Exhibit R-2, RDT&E Budget Item Justification: PB 2019 Defense Health Agency											Date: February 2018	
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 2017**	**FY 2018**	**FY 2019 Base**	**FY 2019 OCO**	**FY 2019 Total**	**FY 2020**	**FY 2021**	**FY 2022**	**FY 2023**	**Cost To Complete**	**Total Cost**
Total Program Element	967.402	156.960	99.039	117.529	-	117.529	128.055	132.331	142.252	145.097	Continuing	Continuing
374A: *GDF-Medical Products Support and Advanced Concept Development*	706.702	91.337	95.039	113.529	-	113.529	124.055	128.251	138.090	140.852	Continuing	Continuing
400Z: *CSI - Congressional Special Interests*	249.791	61.769	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)*	10.909	3.854	4.000	4.000	-	4.000	4.000	4.080	4.162	4.245	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.

Exhibit R-2, RDT&E Budget Item Justification: PB 2019 Defense Health Agency	Date: February 2018
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 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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total
Previous President's Budget	96.602	99.039	117.529	-	117.529
Current President's Budget	156.960	99.039	117.529	-	117.529
Total Adjustments	60.358	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	61.769	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-1.411	-			

Congressional Add Details ($ in Millions, and Includes General Reductions)	FY 2017	FY 2018
Project: 400Z: *CSI - Congressional Special Interests*		
Congressional Add: *427A - Traumatic Brain Injury / Psychological Health*	4.665	-
Congressional Add: *441A - Joint Warfighter Medical Research Program*	20.000	-
Congressional Add: *464A – Program Increase: Restore Core Research Funding Reduction (GDF)*	29.104	-
Congressional Add: *PC 540 - CSI HIV/AIDSPrevention Program*	8.000	-
Congressional Add Subtotals for Project: 400Z	61.769	-
Congressional Add Totals for all Projects	61.769	-

Exhibit R-2, RDT&E Budget Item Justification: PB 2019 Defense Health Agency	Date: February 2018
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*

Change Summary Explanation

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: PB 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
374A: *GDF-Medical Products Support and Advanced Concept Development*	706.702	91.337	95.039	113.529	-	113.529	124.055	128.251	138.090	140.852	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 2017	FY 2018	FY 2019
Title: GDF – Medical Product Support and Advanced Concept Development	91.337	95.039	113.529
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 2018 Plans: Medical simulation and information sciences is conducting engineering and manufacturing development in two primary research tasks: medical simulation and health information technology and informatics (HITI). Under the medical simulation task: Completing work on the Advanced Modular Manikin core (torso). Low and mid fidelity peripherals that attach or insert onto the core manikin are being developed. Conducting research on the underlying architecture to support the development of the			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
future Joint Evacuation and Transport Simulation (JETS) System of Systems. Research is being conducted 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. Under the HITI task: Conducting 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 associated with the modernization of existing Military Health System legacy systems in support of Defense Health System Modernization for MHS Genesis and Joint Operational Medical Information System (JOMIS) in accordance with FY16 NDAA Section 217. Demonstrating and defining 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. Supporting 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. Completing Digital Biobank research to share genomic data with Department of Defense and Veterans Affairs in support of the Precision Medicine Initiative. Military Infectious Diseases supports studies aligning to the National Action Plan for Combating Antibiotic-Resistance. It supports the ongoing development of prototype diagnostic devices and the evaluation of assay performance in an operational environment to detect pathogen associated nucleic acids, proteins and toxins. Efforts involve prospective collection and evaluation of standardized infection data including therapy, microbiology, and clinical outcomes of combat-related injuries across treatment facilities. Continue optimization and clinical validation studies for a malaria, dengue, chikungunya, and leptospirosis nucleic acid-based assay panel to be used on the Next Generation Diagnostic System. Complete skin and soft tissue infection clinical study in military trainees at Fort Benning, Georgia, with results are expected to inform potential prevention and treatment strategies. Continue to support Adenovirus vaccine production modernization efforts. Military Operational Medicine: Develop guidance regarding calcium and vitamin D intake to support optimal bone health during training. Will optimize and validate brief cognitive behavior therapies for decreasing suicide. 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. Continue to prepare for a clinical study for pharmaceutical (drug) interventions for noise induced hearing loss. Prepare for study assessing new pharmacotherapeutics to foster recovery of Service members and Veterans with combat-related posttraumatic stress disorder. Assess a biomarker panel to predict the risk of Acute Mountain Sickness for Service members who rapidly ascent to high altitude to perform their mission.			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
Clinical and rehabilitative medicine: Continue efforts in the areas of military-relevant pain management focusing on the validation of non-pharmacologic approaches to managing pain. Conduct studies pursuing a route of administration change for ketamine, a pain management product for use after surgery, from intravenous to oral transmucosal. Perform an Analysis of Alternatives for a nerve repair biologic product to guide a Milestone A decision. Perform an Analysis of Alternatives for a functional skin regeneration product to guide a Milestone A decision. 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 2019 Plans:*** Medical simulation and information sciences will conduct engineering and manufacturing development in two primary research tasks: medical simulation and health information technology and informatics (HITI). Under the medical simulation task: Will continue the development of low and mid fidelity peripherals that attach or insert onto the core manikin. Research will continue on 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. 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. Military infectious diseases research will continue to support studies aligning to the National Action Plan for Combating Antibiotic-Resistant Bacteria. Will continue to support the ongoing development of prototype diagnostic devices and the evaluation of assay performance in an operational environment to detect pathogen associated nucleic acids, proteins and toxins. Efforts will involve prospective collection and evaluation of standardized clinical data including therapy, microbiology, and clinical outcomes of combat-related injuries across treatment facilities. Will continue to support optimization and 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 continue to support Adenovirus vaccine production modernization efforts. Military Operational Medicine: Will continue to develop guidance regarding calcium and vitamin D intake to support optimal bone health during training. Will continue to optimize and validate brief cognitive behavior therapies for decreasing suicide. Will conduct advanced development on a real-time physiological status monitoring system that integrates algorithms and sensors into			

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
actionable real-time physiological status, health, and readiness information. Continue to advance technologies that support 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 continue to prepare for study assessing new pharmacotherapeutics to foster recovery of Service members and Veterans with combat-related posttraumatic stress disorder. Will complete assessment on a biomarker panel to predict the risk of Acute Mountain Sickness for Service members who rapidly ascent to high altitude to perform their mission. Clinical and rehabilitative medicine: Will continue efforts in the areas of military-relevant pain management focusing on the validation of non-pharmacologic approaches to managing pain. Will continue to conduct studies pursuing a route of administration change for ketamine, a pain management product for use after surgery, from intravenous to oral transmucosal. Will prepare for initiation of a burn trauma clinical study related to functional skin regeneration Tri-Service Translational Research will continue 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, and clinical and rehabilitative medicine. ***FY 2018 to FY 2019 Increase/Decrease Statement:*** Pricing adjustment.			
Accomplishments/Planned Programs Subtotals	91.337	95.039	113.529

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

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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*

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 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
400Z: *CSI - Congressional Special Interests*	249.791	61.769	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 2017	FY 2018
Congressional Add: 427A - Traumatic Brain Injury / Psychological Health	4.665	-
FY 2017 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 2017 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 2017 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.		
Congressional Add: 441A - Joint Warfighter Medical Research Program	20.000	-
FY 2017 Accomplishments: The Joint Warfighter Medical Research Program (JWMRP) provides continuing support for promising research previously funded under Congressional Special Interest programs. The focus is		

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018
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. For FY17, no advanced development projects were solicited to apply for funding. FY17 JWMRP funding was used to continue support for promising research previously funded through the JWMRP. Awards will be made by September 2018. Awards will be made by September 2018.		
Congressional Add: 464A – Program Increase: Restore Core Research Funding Reduction (GDF) ***FY 2017 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).	29.104	-
Congressional Add: PC 540 - CSI HIV/AIDSPrevention Program ***FY 2017 Accomplishments:*** This Congressional Special Interest initiative is directed toward research initiatives for the HIV/AIDs Prevention Program.	8.000	-
Congressional Adds Subtotals	61.769	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Prior year CSI funded research will be assessed for developmental maturity and qualification for initial or continued advanced development funding. If advanced development criteria are met, follow-on development will be solicited through a peer-reviewed process.

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency			Date: February 2018
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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
434A: *Medical Products Support and Advanced Concept Development (AF)*	10.909	3.854	4.000	4.000	-	4.000	4.000	4.080	4.162	4.245	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 2017	FY 2018	FY 2019
Title: Medical Products Support and Advanced Concept Development (AF)	3.854	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 2018 Plans:

Continue development, evaluation, modification, and refinement of the multichannel infusion pump and complete transition to meet customer urgent operational requirement to provide multiple drugs and therapeutics simultaneously for DoD injured personnel. Obtain FDA approval and complete transition of the 59 MDW's vascular shunt sets to all DoD surgical teams. Continue project to develop commercially-available system for producing upon-demand sterile water for injection and generate Intravenous (IV) solutions in deployed EMEDS using onsite water sources that will eventually include reconstitution of dried human plasma when available commercially. Begin development of patient movement and transport product that provides spinal immobilization and reduces potential for secondary injuries during Aeromedical Evacuations (AE). Continue development of an

Exhibit R-2A, RDT&E Project Justification: PB 2019 Defense Health Agency		Date: February 2018
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 2017	FY 2018	FY 2019
enhanced clinical and infectious disease diagnostics capability. Evaluate 6.3 funded projects for future advanced development transition and funding. ***FY 2019 Plans:*** Begin advanced 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. Continue assessment and development of Medical Modernization efforts including, but not limited to, automated/autonomous control of oxygen and ventilation intervention for patient care; continue developing a commercially-available system for producing upon-demand sterile water for injection and 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; technology that utilizes elemental oxygen to cause immediate coagulation in wounds at the point of injury, and ruggedized, portable materiel products for use in expeditionary settings.			
Accomplishments/Planned Programs Subtotals	3.854	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, Department of the Interior (interagency cooperative agreements and use award of delivery orders and task assignments) and medical technology consortiums to perform engineering, manufacturing, and prototype development IDIQ vehicles to include those 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 industry-standard project management processes and DoD Acquisition process managed by the Air Force Life Cycle Management Center (AFLCMC), Wright-Patterson AFB.

E. Performance Metrics

Achievement of affordable and effective fielded medical technologies and capabilities for warfighter; achievement of required TRL for each advanced concept development/product support project and fulfillment of established key performance parameters (KPPs) for projects.