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Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Defense Health Program **Date:** February 2015

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>					R-1 Program Element (Number/Name) PE 0607100HP <i>I Medical Products and Capabilities Enhancement Activities</i>							
COST (\$ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
Total Program Element	22.323	15.097	17.474	17.356	-	17.356	17.647	19.663	20.037	20.439	Continuing	Continuing
377A: <i>GDF-Medical Products and Capabilities Enhancement Activities</i>	22.323	13.761	15.092	17.356	-	17.356	17.647	19.663	20.037	20.439	Continuing	Continuing
457A: <i>AF Advanced Technology Development – Rapid Technology Transition</i>	0.000	1.336	-	-	-	-	-	-	-	-	Continuing	Continuing
700A: <i>CSI - Congressional Special Interests</i>	0.000	-	2.382	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force-Medical Products and Capabilities Enhancement Activities: Funds will support (1) developmental upgrades to medical systems and products that have been fielded or that are routinely used in a fixed facility or that have been approved for full-rate production and for which procurement funding is anticipated in the current fiscal year or subsequent fiscal years, (2) testing and evaluation supporting the enhancement of fielded or procured medical systems/products and medically-related information technology systems, (3) assessment of fielded medical products or medical practices in order to identify the need/opportunity for changes, and (4) analyses of clinical intervention outcomes to enhance and improve military unique clinical practice guidelines. Efforts address the Military Health System family of Concept of Operations documents and follow-on Capabilities Based Assessments/Joint Capability Documents, appropriate Component requirements, legislative and Executive directives (e.g., National Research Action Plan, Office of Management and Budget Combat Casualty Care Assessment, National Defense Authorization Acts, etc.) and others as appropriate.

<u>B. Program Change Summary (\$ in Millions)</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016 Base</u>	<u>FY 2016 OCO</u>	<u>FY 2016 Total</u>
Previous President's Budget	14.646	15.092	17.356	-	17.356
Current President's Budget	15.097	17.474	17.356	-	17.356
Total Adjustments	0.451	2.382	-	-	-
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	2.382			
• Congressional Directed Transfers	-	-			
• Reprogrammings	1.375	-			
• SBIR/STTR Transfer	-0.924	-			

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<u>Congressional Add Details (\$ in Millions, and Includes General Reductions)</u>		FY 2014	FY 2015
Project: 700A: <i>CSI - Congressional Special Interests</i>			
Congressional Add: 467A – <i>Program Increase: Restore Core Research Funding Reduction (GDF)</i>		-	2.382
Congressional Add Subtotals for Project: 700A		-	2.382
Congressional Add Totals for all Projects		-	2.382
<u>Change Summary Explanation</u>			
FY 2014: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0607100-Medical Products and Capabilities Enhancement Activities (-\$0.924 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) Program (+\$0.924 million).			
FY 2014: OMNIBUS Prior Approval Reprogramming (FY 14-11 PA) from Defense Health Program, Operations and Maintenance (DHP O&M) Appropriation (- \$1.375 million) to DHP RDT&E, PE 0607100-Medical Products and Capabilities Enhancement Activities (+\$1.375 million).			
FY 2015: Congressional Special Interest (CSI) Additions to DHP RDT&E, PE 0607100-Medical Products and Capabilities Enhancement Activities (+\$2.382 million).			
FY 2016: No Change.			

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Exhibit R-2A, RDT&E Project Justification: PB 2016 Defense Health Program										Date: February 2015		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0607100HP / Medical Products and Capabilities Enhancement Activities				Project (Number/Name) 377A / GDF-Medical Products and Capabilities Enhancement Activities			
COST (\$ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
377A: GDF-Medical Products and Capabilities Enhancement Activities	22.323	13.761	15.092	17.356	-	17.356	17.647	19.663	20.037	20.439	Continuing	Continuing

A. Mission Description and Budget Item Justification

Guidance for Development of the Force-Medical Products and Capabilities Enhancement Activities: Funds will support (1) developmental upgrades to medical systems and products that have been fielded or that are routinely used in a fixed facility or that have been approved for full-rate production and for which procurement funding is anticipated in the current fiscal year or subsequent fiscal years, (2) testing and evaluation supporting the enhancement of fielded or procured medical systems/products and medically-related information technology systems, (3) assessment of fielded medical products or medical practices in order to identify the need/opportunity for changes, and (3) analyses of clinical intervention outcomes to enhance and improve military unique clinical practice guidelines. Efforts address the Military Health System family of Concept of Operations documents and follow-on Capabilities Based Assessments/Joint Capability Documents, appropriate Component requirements, legislative and Executive directives (e.g., National Research Action Plan, Office of Management and Budget Combat Casualty Care Assessment, National Defense Authorization Acts, etc.) and others as appropriate.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015	FY 2016
Title: 377A: GDF – Medical Products and Capabilities Enhancement Activities	13.761	15.092	17.356
Description: Provide support for developmental efforts to upgrade medical products and capabilities that have been fielded or have received approval for full rate production and anticipate production funding in the current or subsequent fiscal year.			
FY 2014 Accomplishments: Completed sensor characterization of fielded sensor systems. Conducted additional mobility studies to enhance existing injury prediction models. Developed an improved Blast Exposure and Concussion Incident Report search/characterization capability. Completed scheduled system enhancements to the Joint Trauma Analysis and Prevention of Injury in Combat (JTAPIC) Dismounted Incident Collaboration Environment (DICE). Collected data to evaluate the effectiveness of Army Combat Uniforms treated with permethrin as a barrier to ticks and mosquitoes following extended periods of use. Evaluated FDA-approved commercial products to control severe junctional (e.g., groin, pelvis) bleeding. Analyzed outcomes of the use of regional anesthesia for combat casualty care in the U.S. Military Healthcare System from 2003-2012. Evaluated an anti-rotational device to control rotational movement of a litter during patient evacuation by helicopter, and tested commercially available lightweight carbon fiber spine boards (for immobilization and transport of injured persons) to find alternatives to the large, bulky ones currently in use. Carried out assessments of commercially available negative pressure wound therapy devices for cost effectiveness, portability, durability, and logistical footprint as compared to the current device in sets, kits, and outfits in order to			

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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0607100HP / <i>Medical Products and Capabilities Enhancement Activities</i>	Project (Number/Name) 377A / <i>GDF-Medical Products and Capabilities Enhancement Activities</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2014	FY 2015
<p>make a recommendation for a Joint product of choice. Completed study assessing the safe use of mechanical ventilators in low pressure environments such as altitudes used for air evacuation of patients.</p> <p>FY 2015 Plans: Utilize medical Information Management/Information Technology systems that analyze data from fielded blast sensor systems to assess sensor characterization data of fielded sensor systems. Incorporate results of mobility studies into Operational Requirements-based Casualty Assessment (ORCA) model. Expand test and evaluation and implementation of system enhancements to the JTAPIC DICE. Analyze data on the effectiveness of Army Combat Uniforms treated with permethrin, as a barrier to ticks and mosquitoes, following extended periods of use. Enroll volunteers in a study to determine prevalence of a form of CYP2D6, a drug-metabolizing enzyme which has been linked to malaria relapse following treatment with primaquine (a synthetic drug compound to treat malaria). Initiate study to assess whether a current method of monitoring traumatic brain injury (TBI) patients may worsen clinical outcomes. Begin enrollment in a study to retrospectively evaluate the effectiveness of the Defense and Veterans Brain Injury (DVBIC) Progressive Return to Activity Clinical Recommendation Tool for service members following concussion/mild TBI.</p> <p>FY 2016 Plans: Will analyze data regarding prevalence of a form of CYP2D6, a drug-metabolizing enzyme which has been linked to malaria relapse following treatment with primaquine, and make recommendations for appropriate testing prior to using primaquine to treat relapse. Will continue enrollment and begin data analysis on DVBIC study.</p>			
Accomplishments/Planned Programs Subtotals		13.761	15.092
C. Other Program Funding Summary (\$ in Millions) N/A			
Remarks			
D. Acquisition Strategy Integrate product improvements and enhancements resulting from funded efforts. Use post marketing studies and surveillance to survey impact.			
E. Performance Metrics Principal Investigators will provide quarterly reports and a final report. Performance is measured based on the number of products for which testing either certifies use in a given environment (e.g., sufficiently ruggedized, airworthiness testing) and/or results in a recommendation of a specific product, and delivery of an enhanced product or knowledge product. The benchmark performance metric for research supported in this PE will be the enhancement of a maturity level that is typical of TRL 9.			

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Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0607100HP / <i>Medical Products and Capabilities Enhancement Activities</i>				Project (Number/Name) 457A / <i>AF Advanced Technology Development – Rapid Technology Transition</i>			
COST (\$ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
457A: <i>AF Advanced Technology Development – Rapid Technology Transition</i>	-	1.336	-	-	-	-	-	-	-	-	Continuing	Continuing
A. Mission Description and Budget Item Justification Air Force -Medical Products and Capabilities Enhancement Activities: Funds will support (1) developmental upgrades to medical systems and products that have been fielded or that are routinely used in a fixed facility or that have been approved for full-rate production and for which procurement funding is anticipated in the current fiscal year or subsequent fiscal years.												
B. Accomplishments/Planned Programs (\$ in Millions)										FY 2014	FY 2015	FY 2016
Title: AF Advanced Technology Development – Rapid Technology Transition Description: Provide support for developmental efforts to upgrade medical products and capabilities that have been fielded or have received approval for full rate production and anticipate production funding in the current or subsequent fiscal year. FY 2014 Accomplishments: Due to late receipt of funding, FY 2014 accomplishments for this initiative has not yet been finalized. FY 2015 Plans: No funding programmed. FY 2016 Plans: No funding programmed.										1.336	-	-
Accomplishments/Planned Programs Subtotals										1.336	-	-
C. Other Program Funding Summary (\$ in Millions) N/A Remarks D. Acquisition Strategy N/A E. Performance Metrics N/A												

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Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0607100HP / <i>Medical Products and Capabilities Enhancement Activities</i>				Project (Number/Name) 700A / <i>CSI - Congressional Special Interests</i>			
COST (\$ in Millions)	Prior Years	FY 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
700A: <i>CSI - Congressional Special Interests</i>	-	-	2.382	-	-	-	-	-	-	-	Continuing	Continuing

A. Mission Description and Budget Item Justification
 The FY15 DHP Congressional Special Interest (CSI) funding is directed toward core research initiatives in Program Element (PE) 0607100 - Medical Products and Capabilities Enhancement Activities. Because of the CSI annual structure, out-year funding is not programmed.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2014	FY 2015
<i>Congressional Add:</i> 467A – Program Increase: Restore Core Research Funding Reduction (GDF)	-	2.382
<i>FY 2014 Accomplishments:</i> No funding programmed. This is an FY 2015 DHP Congressional Special Interest (CSI) spending item.		
<i>FY 2015 Plans:</i> FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in the Medical Products and Capabilities Enhancement Activities Program Element (PE) - 06071000.		
Congressional Adds Subtotals	-	2.382

C. Other Program Funding Summary (\$ in Millions)
 N/A

Remarks

D. Acquisition Strategy
 N/A

E. Performance Metrics
 N/A