report. Continue recruitment of mildly affected TBI subjects for of safety, effectiveness, and dose trials of NNZ-2566. Continue to develop a clinically useful classification system for TBI, across the spectrum of severity. Begin research to			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110DHA / *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 2015	FY 2016	FY 2017
fill knowledge gaps in the treatment of casualties with moderate to severe TBI from the point of injury and during transport, in order to mitigate the progression of TBI and secondary brain injury. Forward Surgical and Critical Care and Enroute Care is advancing the development of a system to provide advanced intensive care capabilities, and data collection systems for battlefield point of injury, mainly in the field of decision assist tools using a physiological opened loop system. Treatments for Tissue Injury continues to evaluate and promote the development of technologies with the potential to be transitioned from the Peer Reviewed Orthopedic Research Program. Clinical and rehabilitative medicine initiates clinical trials to support evidence-based use of FDA-approved drugs to eliminate heterotopic ossification, a process by which bone tissue forms outside the skeleton. Support Phase 3 FDA-regulated clinical trial enrollment for Sufentanil Nanotab, a battlefield pain management product, and submit a New Drug Application to the FDA. Start FY 2015 tri-Service translational research studies at Military Treatment Facilities recommended for funding to include the recruitment, screening, and enrollment of patients. These efforts focus on advanced concept development efforts in combat casualty care, operational medicine, infectious diseases, clinical and rehabilitative medicine, and/or health services research. ***FY 2017 Plans:*** Medical simulation and information sciences will conduct research in two primary research tasks: Medical Simulation and Health Information Technology (IT). Under the Medical Simulation task: Will initiate studies to optimize individual learning/optimal timing of an individual's insertion into military medical teams in order to improve the quality of care and patient safety. Will evaluate current augmented reality (AR) capabilities, assess AR capability gaps related to military medical applications as compared to current industry practices, and explore anticipated future AR needs. Under the Health IT task: Will implement options to reduce risk associated with the modernization of existing Military Health System legacy systems in support of Healthcare Management System Modernization Electronic Health Record implementation and future integrated MHS applications. Will prototype, test, and support the transition of technology products and services to address operational medicine health information technology capability gaps, such as capturing and transmitting point of injury data to improve quality of care and patient safety. Will incorporate Theater Operational Medicine health information into Department of Defense and Veterans Affairs global health systems to support the Precision Medicine Initiative. Military infectious diseases will complete optimization and prepare for clinical validation of infectious disease (malaria, dengue, chikungunya) polymerase chain reaction-based assay panel to be used on the Next Generation Diagnostic System. Will complete skin and soft tissue infection clinical study in military trainees at Fort Benning, GA, and apply results towards the prevention and treatment of skin and soft tissue infections. Will test and evaluate promising antibacterials, solicit proposals focused on advanced development of antibacterials. These studies will support the National Strategy for Combating Antibiotic Resistance.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110DHA / *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 2015	FY 2016	FY 2017
Military operational medicine will validate lower extremity injury models using biofeedback sensors. Will complete a study testing the efficacy of omega-3 supplementation to prevent and/or reduce suicide behaviors. Will conduct clinical studies to evaluate the association between diet composition and health status. Will perform studies to evaluate the efficacy of a dietary intervention to improve Warfighters' omega-3 fatty acid status in a garrison feeding environment. Will begin to conduct studies aimed at optimizing suicide prevention interventions. Will continue objective, blood-based PTSD biomarker screening assay development with an industry partner. Will initiate psychopharmacologic study(s) via a RFP process following State-of-the-Science for PTSD Psychopharmacologic Intervention Target meeting to be held in late spring of 2016. Will begin to evaluate nutritional and other interventions that may prevent and/or minimize musculoskeletal injury in female Warfighters. Will transition a predictive model measuring thermal work strain using non-invasive measurements (e.g., skin temperature and heart rate) and energy consumption for military tasks to a physiological status monitoring system. Will continue to test and refine algorithms to be embedded into the physiologic status monitor system that will provide actionable physiological health status information in real-time to the Service member and unit leader. Will begin Phase III clinical trials of pharmaceutical interventions for hearing loss and tinnitus. Combat casualty care. Hemorrhage: Will initiate safety, effectiveness, and dose studies supporting FDA Biologic License Application for a spray-dried plasma product. Will complete the clinical studies on the pre-hospital use of plasma for traumatic hemorrhage. Will complete clinical studies on the use of tranexamic acid, a drug to help control severe bleeding. Will continue clinical trials on an intracavitary hemostatic product to control bleeding (Wound Stasis System). Will complete safety/initial effectiveness studies in humans, and will continue safety, effectiveness, and dose studies on valproic acid as part of an assessment of its ability to prolong patient survival after severe hemorrhage. Will complete safety/initial effectiveness studies in humans using Ethinyl Estradiol 3 sulfate, a drug for low volume resuscitation of patients with hemorrhagic shock following severe bleeding after trauma, and support ongoing clinical trials assessing the ability of similar low volume resuscitation drugs. Will continue clinical trial to extend the shelf life of platelets in theatre. Neurotrauma: will pursue studies advancing the development of traumatic brain injury (TBI) biomarker detection tools with primary objective of monitoring progression of injury condition with treatment. Will continue clinical trials on a point-of-care tool for diagnosing TBI in conjunction with the validation of a bio-marker specific assay system and downselect one device for use in the forward operating environment. Will complete recruitment of mildly affected TBI subjects for of safety, effectiveness, and dose trials of NNZ-2566, analyze results, and prepare final report. Will identify and clinically relevant TBI endpoints, across the spectrum of injury severity, to support regulatory approvals and applicability for use in research tests and clinical trials with the ultimate goal of improving clinical trial design and accelerating FDA approval. Continue studies to advance knowledge of treatment and management of casualties with moderate to severe TBI from the point of injury and during transport in order to mitigate the progression of TBI and secondary brain injury. Forward Surgical and Critical Care and Enroute Care will advance a system to provide advanced intensive care capabilities such as the implementation of automated systems to enroute care clinicians to include an understanding of the appropriate provider skill levels involved and			

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Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110DHA / *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 2015	FY 2016	FY 2017
the impact on patient outcomes. Will start testing decision assist tools using a physiological closed loop system. Specifically, an intravenous anesthesia closed loop device will be moving through the FDA approval process in the next 3-5 years. Treatments for Tissue Injury will continue to evaluate and promote the development of technologies with the potential to be transitioned from the Peer Reviewed Orthopedic Research Program. Clinical and rehabilitative medicine will continue efforts in the areas of military-relevant pain management and regenerative medicine. Complete Phase 3 FDA-regulated clinical trials for Sufentanil Nanotab, a battlefield pain management product. Implement inter-agency clinical trials on individualized (precision medicine), integrative pain management for Wounded Warriors. Continue FY 2015 efforts, and begin FY 2016 tri-Service translational research studies at Military Treatment Facilities recommended for funding. Applications will be solicited to focus on advanced concept development efforts in combat casualty care, operational medicine, infectious diseases, clinical and rehabilitative medicine, and/or health services research.			
Accomplishments/Planned Programs Subtotals	85.628	99.443	92.602

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 Food and Drug Administration approval and Environmental Protection Agency registration.

E. Performance Metrics

Research is evaluated through In-Progress Reviews, DHP-sponsored review and analysis meetings, quarterly and annual status reports, and is subject to Program Office or Program Sponsor Representatives progress reviews to ensure that milestones are met and deliverables are transitioned on schedule. In addition, Integrated Product Teams, if established for a therapy or device, will monitor progress in accordance with the DoD Instruction 5000 series on the Operation of the Defense Acquisition System. 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 7.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0604110DHA / *Medical Products Support and Advanced Concept Development*	Project (Number/Name) 400Z / *CSI - Congressional Special Interests*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
400Z: *CSI - Congressional Special Interests*	116.933	60.783	72.075	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The FY 2015 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 2015	FY 2016
Congressional Add: 427A - Traumatic Brain Injury / Psychological Health	20.000	21.375
FY 2015 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 combat-related 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 TBI/PH research program are to support projects aligned with the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service members, and Military Families; address Congressional intent; enable significant research collaborations; and complement ongoing Department of Defense (DoD) efforts to ensure the health and readiness of our military forces by improving upon and optimizing the standards of care for PH and TBI in the areas of prevention, detection, diagnosis, treatment, and rehabilitation. A Broad Agency Announcement application for the Military Suicide Research Consortium was recommended for funding and will build upon prior work to deliver state-of-the-art, evidence-based, effective suicide prevention tools and interventions to the DoD. Among the identified high-priority areas of TBI that received FY 2015 funds are the Federal Interagency TBI Research Database, advances in neuro-imaging and biomarker detection capabilities, prevention of the progression of TBI, and studies to improve the detection of mild TBI.		
FY 2016 Plans: This Congressional Special Interest initiative is for Traumatic Brain Injury / Psychological Health.		
Congressional Add: 441A - Joint Warfighter Medical Research Program	20.000	20.000
FY 2015 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		

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110DHA / *Medical Products Support and Advanced Concept Development*	**Project (Number/Name)** 400Z / *CSI - Congressional Special Interests*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016
medical research in military infectious diseases, combat casualty care, military operational medicine, medical simulation and 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 pre-application and full application for the next level of effort. The scientific peer review was in May 2015 and programmatic review occurred in June 2015. Awards will be completed by September 2016. ***FY 2016 Plans:*** This Congressional Special Interest initiative is for Joint Warfighter Medical Research Program.		
Congressional Add: 455A - Therapeutic Service Dog Training Program (USUHS) ***FY 2015 Accomplishments:*** This Congressional Special Interest research initiative is for Therapeutic Service Dog Training Program (USUHS). ***FY 2016 Plans:*** No Funding Programmed. Therapeutic Service Dog Training Program transferred to DHP O&M Account.	3.000	0.000
Congressional Add: 464A – Program Increase: Restore Core Research Funding Reduction (GDF) ***FY 2015 Accomplishments:*** FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in PE 0604110. Funds supported advanced development efforts for medical simulation and information sciences, military operational medicine, and combat casualty care (Project 374A). ***FY 2016 Plans:*** FY 2016 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in PE 0604110. Funds supported advanced development efforts for medical simulation and information sciences, military operational medicine, and combat casualty care (Project 374A).	17.783	30.700
Congressional Adds Subtotals	60.783	72.075

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110DHA / *Medical Products Support and Advanced Concept Development*	**Project (Number/Name)** 400Z / *CSI - Congressional Special Interests*

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 2017 Defense Health Agency			Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110DHA / *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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
434A: *Medical Products Support and Advanced Concept Development (AF)*	6.909	0.000	4.000	4.000	-	4.000	4.000	4.000	4.000	4.080	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 transition of those technologies to operators in the field. Development, Modification and Enhancement projects will emphasize technologies supporting Expeditionary Medicine, Human Performance, En-Route Care, Force Health Protection and Operational Medicine. Funding provides critical flexibility to make and act on materiel 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. Program 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.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: Medical Products Support and Advanced Concept Development (AF)	0.000	4.000	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 2015 Accomplishments: Awarded effort to refine and commercialize the Cardiovascular Sonospectrographic Analyzer (CSA). Conducted developmental engineering activities to ready the device for inclusion in advanced clinical trials and guiding it to the FDA regulatory approval pathway. Began evaluation of developing a next generation multichannel infusion pump via a modified-commercial 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:			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110DHA / *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 2015	FY 2016	FY 2017
Award effort to begin development of a next generation multi-channel infusion pump via a request for proposal (RFP) approach to provide medics with the ability to rapidly and safely deliver multiple drugs and therapeutics to DoD wounded, ill and injured personnel in the field, in the air and while awaiting evacuation to definitive care. Will also begin transitioning of 59 MDW project for aortic hemostasis and resuscitation balloon treatment for combat casualty care under the Expeditionary Medicine portfolio. We are reaching a point where an Advanced Development investment needs to be made to get a catheter with packaging and inserts for FDA approval and clinical trials. 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. ***FY 2017 Plans:*** Continue development and refinement of the multichannel infusion pump to enable medics in the field to provide multiple drugs and therapeutics simultaneously to DoD wounded, ill and injured personnel in the field, in the air and while awaiting evacuation to definitive care. Will transition 59 MDW project for aortic hemostasis and resuscitation balloon treatment for combat casualty care under the Expeditionary Medicine portfolio in preparation of developing a prototype field catheter with packaging and inserts for eventual FDA approval and pending clinical trials. Evaluation of various technologies to assess operator physiological health and performance, modifiable for field use. Evaluation of candidate technologies to assess airmen environmental hazards. Evaluation of various technologies to assess operator physiological health and performance, modifiable for field use. Evaluation of candidate technologies to assess airmen environmental hazards.			
Accomplishments/Planned Programs Subtotals	0.000	4.000	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 manufacturing 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. Will also utilize the Request for Proposal (RFP) process managed by the Life Cycle Management Center LCMC and awarded by the Air Force Aeronautical Systems Center, Wright-Patterson AFB.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Defense Health Agency		Date: February 2016
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0604110DHA / *Medical Products Support and Advanced Concept Development*	**Project (Number/Name)** 434A / *Medical Products Support and Advanced Concept Development (AF)*

E. Performance Metrics

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

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