Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
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 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
Total Program Element	795.298	172.104	96.602	99.039	-	99.039	117.529	128.055	132.331	142.252	Continuing	Continuing
374A: *GDF-Medical Products Support and Advanced Concept Development*	610.673	96.029	92.602	95.039	-	95.039	113.529	124.055	128.251	138.090	Continuing	Continuing
400Z: *CSI - Congressional Special Interests*	177.716	72.075	0.000	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	4.000	4.000	4.000	-	4.000	4.000	4.000	4.080	4.162	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force - 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 (MHS), 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 Department of Defense and multiagency 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, improving deployment military occupational and environmental exposure monitoring, and the strengthening of the scientific basis for decision-making in patient safety and quality performance in the MHS. 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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The Army Medical Command received FY 2016 DHP Congressional Special Interest (CSI) research funding focused on Peer-Reviewed Traumatic Brain Injury/ Psychological Health, Joint Warfighter Medical Research, and Core Research funding. 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 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total
Previous President's Budget	103.443	96.602	107.382	-	107.382
Current President's Budget	172.104	96.602	99.039	-	99.039
Total Adjustments	68.661	0.000	-8.343	-	-8.343
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	72.075	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-3.414	-			
• Cancer Moonshot	-	-	-8.343	-	-8.343

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2016	FY 2017
Project: 400Z: *CSI - Congressional Special Interests*		
Congressional Add: *427A - Traumatic Brain Injury / Psychological Health*	21.375	0.000
Congressional Add: *441A - Joint Warfighter Medical Research Program*	20.000	0.000
Congressional Add: *455A - Therapeutic Service Dog Training Program (USUHS)*	0.000	0.000
Congressional Add: *464A – Program Increase: Restore Core Research Funding Reduction (GDF)*	30.700	0.000
Congressional Add Subtotals for Project: 400Z	72.075	0.000
Congressional Add Totals for all Projects	72.075	0.000

Exhibit R-2, RDT&E Budget Item Justification: FY 2018 Defense Health Agency	Date: May 2017
Appropriation/Budget Activity 0130: *Defense Health Program* / BA 2: *RDT&E*	**R-1 Program Element (Number/Name)** PE 0604110DHA / *Medical Products Support and Advanced Concept Development*

Change Summary Explanation

FY 2016: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) 0604110-Medical Products Support and Advanced Concept Development (-$72.075 million) to DHP RDT&E, PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+$72.075 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).

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).

FY 2018: Realignment from GDF DHP RDTE PE 0604110-Medical Products Support and Advanced Concept Development (-$8.343 million) to DHP RDTE PE 0603115-Medical Technology Development, Uniformed Services University, Applied Proteogenomics Organization Learning and Outcomes (APOLLO) Consortium (+$8.343 million) so support the White House-directed Cancer Moonshot initiative.

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency			Date: May 2017
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 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
374A: *GDF-Medical Products Support and Advanced Concept Development*	610.673	96.029	92.602	95.039	-	95.039	113.529	124.055	128.251	138.090	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force -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- The Medical Simulation and Information Sciences 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. 2- The Military Infectious Diseases 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- The Military Operational Medicine 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 JPC supports clinical trials such as those assessing biomarkers (biological indicators) for Traumatic Brain Injury (TBI), and advanced product development related to hemorrhage, extremity trauma, pre-hospital combat casualty care, and en route care. 5- Clinical and Rehabilitative Medicine JPC supports clinical research related to pain management and regenerative medicine.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Title: GDF – Medical Product Support and Advanced Concept Development	96.029	92.602	95.039
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 2016 Accomplishments: Medical simulation and information sciences conducted engineering and manufacturing development in two primary research tasks -- medical simulation and health information technology and informatics (HITI). Under the medical simulation task: Initiated further development of the Advanced Modular Manikin Core effort, focusing on the development of standardized connectors so that curricula specific peripherals could be attached. Medical Simulation also started development of a proof-of-concept			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
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 2016	FY 2017	FY 2018
task performance assessment tool that incorporates personality and emotional state as determinant components to predict healthcare provider performance during combat casualty care scenarios. Under the HITI task: Began to develop the Digital Biobank prototype which informed the technical, storage, and data policy requirements for DHA Precision Medical and Genomic data integration with MHS Genesis system. Shifted HITI Research focus away from garrison Infrastructure and data management and toward addressing theater/operational medicine information technology research gaps such as capturing and transmitting point of injury data, hands-free data entry for warfighters, aiding DoD stakeholders and in particular military medically related program offices in further defining requirements for the Joint Operational Medical Information System (JOMIS). Revised HITI research roadmap to refine and focus the program of research to information technologies and informatics to support theater and operational medicine. Conducted research product transition efforts ensuring seamless transition of research products to DoD/ VA/Commercial organizations. Worked closely with Department of Veterans Affairs Chief of Informatics for a healthcare data interoperability proof of concept study on Linked Data using JSON (the underlying capability in Bing, Google, Amazon and other prominent web offerings) allowing visibility of data to VA and DoD stakeholders. Military infectious diseases continued optimization of a malaria, dengue, chikungunya, and leptospirosis nucleic acid-based assay panel for the Next Generation Diagnostic System. Continued to support a skin and soft tissue infection clinical study in military trainees at Fort Benning, Georgia. This study is aligned with the National Strategy for Combating Antibiotic Resistance. Military operational medicine continued the evaluation and validation of lower extremity injury risk prediction models targeted towards quantifying fitness for duty in military training and operational populations, biofeedback sensors for use as tools to validate injury models, and mobile technology designed to reduce lower back pain in the military. Collaborated with Defense Center of Excellence to develop clinical practice guidelines for: improved psychotherapies (psychological treatment of mental disorders) for post-traumatic stress disorder (PTSD), 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. Completed a study evaluating the efficacy of an intervention designed to support families and Service members throughout the deployment lifecycle. Continued the advanced development of an objective, blood-based PTSD biomarker assay. Continued the advanced development of pharmaceutical (drug) interventions for hearing loss and tinnitus. Continued the validation of clinical protocols that assess the use of nutritional strategies and dietary supplements. Developed gender-specific and gender-neutral standards that apply across garrison and combat operations that are focused on reducing injuries in the total force. Supported the refinement of algorithms to predict core body temperature and estimate physiological work strain from real-time non-invasive measurements (e.g., skin temperature and heart rate) that will be integrated into a physiological health status monitoring system.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Combat casualty care hemorrhage and resuscitation research: Completed an initial FDA safety study in humans in support of a FDA Biologic License Application for a spray-dried plasma product; initiated preparation for a larger safety and effectiveness study. Continued clinical studies on the prehospital use of plasma for treatment of patients with traumatic hemorrhage. Continued clinical studies on the use of tranexamic acid, a drug to help control severe bleeding. Continued clinical trials and analyzed research data on a device for killing infectious organisms in fresh whole blood; device will reduce the risk of transmission of pathogens (viruses, bacteria, parasites) and Graft Versus Host Disease (GVHD) in whole blood collected and transfused on the battlefield. Transitioned valproic acid, a drug with the potential to prolong patient survival following severe hemorrhage, from the Navy science and technology program into advanced development; continued initial safety studies in normal volunteers and began effectiveness studies in patients. Transitioned 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 a joint development program and began preparation for clinical trials. Started clinical studies on extending the shelf life of platelets used for transfusion in theatre. Combat casualty care neurotrauma research Identified advanced technologies/devices that will enable first responders to more precisely triage, assess and monitor severe Traumatic Brain Injury (TBI) casualties in a far forward environment. Continued advanced development of novel biomarker-based TBI diagnostics and point of care diagnostic devices. Completed clinical validation of a smooth pursuit eye tracking device for the treatment of mild TBI associated nystagmus (cross eye) and received FDA clearance. In subjects with moderate to severe TBI, demonstrated no difference in patient and control groups in safety and effectiveness studies of NNZ-2566. In subjects with mild TBI, halted recruitment for safety, effectiveness, and dose trials of NNZ-2566 due to lack of effectiveness. Combat casualty care forward surgical and critical care and en route care research: Continued development of a system providing advanced en route intensive care capabilities. Continued development of data collection systems for battlefield point of injury, mainly in the field of decision assist tools using a physiological opened loop system. Combat casualty care treatments for tissue injury research: Continued 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 initiated clinical trials examining the use of evidence-based FDA-approved drugs to eliminate heterotopic ossification, a process by which bone tissue forms outside the skeleton. Expanded FDA-regulated clinical trial enrollment for Sufentanil Nanotab, a battlefield pain management product; submitted a New Drug Application to the FDA. Tri-Service Translational Research continued FY 2014 and started FY 2015 research studies at Military Treatment Facilities recommended for funding to include the recruitment, screening, and enrollment of patients. These efforts focused on advanced concept development efforts in combat casualty care, operational medicine, infectious diseases, clinical and rehabilitative			

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
medicine, and health services research. For FY 2016, applications focused on precision medicine are being solicited from intramural organizations. ***FY 2017 Plans:*** Medical simulation and information sciences conducts engineering and manufacturing development in two primary research tasks: medical simulation and health information technology (HITI). Under the medical simulation task: Initiating studies designed to optimize individual learning/optimal timing of an individual's insertion into military medical teams to improve the quality of care and patient safety. Beginning research to develop the underlying architecture to support the development of the future Joint Evacuation and Transport Simulation (JETS) System of Systems. The Gesture Interface effort is further developing candidate interface controls for enhancements to provide for more natural and intuitive medical simulation user interface plus conduct preliminary testing and evaluation of prototyped interface controls. Continues work on the physiology engine to refine algorithms in the current beta version and to increase the content to comply with government needs. Initiating work on defining and validating learning strategies that foster inter-professional team-based learning during the early stages of medical skills training. Medical Simulation and Information Science is updating several serious medical games and transitioning them to the advanced developer. Under the HITI task: conducting research in four topic areas that support Theater and Operational Medicine to include Medical Command and Control: Leading edge options for tracking logistics items across theater using sensors or other novel approaches being used in industry, Synchronous/asynchronous theater/operational medicine approaches for teleconsultation and telementoring, and hands-free electronic record data entry. In accordance with the FY16 NDAA Section 217 above topics are being researched to reduce risk associated with the modernization of existing Military Health System legacy systems in support of Defense Health System Modernization for MHS Genesis and the Joint Operational Medical Information System (JOMIS) MAIS. Conducting prototyping, testing, and supporting 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 in a hands-free manner more usable for warfighters to improve quality of care and patient safety. Continue Linked Data proof of concept study on healthcare data interoperability between the DoD and VA. Continue Digital Biobank research to share, store and utilize genomic data with Department of Defense and Veterans Affairs in support of the Precision Medicine Initiative and theater/operational medicine needs. Military infectious diseases is continuing optimization studies and preparing for clinical validation studies for a malaria, dengue, chikungunya, and leptospirosis nucleic acid-based assay panel to be used on the Next Generation Diagnostic System. Continuing a skin and soft tissue infection clinical study in military trainees at Fort Benning, GA; applying the results towards the prevention and treatment. Initiating a clinical study focusing on the development of a vaccine against S.aureus (bacteria). These studies support the National Strategy for Combating Antibiotic Resistance.			

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Military operational medicine is continuing the validation of lower extremity injury models using biofeedback sensors. Conducting studies aimed at optimizing suicide prevention interventions. Continuing the advanced development of an objective, blood-based for post-traumatic stress disorder (PTSD) biomarker screening assay development with an industry partner. Preparing for the initiation of a clinical study assessing pharmaceutical (drug) interventions for hearing loss and tinnitus. Completing a study testing the efficacy of omega-3 supplementation to prevent and/or reduce suicide behaviors. Conducting clinical studies to evaluate the association between diet composition and health status. Performing studies to evaluate the efficacy of a dietary intervention to improve Warfighters' omega-3 fatty acid status in a garrison feeding environment. Initiating the evaluation of nutritional and other interventions that may prevent and/or minimize musculoskeletal injury in female Warfighters. Transitioning 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. Testing and refining algorithms that provide actionable physiological health status to the Service member and unit leader with the goal of integration into a physiologic status monitor system. Combat casualty care hemorrhage and resuscitation research: Initiating expanded safety, effectiveness, and dose studies in humans in support of a FDA Biologic License Application for a spray-dried plasma product. Completing clinical studies on the pre-hospital use of plasma for traumatic hemorrhage. Completing clinical studies on the use of tranexamic acid, a drug to help control severe bleeding. Initiating clinical studies on the Wound Stasis System, a product to control non-compressible hemorrhage within a body cavity. For valproic acid, a drug with the potential to prolong patient survival following severe hemorrhage, completing initial safety studies in normal volunteers and initiating safety, effectiveness, and dose studies in patients. Initiating safety studies in humans using Ethinyl Estradiol 3 sulfate, a drug for low volume resuscitation of patients with hemorrhagic shock following severe bleeding after trauma. Continuing clinical studies on extending the shelf life of platelets used for transfusion in theatre. Combat casualty care neurotrauma research is initiating studies to further develop devices to enable first responders to more precisely triage, assess and monitor moderate and severe Traumatic Brain Injury (TBI) casualties in a far forward environment. Continuing advanced development of novel blood-based biomarker diagnostics for TBI to be used in the hospital and at the point of care to enable monitoring of progression of injury and efficacy of treatment. Validating clinical recommendations for the management of dizziness in mild-TBI patients that includes a comprehensive review and analysis of TBI management and patient outcomes from OIF/ORF. Investigating the utility of transcranial Doppler for the detection of dysfunction in autoregulation of the middle cerebral artery blood flow velocity in mild TBI. Combat casualty care forward surgical and critical care and en route care research: Continuing development of a system providing advanced en route intensive care capabilities such as automated systems; involves studying the impact on patient care outcomes and the provider skill levels required. Initiating assessment of decision assist tools for application on a physiological closed loop system; specifically, an intravenous anesthesia closed loop device. Combat care treatments for tissue injury research: continuing to evaluate and promote the development of technologies with the potential to be transitioned from the Peer Reviewed Orthopedic Research Program.			

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Clinical and rehabilitative medicine is continuing efforts in the areas of military-relevant pain management. Completing advanced clinical trials for Sufentanil Nanotab, a battlefield pain management product. Implementing inter-agency clinical trials on individualized (precision medicine), integrative pain management for Wounded Warriors. Conducting clinical research into protocols for reduction of immunosuppressive drug regimens following composite tissue transplantation. Conducting clinical trials for skin regeneration and muscle regeneration therapies following burn injuries. Tri-Service Translational Research is continuing FY 2014 and 2015 efforts, and beginning FY 2016 tri-Service translational research studies at Military Treatment Facilities and intramural organizations recommended for funding. Applications are being solicited to focus on advanced concept development efforts in combat casualty care, operational medicine, infectious diseases, and clinical and rehabilitative medicine. ***FY 2018 Plans:*** Medical simulation and information sciences will conduct engineering and manufacturing development in two primary research tasks: medical simulation and health information technology (HITI). Under the medical simulation task: Will complete work on the Advanced Modular Manikin core (torso). Will initiate development of low and mid fidelity peripherals that attach or insert onto the core manikin. Research will continue to develop the underlying architecture to support the development of the future Joint Evacuation and Transport Simulation (JETS) System of Systems. Research will continue on the integration of virtual standardized patients and virtual technology applications to represent a broader range of burn training scenarios with increased physiological responsiveness to not only the user's actions but also further environmental exposure. HITI will conduct proof of concept demonstrations for Theater and Operational Medicine, to include Medical Command and Control, Leading edge options for tracking logistics items across theater using sensors or other novel approaches being used in industry, Synchronous/ asynchronous theater/operational medicine approaches for teleconsultation and telementoring, and hands-free electronic record data entry. These topics are being studied to reduce risk in accordance with FY16 NDAA Section 217. Will demonstrate and define medical device interoperability requirements for use of medical devices and patient data in a closed loop to deliver medical care during prolonged field care scenarios in collaboration with FDA, NIST, NIH and other Federal Agencies and industry partners. Will continue efforts to transition technology products and services to external stakeholders in order 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 advance Digital Biobank research to store, protect, analyze and share genomic data with Department of Defense and Veterans Affairs in support of the Precision Medicine Initiative. Military infectious diseases will complete optimization studies and continue clinical validation studies for a malaria, dengue, chikungunya, and leptospirosis nucleic acid-based assay panel to be used on the Next Generation Diagnostic System. Will complete a skin and soft tissue infection clinical study in military trainees at Fort Benning, GA, and will apply results towards the			

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
prevention and treatment. Will prototype diagnostic devices and assay performance in an operational environment to evaluate the potential field application of the assays/device to detect nucleic acids, proteins and/toxins. Will prospectively collect and evaluate standardized infection data including therapy, microbiology, and clinical outcomes of combat-related injuries across treatment facilities. These studies will support the National Strategy for Combating Antibiotic Resistance. Will support adenovirus vaccine production modernization efforts. Military operational medicine will conduct advanced development on a real-time physiological status monitor system. Will initiate development of monitors detecting oxygen toxicity in combat and training environments. Will advance technologies supporting the Integrated Soldier Sensor System to include sensor(s) quantifying the impact of energy expenditure and physical load on Soldier Service members' performance, improved metabolic monitoring in training environments, and the assessment of cognitive status in operational settings via the monitoring of fatigue and nutritional status. Will initiate a clinical study for pharmaceutical (drug) interventions for noise induced hearing loss. Will optimize and validate brief cognitive behavior therapies for decreasing suicide. Will develop guidance regarding calcium and vitamin D intake to support optimal bone health during training. Combat casualty care hemorrhage and resuscitation research: Will continue the expanded safety, effectiveness, and dose studies in humans in support of a FDA Biologic License Application for a spray-dried plasma product. Will continue clinical studies on the Wound Stasis System, a product to control non-compressible hemorrhage within a body cavity. Will pursue knowledge related to new technologies and techniques for the treatment of non-compressible torso hemorrhage on the battlefield. Will complete the clinical trials/clinical effectiveness study and data analysis on a device for killing infectious organisms in fresh whole blood and will initiate preparation of various pre-market application modules for FDA clearance; device will reduce the risk of transmission of pathogens (viruses, bacteria, parasites) and Graft Versus Host Disease (GVHD) in whole blood collected and transfused on the battlefield. Will continue clinical studies supporting FDA licensure of valproic acid, a drug to prolong survival following severe hemorrhage. Continuing clinical studies on extending the shelf life of platelets used for transfusion in theatre. Combat casualty care neurotrauma research will further develop devices to enable first responders to more precisely triage, measure and monitor physiological parameters relevant to the progression of moderate and severe Traumatic Brain Injuries in the battlefield. The program will also leverage data from Combat Operations to improve management of TBI by correlating injury events and medical records. Combat casualty care forward surgical and critical care and en route care research: Will continue advanced development of technology that electronically captures, records, and transmits combat casualty clinical data during evacuation to higher echelons of care. Will continue advanced development efforts towards increment 1 production of an advanced medical monitoring capability, which emphasizes algorithms for early hemorrhage detection. Will continue studies pursuing a trauma indication for restoring blood flow in cases of damaged blood vessels. Will support knowledge studies related to multi-functional resuscitation fluids, the translation of joint En Route care research, safe patient handoffs, and life support in a pre-hospital setting.			

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
Clinical and rehabilitative medicine will continue efforts in the areas of military-relevant pain management to include the validation of non-pharmacologic approaches to managing pain. Will continue regenerative medicine to include validation of strategies to modulate the immune system in order to reduce the need for lifelong immunosuppression following transplantation. Will expand advanced clinical trials for oral transmucosal Ketamine, a fast acting, easily dispensed oral battlefield pain management product to assess its effectiveness in managing pain after surgery. Tri-Service Translational Research will continue FY 2015 and FY 2016 tri-Service translational research studies at Military Treatment Facilities and intramural organizations 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.			
Accomplishments/Planned Programs Subtotals	96.029	92.602	95.039

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 is evaluated through In-Progress Reviews, Defense Health Program-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: FY 2018 Defense Health Agency			Date: May 2017
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 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
400Z: *CSI - Congressional Special Interests*	177.716	72.075	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The FY 2016 Defense Health Program 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 2016	FY 2017
Congressional Add: 427A - Traumatic Brain Injury / Psychological Health	21.375	0.000
FY 2016 Accomplishments: This Congressional Special Interest initiative provided funds for research aimed to prevent, mitigate, and treat the effects of combat-relevant traumatic stress and combat-related traumatic brain injury (TBI) on the function, wellness, and overall quality of life, including interventions across the deployment lifecycle for Service members and Veterans, as well as their family members, caregivers, and communities. Key priorities of the FY 2016 Traumatic Brain Injury and Psychological Health (TBI/PH) Research Program were supporting projects aligned with the National Research Action Plan for Improving Access to Mental Health Services for Veterans, Service members, and Military Families; enabling significant research collaborations; and complementing 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. In support, the FY 2016 Military Operational Medicine Research Program continued to fund the Military Suicide Research Consortium toward development of state-of-the-art, evidence-based, effective suicide prevention tools and interventions to the DoD. The FY 2016 Combat Casualty Care Research Program initiated studies to inform clinical practice guidelines for the management of TBI by analyzing the Deployed Warrior Medical Management Center and the DoD Trauma Registry casualty treatment data containing Operation Iraqi Freedom/ Operation Enduring Freedom (OIF/OEF) TBI clinical management to determine the best treatment outcome for TBI casualties. Moreover, a clinical study was initiated to validate Virtual Care, Telehealth, and Mobile technology applications to enable far forward medical care for the management of TBI. ***FY 2017 Plans:*** No funding programmed.		
Congressional Add: 441A - Joint Warfighter Medical Research Program	20.000	0.000

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017
FY 2016 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 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 and Advanced Development Program Managers 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. All pre-applications were reviewed and full application request for proposals went out in February 2016. The scientific peer review occurred in late May 2016 and programmatic review in late June 2016. Eleven projects were recommended for funding. Awards will be completed by September 2017. ***FY 2017 Plans:*** No funding programmed.		
Congressional Add: 455A - Therapeutic Service Dog Training Program (USUHS) ***FY 2016 Accomplishments:*** No Funding Programmed. Therapeutic Service Dog Training Program transferred to DHP O&M Account. ***FY 2017 Plans:*** No funding programmed.	0.000	0.000
Congressional Add: 464A – Program Increase: Restore Core Research Funding Reduction (GDF) ***FY 2016 Accomplishments:*** This Congressional Special Interest initiative was directed toward DHP core research initiatives in PE 0604110. Funds supported medical products support and advanced concept development in medical simulation and information sciences, military infectious diseases and combat casualty care, and clinical and rehabilitative medicine (Project 374A). ***FY 2017 Plans:*** No funding programmed.	30.700	0.000
Congressional Adds Subtotals	72.075	0.000

C. Other Program Funding Summary ($ in Millions)

N/A

Exhibit R-2A, RDT&E Project Justification: FY 2018 Defense Health Agency		Date: May 2017
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*

C. Other Program Funding Summary ($ in Millions)

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: FY 2018 Defense Health Agency			Date: May 2017
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 2016	FY 2017	FY 2018 Base	FY 2018 OCO	FY 2018 Total	FY 2019	FY 2020	FY 2021	FY 2022	Cost To Complete	Total Cost
434A: *Medical Products Support and Advanced Concept Development (AF)*	6.909	4.000	4.000	4.000	-	4.000	4.000	4.000	4.080	4.162	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 2016	FY 2017	FY 2018
Title: Medical Products Support and Advanced Concept Development (AF)	4.000	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 address capability gaps and requirements with affordable state-of-the art commercial technologies in support of the operational mission. Provide core capability to logically progress initiatives and concepts from S&T and translational/knowledge-focused programs (6.1-6.3) into materiel solutions and conduct the advanced development and transition activities needed to ensure those products are fielded in an effective, affordable, timely and efficient manner.

FY 2016 Accomplishments:

Began development of a next generation multi-channel infusion pump via commercially-available technology approach to provide medics with the ability to rapidly and safely deliver multiple drugs and therapeutics to DoD injured personnel in the field, in the air, and awaiting evacuation to meet customer urgent operational requirements. Will also began transitioning of 59 MDW-developed vascular shunt for restoring blood flow to extremities and 60 MDW project for creating ability to vary blood flow for aortic hemostasis and resuscitation balloon treatment for combat casualty care in the Expeditionary Medicine portfolio. Continued development of the Cardiovascular Sonospectrographic Analyzer (CSA) technology through case-evaluations that improve the sensitivity, specificity, and form factor of the device, enabling it to process sound signatures of turbulent blood through partially

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2016	FY 2017	FY 2018
occluded arteries to the sensitivity level of a CT angiography. Launched project to develop an inline fluid warmer system for special force's medics that reduced weight and cube of existing fluid warmers by 30% and enable treatment at point of injury. ***FY 2017 Plans:*** Continue development, evaluation, modification, and refinement of the multichannel infusion pump to meet customer urgent operational requirement to provide multiple drugs and therapeutics simultaneously for DoD injured personnel. Will obtain FDA approval and complete transition of the 59 MDW's vascular shunt sets to all DoD surgical teams. Will continue development and refinement of variable-flow aortic hemostasis and resuscitation balloon treatment for combat casualty care in developing a prototype field catheter with packaging and inserts for testing in preparation of FDA approval and pending clinical trials. Initiate project to develop commercially-available system for producing upon-demand Intravenous (IV) solutions in deployed EMEDS using onsite water sources that will eventually include reconstitution of dried human plasma when available commercially. ***FY 2018 Plans:*** Complete transition and begin fielding of the multichannel infusion pump to meet urgent operational mission requirement to replace existing multichannel pumps in the MEFPAK inventory that are discontinued by the manufacturer. Will continue development of Medical Modernization efforts including but not limited to transition of the variable-flow aortic hemostasis and resuscitation balloon treatment device for treating combat casualties to licensed vendor who will refine design, obtaining FDA approval, and field catheter kit with packaging and inserts for DoD use and commercial sales; develop commercially-available system for producing upon-demand Intravenous (IV) solutions in deployed EMEDS and Naval vessels using onsite/onboard water sources that will eventually include reconstitution of dried human plasma when available commercially; assess technology that utilizes elemental oxygen to cause immediate coagulation in wounds at the point of injury.			
Accomplishments/Planned Programs Subtotals	4.000	4.000	4.000

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Partnership with the USAMRMC, Navy Medical Research Center (NMRC), AFRL, AFLCMC, and the Department of the Interior in inter-agency agreements and use (award of delivery orders and task assignments) to engineering, manufacturing, and prototype development IDIQ vehicles awarded under SBIR phase III provisions or similar. 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 utilize the Acquisition process managed by the Air Force Life Cycle Management Center (AFLCMC), Wright-Patterson AFB.

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E. Performance Metrics

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