

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: 9
Medical Products and Support Systems Dev
0605145HP

COST: (Dollars in Millions)

	2011 Actual	2012 Estimate	2013 Estimate	2014 Estimate	2015 Estimate	2016 Estimate	2017 Estimate
Total PE 0605145	0.000	33.695	17.116	13.476	20.455	36.013	37.694
GDF-Medical Products and Support Systems Development (GDF-MPSSD)	0.000	18.485	8.521	13.476	20.455	36.013	37.694
Hyperbaric Oxygen Therapy Clinical Trial (Army)	0.000	15.210	8.595	0.000	0.000	0.000	0.000

A. MISSION DESCRIPTION AND BUDGET ITEM JUSTIFICATION: Guidance for Development of the Force (GDF) - Medical Products and Support Systems Development: 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. 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 (RDT&E) funding. The work includes development and demonstration of medical modeling and simulation systems for training/education/treatment, and medical system development and demonstration.

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The Army Medical Command receives funding to support product development of hyperbaric oxygenation for chronic, mild traumatic brain injury (TBI). 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 mild TBI.

B. PROGRAM CHANGE SUMMARY:

	<u>2011</u>	<u>2012</u>	<u>2013</u>	<u>2014</u>
FY13 Budget Estimate RDT&E	0.000	34.559	16.834	13.365
Change Proposal	0.000	0.000	0.282	0.111
SBIR	0.000	-0.864	0.000	0.000
FY13 Budget Submission RDT&E	0.000	33.695	17.116	13.476

PROGRAM CHANGE SUMMARY EXPLANATION:

FY 2011: No Change.

FY 2012: SBIR Transfer from DHP RDT&E, PE 0605145-Medical Products and Support Systems Development (-\$0.864 million) to DHP RDT&E, PE 0605502 - Small Business Innovation Research (SBIR) program (+\$0.864 million).

FY 2013: Change Proposal for inflation adjustment to DHP RDT&E, PE 0605145-Medical Products and Support Systems Development (+\$0.282 million).

FY 2013: Change Proposal for inflation adjustment to DHP RDT&E, PE 0605145-Medical Products and Support Systems Development (+\$0.111 million).

C. OTHER PROGRAM FUNDING SUMMARY: None.

D. ACQUISITION STRATEGY: Test and evaluate medical procedures and prototype devices in government-managed Phase 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.

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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 8.