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Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Defense Health Agency										Date: February 2016		
Appropriation/Budget Activity 0130: Defense Health Program I BA 2: RDT&E					R-1 Program Element (Number/Name) PE 0607100DHA I Medical Products and Capabilities Enhancement Activities							
COST (\$ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
Total Program Element	37.420	16.413	17.356	14.998	-	14.998	14.938	18.214	19.819	20.215	Continuing	Continuing
377A: GDF-Medical Products and Capabilities Enhancement Activities	36.084	14.031	17.356	14.998	-	14.998	14.938	18.214	19.819	20.215	Continuing	Continuing
457A: AF Advanced Technology Development – Rapid Technology Transition	1.336	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
700A: CSI - Congressional Special Interests	0.000	2.382	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	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, 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 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, Precision Medicine Initiative, Office of Management and Budget Combat Casualty Care Assessment, National Defense Authorization Acts, etc.), and others as appropriate.

<b>B. Program Change Summary (\$ in Millions)</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017 Base</b>	<b>FY 2017 OCO</b>	<b>FY 2017 Total</b>
Previous President's Budget	17.474	17.356	17.647	-	17.647
Current President's Budget	16.413	17.356	14.998	-	14.998
Total Adjustments	-1.061	0.000	-2.649	-	-2.649
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	2.382	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-2.127	-			
• SBIR/STTR Transfer	-1.316	-			
• Realignment to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Care	-	-	-2.291	-	-2.291

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<b>Appropriation/Budget Activity</b>	<b>R-1 Program Element (Number/Name)</b>
0130: <i>Defense Health Program I BA 2: RDT&amp;E</i>	PE 0607100DHA I <i>Medical Products and Capabilities Enhancement Activities</i>

• Realignment of the Breast, GYN and Prostate Cancer Centers of Excellence	-	-	-0.358	-	-0.358
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**Congressional Add Details (\$ in Millions, and Includes General Reductions)**

**Project:** 700A: *CSI - Congressional Special Interests*

Congressional Add: 467A – *Program Increase: Restore Core Research Funding Reduction (GDF)*

Congressional Add Subtotals for Project: 700A

Congressional Add Totals for all Projects

	FY 2015	FY 2016
Congressional Add Subtotals for Project: 700A	2.382	0.000
Congressional Add Totals for all Projects	2.382	0.000

**Change Summary Explanation**

FY 2015: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0607100-Medical Products and Capabilities Enhancement Activities (-\$1.316 million) to DHP RDT&E PE 0605502-Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR) Program (+\$1.316 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.

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), Program Element (PE) PE 0607100-Medical Products and Capabilities Enhancement Activities (-\$2.291 million) to DHP O&M Account, Budget Activity Group (BAG) 3 - Private Sector Caree (+\$2.291 million).

FY 2017: Realignment from Defense Health Program, Research, Development, Test and Evaluation (DHP RDT&E), PE 0607100-Medical Products and Capabilities Enhancement Activities (-\$0.358 million) to USU DHP RDT&E PE 0603115 Breast, GYN and Prostate Cancer Centers of Excellence (+\$0.358 million).

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2017 Defense Health Agency										<b>Date:</b> February 2016		
<b>Appropriation/Budget Activity</b> 0130 / 2					<b>R-1 Program Element (Number/Name)</b> PE 0607100DHA / <i>Medical Products and Capabilities Enhancement Activities</i>				<b>Project (Number/Name)</b> 377A / <i>GDF-Medical Products and Capabilities Enhancement Activities</i>			
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017 Base</b>	<b>FY 2017 OCO</b>	<b>FY 2017 Total</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
377A: <i>GDF-Medical Products and Capabilities Enhancement Activities</i>	36.084	14.031	17.356	14.998	-	14.998	14.938	18.214	19.819	20.215	Continuing	Continuing

**A. Mission Description and Budget Item Justification**

The goal of the Medical Products and Capabilities Enhancement is to test, evaluate, and support enhancement of existing medical products and medically-related IT systems within the areas of medical simulation, infectious disease, tactical combat casualty care, military operational medicine, and clinical and rehabilitative medicine. Additionally, funding supports the investigation of clinical intervention outcomes to support, enhance, and improve militarily unique Clinical Practice Guidelines. Program Element 6.7 efforts are short-term, high-impact projects. It is an intramural research program focused on the evaluation of new commercial medical capabilities suitable for theater, the testing of a fielded capability to function in an expanded or altered operationally-relevant environment, and investigating the potential to incorporate emerging medical or non-medical technologies into fielded medical systems. The program structure provides a flexible and responsive mechanism to accomplish these objectives. A solicitation is released annually with two submission deadlines. Civilian and military intramural investigators are eligible to apply. Submitted proposals undergo a two-level review – one technical and one programmatic. A technical assessment of the proposals is solicited from the respective subject matter experts within the Joint Program Committees and the advanced development community. Following this, a programmatic review is performed by senior Service experts representing the science and technology base and advanced development. After the programmatic review, funding recommendations are forwarded to the Director, Research, Development and Acquisition, Defense Health Agency for final approval.

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

	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
<b>Title:</b> 377A: GDF – Medical Products and Capabilities Enhancement Activities	14.031	17.356	14.998
<b>Description:</b> 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.			
<b>FY 2015 Accomplishments:</b>			
One hundred and four (104) proposals were received in response to the FY 2015 solicitation. Of these, 20 were selected for funding. For ongoing Joint Trauma Analysis and Prevention of Injury in Combat (JTAPIC) managed efforts: Analyzed sensor characterization data of fielded blast sensor system; incorporated the results of mobility studies into an Operational Requirements-based Casualty Assessment model; implemented IT-system enhancements to the JTAPIC environment. For other funded efforts: Analyzed test data assessing the ability of Army Combat Uniforms treated with the insecticide permethrin to serve as a barrier to ticks and mosquitoes after extended periods of use; started project to determine the population prevalence of a form of CYP2D6, a drug-metabolizing enzyme which has been linked to malaria relapse following treatment with primaquine (a drug to treat malaria); began planning for a study to assess whether a current method of monitoring traumatic brain injury (TBI) patients may worsen clinical outcomes; initiated a study to retrospectively evaluate the effectiveness of the Defense and Veterans Brain Injury Center (DVBIC) Progressive Return to Activity Clinical Recommendation Tool for Service members following concussion/mild TBI;			

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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
<p>investigated improved methods to detect acute kidney injury by comparing a commercially available device measuring injury specific biomarkers against the current standard of practice; began assessment of a marksmanship trainer, the Conflict Kinetics Gunfighting Gym as a potential tool/metric to measure neurocognitive status/mental performance; progressed testing on improved junctional and extremity tourniquets to stop excessive bleeding.</p> <p><b>FY 2016 Plans:</b> Solicit, review, and make awards for intramural proposals consistent with the intent of Program Element 6.7. Funded efforts: Analyze data on the population prevalence of a form of CYP2D6, a drug-metabolizing enzyme which has been linked to malaria relapse following treatment with primaquine, and recommendations on primaquine use to treat malarial relapse; begin patient enrollment in study to assess whether a current method of monitoring TBI patients may worsen clinical outcomes; continue patient enrollment on the effectiveness of the Defense and Veterans Brain Injury Center Progressive Return to Activity Clinical Recommendation Tool for Service members following concussion/mild TBI; complete data collection and data analysis on comparison of a commercially available device measuring injury specific biomarkers of acute kidney injury versus the current standard of practice; complete assessment on the use of a marksmanship trainer, the Conflict Kinetics Gunfighting Gym, as a potential tool/metric to measure neurocognitive status/mental performance; evaluate technologies designed to fabricate custom ear pieces for hearing protection; collect retrospective data and begin a prospective study evaluating the efficacy of a peripheral nerve block to correct heterotopic ossification, which can occur after battlefield injuries, severe burn injuries and following amputation; continue evaluations of junctional and extremity tourniquets to stop excessive bleeding.</p> <p><b>FY 2017 Plans:</b> Will solicit, review, and make awards for intramural proposals consistent with the intent of Program Element 6.7. Funded efforts: will continue patient recruitment and begin data analysis for a study assessing whether a current method of monitoring TBI patients may worsen clinical outcomes; will complete patient enrollment and begin data analysis on the Defense and Veterans Brain Injury Center Progressive Return to Activity Clinical Recommendation Tool for Service members following concussion/ mild TBI; will provide recommendations on the use of a marksmanship trainer, the Conflict Kinetics (CK) Gunfighting Gym, as a potential tool/metric to measure neurocognitive status/mental performance and provide a plan to translate the tests designed for the larger CK platform to smaller platforms; will continue data collection on the efficacy of a peripheral nerve block during corrective surgery for heterotopic ossification, a condition which can occur after battlefield injuries, severe burn injuries, and following amputation.</p>				
<b>Accomplishments/Planned Programs Subtotals</b>		14.031	17.356	14.998
<b>C. Other Program Funding Summary (\$ in Millions)</b>				
N/A				
<b>Remarks</b>				

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<b>Appropriation/Budget Activity</b> 0130 / 2	<b>R-1 Program Element (Number/Name)</b> PE 0607100DHA / <i>Medical Products and Capabilities Enhancement Activities</i>	<b>Project (Number/Name)</b> 377A / <i>GDF-Medical Products and Capabilities Enhancement Activities</i>

**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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COST (\$ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
457A: AF Advanced Technology Development – Rapid Technology Transition	1.336	0.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

**A. Mission Description and Budget Item Justification**

Air Force - Medical Products and Capabilities Enhancement Activities: Funds support a developmental upgrade to a medical product that has been fielded and for which procurement funding is anticipated subsequent fiscal years.

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

	FY 2015	FY 2016	FY 2017
<b>Title:</b> AF Advanced Technology Development – Rapid Technology Transition	0.000	0.000	0.000
<b>Description:</b> 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.			
<b>FY 2015 Accomplishments:</b> Acquisition strategy approved and contract awarded for the enhancement of the XSTAT-30 Advanced Junctional Non-Compressible Hemorrhage Control Agent product.			
<b>FY 2016 Plans:</b> Complete enhancements and modifications to the XSTAT-30 Advanced Junctional Non-Compressible Hemorrhage Control Agent product, submit data package to the FDA regulatory approval process for predicate devices and transition the enhanced device to military operational use.			
<b>FY 2017 Plans:</b> No Funding Programmed.			
<b>Accomplishments/Planned Programs Subtotals</b>	0.000	0.000	0.000

**C. Other Program Funding Summary (\$ in Millions)**

N/A

**Remarks**

\$1.1M FY15/17 Defense Health Program – Air Force Procurement funds

**D. Acquisition Strategy**

Cost-plus Fixed Fee contract award to performer via the Army-Natick Soldier Systems Research Development and Execution Center contracting activity.

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**E. Performance Metrics**

N/A

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<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017 Base</b>	<b>FY 2017 OCO</b>	<b>FY 2017 Total</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
700A: <i>CSI - Congressional Special Interests</i>	0.000	2.382	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	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)**

	<b>FY 2015</b>	<b>FY 2016</b>
<b>Congressional Add:</b> 467A – Program Increase: Restore Core Research Funding Reduction (GDF)	2.382	0.000
<b>FY 2015 Accomplishments:</b> FY 2015 DHP Congressional Special Interest (CSI) spending item directed toward the restoral of core research initiatives in PE 0607100. Funds supported development of product enhancements within the core program (Project 377A).		
<b>FY 2016 Plans:</b> No Funding Programmed.		
<b>Congressional Adds Subtotals</b>	2.382	0.000

**C. Other Program Funding Summary (\$ in Millions)**

N/A

**Remarks**

**D. Acquisition Strategy**

N/A

**E. Performance Metrics**

N/A