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**Exhibit R-2, RDT&E Budget Item Justification:** PB 2021 Defense Health Agency **Date:** February 2020

<b>Appropriation/Budget Activity</b> 0130: <i>Defense Health Program I BA 2: RDT&amp;E</i>					<b>R-1 Program Element (Number/Name)</b> PE 0604110DHA I <i>Medical Products Support and Advanced Concept Development</i>							
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021 Base</b>	<b>FY 2021 OCO</b>	<b>FY 2021 Total</b>	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
Total Program Element	1,264.357	158.933	138.055	132.331	-	132.331	142.252	145.097	147.999	150.959	Continuing	Continuing
400Z: <i>CSI - Congressional Special Interests</i>	354.527	46.816	10.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
434A: <i>Medical Products Support and Advanced Concept Development (AF)</i>	18.617	4.000	4.000	4.080	-	4.080	4.162	4.245	4.330	4.417	Continuing	Continuing
374: <i>GDF - Medical Products Support and Advanced Concept Development</i>	891.213	108.117	124.055	128.251	-	128.251	138.090	140.852	143.669	146.542	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: advanced concept development of medical products that are regulated by the US Food and Drug Administration (FDA); clinical and field validation studies supporting the transition of FDA-licensed and unregulated products and medical practice guidelines to the military operational user; prototyping; risk reduction and product transition efforts for medical information technology applications such as coordination with the Program Execution Offices for integration of medical aspects into other acquisition Programs of Record; and medical simulation and training system technologies.

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.

Program development and execution is coordinated with all of the Military Services and Special Operations Command, 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 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 medical products and support systems development funding, PE 0605145.

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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 0604110DHA I <i>Medical Products Support and Advanced Concept Development</i>				

<b>B. Program Change Summary (\$ in Millions)</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021 Base</b>	<b>FY 2021 OCO</b>	<b>FY 2021 Total</b>
Previous President's Budget	161.094	128.055	132.331	-	132.331
Current President's Budget	158.933	138.055	132.331	-	132.331
Total Adjustments	-2.161	10.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	10.000			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-2.161	-			

**Congressional Add Details (\$ in Millions, and Includes General Reductions)**

**Project:** 400Z: *CSI - Congressional Special Interests*

Congressional Add: *427A - Traumatic Brain Injury / Psychological Health*

Congressional Add: *441A - Joint Warfighter Medical Research Program*

Congressional Add: *464A – CSI - Program Increase: Restore Core Research Funding Reduction (GDF)*

Congressional Add: *PC 540 - CSI HIV/AIDS Prevention Program*

Congressional Add Subtotals for Project: 400Z

Congressional Add Totals for all Projects

	<b>FY 2019</b>	<b>FY 2020</b>
	2.540	0.000
	21.785	10.000
	22.491	0.000
	0.000	0.000
Congressional Add Subtotals for Project: 400Z	46.816	10.000
Congressional Add Totals for all Projects	46.816	10.000

**UNCLASSIFIED**

<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2021 Defense Health Agency										<b>Date:</b> February 2020		
<b>Appropriation/Budget Activity</b> 0130 / 2					<b>R-1 Program Element (Number/Name)</b> PE 0604110DHA / <i>Medical Products Support and Advanced Concept Development</i>					<b>Project (Number/Name)</b> 400Z / <i>CSI - Congressional Special Interests</i>		
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021 Base</b>	<b>FY 2021 OCO</b>	<b>FY 2021 Total</b>	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
400Z: <i>CSI - Congressional Special Interests</i>	354.527	46.816	10.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

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

In FY 2018, 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)**

	<b>FY 2019</b>	<b>FY 2020</b>
<b>Congressional Add:</b> 427A - Traumatic Brain Injury / Psychological Health <i>FY 2019 Accomplishments:</i> CSI Add <i>FY 2020 Plans:</i> N/A	2.540	0.000
<b>Congressional Add:</b> 441A - Joint Warfighter Medical Research Program <i>FY 2019 Accomplishments:</i> CSI Add <i>FY 2020 Plans:</i> CSI Add	21.785	10.000
<b>Congressional Add:</b> 464A – CSI - Program Increase: Restore Core Research Funding Reduction (GDF) <i>FY 2019 Accomplishments:</i> CSI Restoral Add <i>FY 2020 Plans:</i> N/A	22.491	0.000
<b>Congressional Add:</b> PC 540 - CSI HIV/AIDS Prevention Program <i>FY 2019 Accomplishments:</i> CSI Add <i>FY 2020 Plans:</i> N/A	0.000	0.000
<b>Congressional Adds Subtotals</b>	46.816	10.000

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

N/A

**Remarks**

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<b>Appropriation/Budget Activity</b> 0130 / 2	<b>R-1 Program Element (Number/Name)</b> PE 0604110DHA / <i>Medical Products Support and Advanced Concept Development</i>	<b>Project (Number/Name)</b> 400Z / <i>CSI - Congressional Special Interests</i>

**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.

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2021 Defense Health Agency										<b>Date:</b> February 2020		
<b>Appropriation/Budget Activity</b> 0130 / 2					<b>R-1 Program Element (Number/Name)</b> PE 0604110DHA / <i>Medical Products Support and Advanced Concept Development</i>				<b>Project (Number/Name)</b> 434A / <i>Medical Products Support and Advanced Concept Development (AF)</i>			
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021 Base</b>	<b>FY 2021 OCO</b>	<b>FY 2021 Total</b>	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
434A: <i>Medical Products Support and Advanced Concept Development (AF)</i>	18.617	4.000	4.000	4.080	-	4.080	4.162	4.245	4.330	4.417	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 AF/SG's aerospace & operational medicine and medical readiness, enabling AF/SG key mission areas and major programs (e.g. Critical Care Air Transport Teams, Operational Support Teams, Operational Medical Readiness Squadrons) to deliver and sustain medical warfighting capabilities. 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)**

	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>
<b>Title:</b> Medical Products Support and Advanced Concept Development (AF)	4.000	4.000	4.080
<b>Description:</b> 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.			
<b>FY 2020 Plans:</b>			
Continue 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. Begin 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			

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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>
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; Continue development of patient loading and transport products.  <b>FY 2021 Plans:</b> FY 2021 plans continue efforts as outlined in FY 2020.  <b>FY 2020 to FY 2021 Increase/Decrease Statement:</b> Inflationary price increases.			
<b>Accomplishments/Planned Programs Subtotals</b>	4.000	4.000	4.080

**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.

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<b>Appropriation/Budget Activity</b> 0130 / 2					<b>R-1 Program Element (Number/Name)</b> PE 0604110DHA / Medical Products Support and Advanced Concept Development					<b>Project (Number/Name)</b> 374 / GDF - Medical Products Support and Advanced Concept Development			
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021 Base</b>	<b>FY 2021 OCO</b>	<b>FY 2021 Total</b>	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>Cost To Complete</b>	<b>Total Cost</b>	
374: GDF - Medical Products Support and Advanced Concept Development	891.213	108.117	124.055	128.251	-	128.251	138.090	140.852	143.669	146.542	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 materiel development of products that provide solutions for the most pressing medical needs of the Warfighter through advanced concept development of medical products that are regulated by the US Food and Drug Administration (FDA); clinical and field validation studies supporting the transition of FDA-licensed and unregulated products and medical practice guidelines to the military operational user; prototyping; risk reduction and product transition efforts for medical information technology applications such as coordination with the Program Execution Offices for integration of medical aspects into other acquisition Programs of Record; and medical simulation and training system technologies.

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

	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>
<b>Title:</b> GDF – Medical Product Support and Advanced Concept Development	108.117	124.055	128.251
<b>Description:</b> This funding provides product support and advanced concept development of materiel products that meet the medical needs of the warfighter. Materiel development may include accelerated transition of US Food and Drug Administration (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.			
<b>FY 2020 Plans:</b>			
Medical Modeling and Simulation: Programs will focus on development and application of medical simulation and training capabilities for hospital care and operations. The Point-of-Injury and Trauma Simulation program will continue capability development tying together individual, collective, service and Joint training to Warfighters and Medical Professionals across the Department of Defense. The Hospital Training Simulation Systems and Evacuation and Transportation Simulation Systems programs will continue to develop, standardize and baseline the Medical Treatment Facility, Theater Hospital training (care and procedures), and en-route patient care training for interoperability. The Learning, Tactics and Technology Systems program will continue to develop the training courses, hands-on training, and exercises to develop and maintain military medical skills that enhance and maximize the training simulations, manikins and healthcare across the Department of Defense.			
Medical Readiness: Programs will focus on prevention of illness and injury along with optimization of human performance. The Pharmaceutical Intervention for Noise-Induced Hearing Loss-Acute Exposure Treatment program will continue development of the			

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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>
<p>Capability Development Document with Key Performance Parameters and continue progress with an on-going clinical trial with a promising drug treatment candidate.</p> <p>Medical Combat Support: Programs will focus on operational support. The Hemorrhage Detection program will continue development of the Capability Development Document with Key Performance Parameters along with a laboratory-based technology analysis study to inform ability for the capability to be deployed to Roles 1-3. The Traumatic Brain Injury (TBI) Point of Injury Triage Device program will continue to integrate information from end user feedback, field evaluations in the deployed environment, and market research to identify a solution to aid the medical provider in the ability to triage and monitor a moderate/severe TBI. The Non-Compressible Hemorrhage Control program will continue to expand as a family of systems approach to identify potential solutions that would fulfill this gap. Efficacy of developmental items will be evaluated in clinical studies. The Joint Medical Exchange and Documentation of Information for Combat Casualty Care program will continue to conduct prototype demonstrations in operational and simulated field environments.</p> <p>Restoration and Healthcare Systems: Programs will focus on treatments to be used to restore form and function to warfighters as well as improve healthcare. The Traumatic Brain Injury-Drug Treatment program will continue to evaluate market research to identify possible TBI drug candidates that are ready for focused Phase II clinical trials and conduct clinical trial planning. The Post Traumatic Stress Disorder-Drug Treatment program will continue to explore options for simultaneous testing of multiple drugs using an innovative testing design.</p> <p><b>FY 2021 Plans:</b> FY 2021 plans continue efforts as outlined in FY 2020.</p> <p><b>FY 2020 to FY 2021 Increase/Decrease Statement:</b> Pricing adjustment for inflation.</p>			
<b>Accomplishments/Planned Programs Subtotals</b>	108.117	124.055	128.251

<b>C. Other Program Funding Summary (\$ in Millions)</b> N/A
<b>Remarks</b>

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**D. Acquisition Strategy**

This program will test and evaluate pharmaceuticals, devices, medical support systems, and medical information technologies in government-managed clinical trials and user assessments to gather data required for military and regulatory requirements prior to production and fielding, to include FDA approval, Environmental Protection Agency registration, and safe-to-fly evaluation.