

Defense Health Program
Fiscal Year (FY) 2013 Budget Estimates
Exhibit R-2, DHP RDT&E Budget Item Justification

Appropriation/Budget Activity
Defense Health Program/BA: 2

DATE: February 2012
R1 Item Nomenclature: 7
Medical Products Support and Advanced Concept
Development
0604110HP

COST: (Dollars in Millions)

	2011 Actual	2012 Estimate	2013 Estimate	2014 Estimate	2015 Estimate	2016 Estimate	2017 Estimate
Total PE 0604110	155.624	189.844	144.403	128.961	108.135	101.245	102.274
CSI-Joint Warfighter Medical Research (Army)	0.000	9.750	0.000	0.000	0.000	0.000	0.000
CSI-SBIR to the Core Funded RDT&E (Army)	1.170	0.000	0.000	0.000	0.000	0.000	0.000
CSI-Traumatic Brain Injury/Psychological Health (TBI/PH) (Army)	0.293	17.306	0.000	0.000	0.000	0.000	0.000
GDF-Medical Products Support and Advanced Concept Development (GDF-MPSACD)	153.186	162.788	144.403	128.961	108.135	101.245	102.274
Rapid Product Integration & Transition (Air Force)	0.975	0.000	0.000	0.000	0.000	0.000	0.000

A. MISSION DESCRIPTION AND BUDGET ITEM JUSTIFICATION: Guidance for Development of the Force (GDF) - Medical Products Support And Advanced Concept Development: funding is for product support and advanced concept development of medical products that are regulated by the U.S. Food and Drug Administration (FDA); the accelerated transition of 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 prototyping, risk reduction, validation, and product transition for medical

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training systems' technologies.

The resulting advanced development portfolio 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 the 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 (RDT&E) funding. Research supported by this program element includes accelerated transition of medical training and health information sciences, to include efforts at the Pacific Based Joint Information Technology Center, advanced development of rapid pathogen detection in fresh whole blood, field assessment of intervention tools for post traumatic stress disorder (PTSD), and clinical trials on biomarkers for traumatic brain injury (TBI) and spinal cord injury, combat casualty care advanced product development and rehabilitative medicine clinical trials.

The Army Medical Command received FY11 and FY12 DHP Congressional Special Interest (CSI) funding. The CSI strategy is to stimulate innovative research through a competitive, peer-reviewed research program, and focused medical research at intramural and extramural research sites. For FY11, CSI research focused on Traumatic Brain Injury and Psychological Health and the development of Small Business Innovation Research in Multimedia Combat Injury Management Training. For FY12, CSI research focuses on Traumatic Brain Injury and Psychological Health and Joint Warfighter Medical Research.

The project is being managed by Naval Health Research Center in conjunction with the Defense Center of Excellence for Psychological Health and Traumatic Brain Injury.

For the Air Force, funding in this Program Element provides provide for rapid transition of medical products and capabilities from the laboratory to the field to address minor modifications and enhancements required to integrate COTS and near-COTS products available in industry into the military operating environment in support of critical capability requirements for Air Force special operations teams, expeditionary medical system equipment modernization and en-route care modernization/transformation (critical care air transport team requirements). Funding will be used to harden existing COTS technology (embedded sensors/registers) to withstand rigorous / realistic exposure to simulated battlefield scenarios (e.g. blast injury, etc) in support of multiple monitoring and diagnostic

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functions. This program enhancement provides the Air Force with the ability to refine and enhance COTS/near-COTS products available in the market that have high potential for military application but require minor modifications in order to meet military unique mission requirements and rapidly transition these to the field. Given the rapid pace of new technology development, evolution of existing technologies and high costs associated with long-term new technology development for military missions, it is imperative Air Force leverage the commercial sectors advances in technology development for employment in Air Force operations whenever possible. Enabling our military forces to utilize enhanced or modified COTS-based solutions to meet operational requirements is a cost effective technique that should be maximized where possible to ensure warfighters have the appropriate technology at hand to care for our wounded at the point of injury through definitive care and on to rehabilitation and reintegration at the best cost and schedule to the taxpayer and Air Force operational community.

B. PROGRAM CHANGE SUMMARY:

	<u>2011</u>	<u>2012</u>	<u>2013</u>	<u>2014</u>
FY13 Budget Estimate RDT&E	154.649	167.481	142.866	127.668
Change Proposal	0.000	0.000	1.537	1.293
Congressional Rescission	0.000	-0.519	0.000	0.000
Congressional Special Interest	0.000	27.750	0.000	0.000
Reprogramming	1.000	0.000	0.000	0.000
SBIR	-0.025	-4.868	0.000	0.000
FY13 Budget Submission RDT&E	155.624	189.844	144.403	128.961

PROGRAM CHANGE SUMMARY EXPLANATION:

FY 2011: Congressional Special Interest increase to DHP RDT&E, PE 0604110-Medical Products Support and Advanced Concept Development for Rapid Product Integration & Transition (Air Force) (+\$1.000 million).

SBIR Transfer from DHP RDT&E, PE 0604110-Medical Products Support and Advanced Concept Development (-\$0.025 million) to DHP RDT&E, PE 0605502 - Small Business Innovation Research (SBIR) program (+\$0.025 million).

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FY 2012: Congressional Rescission from DHP RDT&E, PE 0604110 – Medical Products Support and Advanced Concept Development for Federally Funded Research and Development Centers (FFRDC) (-\$0.519 million).

Congressional Special Interest increase for Peer-Reviewed Traumatic Brain Injury/Psychological Health (TBI/PH) to DHP RDT&E, PE 0604110 – Medical Products Support and Advanced Concept Development (+\$17.750 million).

Congressional Special Interest increase for Joint Warfighter Medical Research to DHP RDT&E, PE 0604110 – Medical Products Support and Advanced Concept Development (+\$10.000 million).

SBIR Transfer from DHP RDT&E, PE 0604110 – Medical Products Support and Advanced Concept Development (-\$4.868 million) to DHP RDT&E, PE 0605502 – Small Business Innovation Research (SBIR) program (+\$4.868 million).

FY 2013: Change Proposal for inflation adjustment to DHP RDT&E, PE 0604110-Medical Products Support and Advanced Concept Development (+\$1.537 million).

FY 2014: Change Proposal for inflation adjustment to DHP RDT&E, PE 0604110-Medical Products Support and Advanced Concept Development (+\$1.293 million).

C. OTHER PROGRAM FUNDING SUMMARY: None.

D. ACQUISITION STRATEGY: Test and evaluate medical device prototypes, medical procedures, and drug and vaccine candidates in government-managed Phase 1/2 clinical trials to gather data required for military and regulatory requirements prior to production and fielding, to include FDA licensure and Environmental Protection Agency registration.

E. PERFORMANCE METRICS:

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 7 or the equivalent for TRL 8, such as practice guidelines and standards, which are intended for rapid transition to operational use.