Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency											Date: February 2020	
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0605145DHA *I Medical Products and Support Systems Development*							
COST ($ in Millions)	**Prior Years**	**FY 2019**	**FY 2020**	**FY 2021 Base**	**FY 2021 OCO**	**FY 2021 Total**	**FY 2022**	**FY 2023**	**FY 2024**	**FY 2025**	**Cost To Complete**	**Total Cost**
Total Program Element	135.678	24.921	21.589	21.068	-	21.068	21.489	21.919	22.357	22.804	Continuing	Continuing
399A: *Hyperbaric Oxygen Therapy Clinical Trial (Army)*	27.762	0.857	0.935	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
500A: *CSI - Congressional Special Interests*	13.031	5.351	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
375: *GDF - Medical Products and Support System Development*	94.885	18.713	20.654	21.068	-	21.068	21.489	21.919	22.357	22.804	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force – Medical Products and Support Systems Development: This program element (PE) provides funding for system development and demonstration of medical commodities delivered from the various medical advanced development and prototyping Department of Defense (DoD) Components that are directed at meeting validated requirements prior to full-rate initial production and fielding, including initial operational test and evaluation and clinical trials for products that require US Food and Drug Administration approval.

Development, test, and evaluation in this PE is designed to address requirements identified through the Joint Capabilities Integration and Development System and other Department of Defense operational needs. Medical development, test, and evaluation priorities for the Defense Health Program (DHP) are guided by, and will support, the National Defense Strategy, the Joint Staff Surgeon's Joint Concept for Health Services, and other overarching DoD strategic framework documents.

Coordination occurs through the planning and execution activities of the Defense Health Agency Component Acquisition Executive (DHA CAE) as the Milestone Decision Authority for medical materiel development efforts. As technologies mature, the most promising efforts will transition to production and deployment.

Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Defense Health Agency					Date: February 2020
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*			R-1 Program Element (Number/Name) PE 0605145DHA *I Medical Products and Support Systems Development*		
B. Program Change Summary ($ in Millions)	**FY 2019**	**FY 2020**	**FY 2021 Base**	**FY 2021 OCO**	**FY 2021 Total**
Previous President's Budget	25.745	21.589	22.022	-	22.022
Current President's Budget	24.921	21.589	21.068	-	21.068
Total Adjustments	-0.824	0.000	-0.954	-	-0.954
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.824	-			
• Reprogrammings	-	-	-0.954	-	-0.954

Congressional Add Details ($ in Millions, and Includes General Reductions)	**FY 2019**	**FY 2020**
Project: 500A: *CSI - Congressional Special Interests*		
Congressional Add: *CSI Restoral*	5.351	-
Congressional Add Subtotals for Project: 500A	5.351	-
Congressional Add Totals for all Projects	5.351	-

Change Summary Explanation

FY 2021: Programmed funding transferred to the Department of the Army (PE 0605145A Project CD6) as part of the Readiness Transfer for FY 2021.

Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency			Date: February 2020
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605145DHA / *Medical Products and Support Systems Development*	Project (Number/Name) 399A / *Hyperbaric Oxygen Therapy Clinical Trial (Army)*	

COST ($ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
399A: *Hyperbaric Oxygen Therapy Clinical Trial (Army)*	27.762	0.857	0.935	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

For the Army, the Hyperbaric Oxygen Therapy (HBO2) clinical trials focus on research related to the development of treatment modalities using HBO2 for chronic post-concussion syndrome after mild traumatic brain injury (mTBI). Three HBO2 human clinical trials were designed to evaluate the effectiveness of HBO2 treatments for Service members who have experienced one or more concussions and who are symptomatic at, or after, the time of post-deployment health reassessments: 1- A pilot phase II (narrow population safety and effectiveness) study of hyperbaric oxygen for persistent post-concussive symptoms after mild traumatic brain injury (HOPPS), 2- Brain Injury and Mechanisms of Action of Hyperbaric Oxygen for Persistent Post-Concussive Symptoms after Mild Traumatic Brain Injury (BIMA), and 3- Development of Normative Datasets for Assessments Planned for Use in Patients with Mild Traumatic Brain Injury (Normal). A fourth retrospective study, Long Term Follow-up (LTFU), is focused on the lessons learned from long-term follow-up of subjects enrolled in the Department of Defense (DoD) primary HBO2 trials. To support these protocols, four HBO2 study sites were established within the Military Health System. Each of the research sites consisted of a hyperbaric oxygen chamber enclosed in a mobile trailer, a second mobile trailer for testing and evaluation of the subjects, and a third subject staging trailer. This information is intended to inform DoD policy decisions regarding the use of HBO2 therapy as a treatment for mTBI.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
Title: Hyperbaric Oxygen Therapy Clinical Trial (Army)	0.857	0.935	0.000
Description: The Hyperbaric Oxygen (HBO2) clinical trials are designed to test the effectiveness of HBO2 treatments for Service members who have experienced one or more concussions and who are symptomatic at, or after, the time of post-deployment health reassessments. ***FY 2020 Plans:*** Concluded the Hyperbaric Oxygen Therapy clinical trial and other associated project effort. The project determined that no clinically statistical significance existed related to the use of hyperbaric oxygen interventions. ***FY 2021 Plans:*** Programmed funding transferred to the Department of the Army (PE 0605145A Project CD6) as part of the Readiness Transfer for FY 2021. ***FY 2020 to FY 2021 Increase/Decrease Statement:*** Programmed funding transferred to the Department of the Army (PE 0605145A Project CD6) as part of the Readiness Transfer for FY 2021.			
Accomplishments/Planned Programs Subtotals	0.857	0.935	0.000

Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency		Date: February 2020
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605145DHA / *Medical Products and Support Systems Development*	**Project (Number/Name)** 399A / *Hyperbaric Oxygen Therapy Clinical Trial (Army)*

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

The acquisition outcome of this effort is a knowledge product, with the results intended to inform DoD mTBI treatment and reimbursement policies. The decision to pursue FDA registration/off-label application of an existing drug-device combination product will be made as part of a formal decision by leadership after the DoD HBO2 trial results are reviewed. If future work using HBO2 proves beneficial in the treatment of PTSD this knowledge product would inform DoD treatment and reimbursement policies.

Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency			Date: February 2020
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605145DHA / *Medical Products and Support Systems Development*	Project (Number/Name) 500A / *CSI - Congressional Special Interests*	

COST ($ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
500A: *CSI - Congressional Special Interests*	13.031	5.351	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

In FY 2019, the Defense Health Program funded Congressional Special Interest (CSI) directed research. The strategy for the FY 2018 Congressionally-directed research program is to stimulate innovative research through a competitive, focused, peer-reviewed medical research at intramural and extramural research sites. Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020
Congressional Add: CSI Restoral	5.351	-
FY 2019 Accomplishments: In FY 2019, the Defense Health Program funded Congressional Special Interest (CSI) directed research. The strategy for the FY 2018 Congressionally-directed research program is to stimulate innovative research through a competitive, focused, peer-reviewed medical research at intramural and extramural research sites. Because of the CSI annual structure, out-year funding is not programmed.		
Congressional Adds Subtotals	5.351	-

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency			Date: February 2020
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605145DHA / *Medical Products and Support Systems Development*	Project (Number/Name) 375 / *GDF - Medical Products and Support System Development*	

COST ($ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
375: *GDF - Medical Products and Support System Development*	94.885	18.713	20.654	21.068	-	21.068	21.489	21.919	22.357	22.804	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force-Medical Products and Support Systems Development: This funding supports materiel development activities that further system development and demonstration prior to initial full rate production and fielding of commodities.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
Title: GDF - Medical Products and Support Systems Development (GDF-MPSSD)	18.713	20.654	21.068

Description: GDF-Medical Products and Support Systems Development: This funding supports activities to support system development and demonstration prior to initial full rate production and fielding of medical commodities delivered from 0604110HP (Medical Products Support and Advanced Concept Development). Materiel development may include accelerated transition of US Food and Drug Administration (FDA)-licensed and unregulated products through clinical and field validation studies, advanced prototyping, risk reduction, operational test and evaluation, manufacturing, and product transition efforts for medical information technology applications and medical training systems technologies.

FY 2020 Plans:

Medical Modeling and Simulation: Programs will focus on development and application of medical simulation and training capabilities for hospital care and operations. Medical Simulation Training Systems will begin to develop standardized training capabilities for point of injury, trauma simulation, hospital training, along with a common platform architecture that improves medical care across the DoD.

Medical Readiness: Programs will focus on prevention of illness and injury along with optimization of human performance. The Health Readiness and Performance System will continue to refine technologies including wearable sensors to monitor non-diagnostic physiologic date in real-time to improve Warfighter health, readiness and performance, reduce casualties, and increase situational awareness.

Medical Combat Support: Programs will focus on operational support. The Next Generation Diagnostic System-Infectious Disease Panel program will continue to refine a diagnostic assay for malaria, dengue fever, chikungunya, and leptospirosis that can be use in the operational setting.

FY 2021 Plans:

Exhibit R-2A, RDT&E Project Justification: PB 2021 Defense Health Agency		Date: February 2020
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605145DHA / *Medical Products and Support Systems Development*	**Project (Number/Name)** 375 / *GDF - Medical Products and Support System Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2019	FY 2020	FY 2021
FY 2021 plans continue efforts as outlined in FY 2020. ***FY 2020 to FY 2021 Increase/Decrease Statement:*** Pricing adjustment for inflation.			
Accomplishments/Planned Programs Subtotals	18.713	20.654	21.068

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

This program will test and evaluate medical products in government-managed clinical trials in order to gather data to meet military and regulatory (e.g., FDA, Environmental Protection Agency) requirements for production and fielding.