Exhibit R-2, RDT&E Budget Item Justification: PB 2015 Defense Health Program											Date: March 2014	
Appropriation/Budget Activity 0130: *Defense Health Program I* BA 2: *RDT&E*					R-1 Program Element (Number/Name) PE 0605145HP *I Medical Products and Support Systems Development*							
COST ($ in Millions)	**Prior Years**	**FY 2013**	**FY 2014**	**FY 2015 Base**	**FY 2015 OCO #**	**FY 2015 Total**	**FY 2016**	**FY 2017**	**FY 2018**	**FY 2019**	**Cost To Complete**	**Total Cost**
Total Program Element	33.073	9.240	18.445	14.499	-	14.499	19.534	24.729	26.841	31.430	Continuing	Continuing
375A: *GDF-Medical Products and Support System Development*	18.062	5.718	13.099	12.694	-	12.694	18.679	23.874	25.941	30.605	Continuing	Continuing
399A: *Hyperbaric Oxygen Therapy Clinical Trial (Army)*	15.011	3.522	5.346	1.805	-	1.805	0.855	0.855	0.900	0.825	Continuing	Continuing

The FY 2015 OCO Request will be submitted at a later date.

A. Mission Description and Budget Item Justification

This Program Element (PE) funds system development and demonstration of medical commodities delivered from the various medical advanced development and prototyping 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. These clinical trials are conducted to obtain US Food and Drug Administration (FDA) approval, a requirement for use of all medical products. Research in this PE is designed to address the following: areas of interest to the Secretary of Defense regarding Wounded Warriors, capabilities identified through the Joint Capabilities Integration and Development System, and the strategy and initiatives described in the Quadrennial Defense Review. Program development and execution is peer-reviewed and fully coordinated with all of the Military Services, appropriate Defense Agencies or Activities and other federal agencies, to include the Department of Veterans Affairs, the Department of Health and Human Services, and Department of Homeland Security. This coordination occurs through the planning and execution activities of the Joint Program Committees, established for the Defense Health Program Research, Development, Test and Evaluation funding. The work includes development and demonstration of medical modeling and simulation systems for training/education/treatment, and medical system development and demonstration. The funding also supports the clinical evaluation of hyperbaric oxygenation for post-concussion syndrome (PCS). The effort encompasses development, initiation, operation, analysis, and subsequent publication of clinical trials to compare and assess the long-term benefit of hyperbaric oxygen (HBO2) therapy on service members with (PCS). As the research efforts mature, the most promising will transition to production and deployment or to industry.

Exhibit R-2, RDT&E Budget Item Justification: PB 2015 Defense Health Program					Date: March 2014
Appropriation/Budget Activity 0130: *Defense Health Program* / BA 2: *RDT&E*		R-1 Program Element (Number/Name) PE 0605145HP / *Medical Products and Support Systems Development*			
B. Program Change Summary ($ in Millions)	**FY 2013**	**FY 2014**	**FY 2015 Base**	**FY 2015 OCO**	**FY 2015 Total**
Previous President's Budget	17.116	18.976	25.855	-	25.855
Current President's Budget	9.240	18.445	14.499	-	14.499
Total Adjustments	-7.876	-0.531	-11.356	-	-11.356
• Congressional General Reductions	-0.023	-			
• Congressional Directed Reductions	-4.964	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-2.889	-0.531			
• Reductions related to Departmental Efficiencies - Project 375A	-	-	-11.261	-	-11.261
• Reductions related to Departmental Efficiencies - Project 399A	-	-	-0.095	-	-0.095

Change Summary Explanation

FY 2013: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0605145-Medical Products and Support Systems Development (-$2.889 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) Program (+$2.889 million).

FY 2013: General Congressional Reductions to DHP RDT&E, PE 0605145-Medical Products and Support Systems Development (-$0.023 million).

FY 2013: Congressional Directed Reductions (Sequestration) to DHP RDT&E, PE 0605145-Medical Products and Support Systems Development (-$4.964 million).

FY 2014: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0605145-Medical Products and Support Systems Development (-$0.531 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) Program (+$0.531 million).

FY 2015: Reduces non-combat injury research funding in order to focus and continue the pace of progress in critical and high priority research areas for DHP RDT&E, PE 0605145-Medical Products and Support Systems Development (-$11.356 million).

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program			Date: March 2014
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605145HP / *Medical Products and Support Systems Development*	Project (Number/Name) 375A / *GDF-Medical Products and Support System Development*	

COST ($ in Millions)	Prior Years	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO #	FY 2015 Total	FY 2016	FY 2017	FY 2018	FY 2019	Cost To Complete	Total Cost
375A: *GDF-Medical Products and Support System Development*	18.062	5.718	13.099	12.694	-	12.694	18.679	23.874	25.941	30.605	Continuing	Continuing

The FY 2015 OCO Request will be submitted at a later date.

A. Mission Description and Budget Item Justification

Activities conducted are intended to support system development and demonstration prior to initial full rate production and fielding of commodities.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Title: GDF - Medical Products and Support Systems Development (GDF-MPSSD)	5.718	13.099	12.694

Description: GDF-Medical Products and Support Systems Development (GDF-MPSSD): Activities conducted are intended 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). Development and demonstration activities will be conducted in the following areas: medical modeling and simulation systems for training/education/treatment, rapid screening for fresh whole blood, and dried plasma and TBI biomarker point of care devices.

FY 2013 Accomplishments:

Medical Training and Health Information Sciences focused on researching the advanced development and validation of technologies and products to improve military relevant training with a focus on combat trauma training.

The Combat Casualty Care research area supported development of a TBI biomarker reference device and clinical development of a TBI biomarker diagnostic assay system.

FY 2014 Plans:

Medical Training and Health Information Sciences is focusing on the advanced development and validation of technologies and products that improve military medicine through healthcare provider training for continuously high state of readiness, technologies to reduce dependency of use of live tissue for training, and facilitate home based training. Continual efforts towards evaluating and validating the effectiveness of currently commercialized or advanced prototype simulation systems for military use are underway.

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program		Date: March 2014
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605145HP / *Medical Products and Support Systems Development*	**Project (Number/Name)** 375A / *GDF-Medical Products and Support System Development*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Combat casualty care research is continuing the advanced development effort of dried plasma and TBI biomarker point of care devices. Clinical trials are underway to evaluate two alternate point-of-care devices in conjunction with the biomarker-specific diagnostic assay system. These clinical trials provide data to support licensure by the Food and Drug Administration (FDA). ***FY 2015 Plans:*** Medical Training and Health Information Sciences will focus on testing and evaluating commercially available, off-the-shelf technologies and advanced prototype products. These efforts will improve military medicine through medical provider training to sustain a continuously high state of readiness and the advanced development of technologies to reduce and refine the use of live tissue for training. Solicitations will be released seeking comparison between current commercialized (or soon-to-be commercialized) Virtual Standardized Patients (Avatars) vs. Standardized Patients (Actors) to better understand strengths and weaknesses of both models. Military infectious disease research will continue, from PE 0604110, to support development of the Nucleic Acid Testing platform for screening whole blood collections in a deployed environment under the rapid screening for fresh whole blood task. FDA mandated phase 2 clinical studies will be initiated during this period. Combat casualty care research will continue clinical development of TBI biomarkers and other indicators of traumatic brain injury in patients with concussive injuries as required by the FDA. Will also continue clinical evaluation of a TBI biomarker point of care device, which uses a novel optical technology. Clinical trials will evaluate two alternate point-of-care devices in conjunction with the biomarker-specific diagnostic assay system. These clinical trials, once completed, will provide conclusive evidence to support effectiveness and accuracy necessary for licensure by the FDA.			
Accomplishments/Planned Programs Subtotals	5.718	13.099	12.694

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Test and evaluate medical procedures and prototype devices in government-managed Phase 2 effectiveness 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

[JPC 1,2,6,PART] Principal investigators will participate in In-Progress Reviews, high-level DHP-sponsored review and analysis meetings, submit quarterly and annual status reports, and are subjected to Program Office or Program Sponsor Representative progress reviews to ensure that milestones are being met and deliverables will

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program		Date: March 2014
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605145HP / *Medical Products and Support Systems Development*	**Project (Number/Name)** 375A / *GDF-Medical Products and Support System Development*

be transitioned on schedule. Integrated Product Teams, if established for a therapy or device, will monitor progress in accordance with DoD Regulation 5000 series. The benchmark performance metric for transition of research supported in this PE will be the attainment of a maturity level that is typical of TRL 8.

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program			Date: March 2014
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0605145HP / *Medical Products and Support Systems Development*	Project (Number/Name) 399A / *Hyperbaric Oxygen Therapy Clinical Trial (Army)*	

COST ($ in Millions)	Prior Years	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO #	FY 2015 Total	FY 2016	FY 2017	FY 2018	FY 2019	Cost To Complete	Total Cost
399A: *Hyperbaric Oxygen Therapy Clinical Trial (Army)*	15.011	3.522	5.346	1.805	-	1.805	0.855	0.855	0.900	0.825	Continuing	Continuing

The FY 2015 OCO Request will be submitted at a later date.

A. Mission Description and Budget Item Justification

For the Army, the Hyperbaric Oxygen Therapy (HBO2) clinical trials will focus on research for development of treatment modalities using HBO2 for chronic post-concussion syndrome (PCS) after mild TBI. Four HBO2 study sites were established within the Military Health System and are fully functional. The research sites consist of a hyperbaric oxygen chamber enclosed in a mobile trailer, another mobile trailer for testing and evaluation of the subjects, and a third subject changing trailer. Human clinical trials will be designed to evaluate and use HBO2 treatments for Service members who are symptomatic at or after the time of post-deployment health reassessments from one or more concussions.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Title: Hyperbaric Oxygen Therapy Clinical Trial (Army)	3.522	5.346	1.805
Description: HBO2 clinical trials are designed to test in humans the use of hyperbaric oxygen treatments for Service members who are symptomatic from one or more concussions at the time of post-deployment health reassessments.			
FY 2013 Accomplishments: The pilot study of low dose HBO2 was completed and analyzed, and results were released to the FDA in the 3rd quarter. The team worked with Navy and Veteran's Affairs (VA) researchers to analyze the results of the complementary dose ranging study, which were also released to the FDA in the 3rd quarter. The team completed a summary of these three studies for review by the national hyperbaric medical professional association, TRICARE, the VA, and Department of Defense policymakers. A study confirming initial findings and evaluating cutting-edge radiologic (X-rays, CAT scans, MRIs) and physiologic biomarker (biological indicators) technology is ongoing until FY2015. The VA continued validation of the Neurobehavioral Symptom Inventory questionnaire per FDA guidelines. A decision is being made to proceed to a FDA-regulated, phase III pivotal trial.			
FY 2014 Plans: HBO2 therapy treatment guidelines will be updated along with education of the end-users, as the results of completed studies warrant (1QFY14). The study confirming initial findings and evaluating cutting-edge radiologic and physiologic biomarker technology will complete enrollment, and volunteers will be followed for one year to assess durability of the responses. Long-term follow-up of study volunteers to evaluate durability of the improvement is planned for five years.			
FY 2015 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2015 Defense Health Program		Date: March 2014
Appropriation/Budget Activity 0130 / 2	**R-1 Program Element (Number/Name)** PE 0605145HP / *Medical Products and Support Systems Development*	**Project (Number/Name)** 399A / *Hyperbaric Oxygen Therapy Clinical Trial (Army)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2013	FY 2014	FY 2015
Will complete the study to confirm initial findings and evaluate cutting-edge radiologic and physiological biomarker technology with 6 month and 12 month subject follow-ups. Will complete FDA data analysis and reporting. The long-term follow-up study (one year or more following last chamber session) of volunteers who have participated in three previous studies evaluating durability of the improvement will complete data collection and progress to the analysis and dissemination phases.			
Accomplishments/Planned Programs Subtotals	3.522	5.346	1.805

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

Off-label use of an existing technology. Knowledge product, with initial results to affect TBI treatment policy and procedure reimbursement policy. Decision to pursue FDA registration will be made as part of a formal acquisition decision after the initial results are reviewed.

E. Performance Metrics

The HBO2 Program Management Office Integrated Product Team monitors performance of contracts through review of monthly, yearly and final progress reports to ensure that milestones are being met; deliverables will be transitioned on schedule and within budget and in accordance with DOD regulation 5000.