

Defense Health Program
 Fiscal Year (FY) 2011 Budget Estimates
 Exhibit R-2, DHP RDT&E Budget Item Justification

Appropriation/Budget Activity
 Defense Health Program/BA: 2

DATE: February 2010
 R1 Item Nomenclature: 7
 Medical Products Support and Advanced Concept
 Development
 0604110HP

COST: (Dollars in Millions)

| | 2009 Actual | 2010 Estimate | 2011 Estimate | 2012 Estimate | 2013 Estimate | 2014 Estimate | 2015 Estimate |
|---|----------------|------------------|------------------|------------------|------------------|------------------|------------------|
| Total PE 0604110 | 122.850 | 205.865 | 160.168 | 170.481 | 146.814 | 106.175 | 77.927 |
| CSI-Hawaii Federal Healthcare Network (TMA) | 0.000 | 5.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| CSI-Orthopedic Research (Army) | 49.725 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| CSI-Traumatic Brain Injury/Psychological Health Research (Army) | 73.125 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| GDF-Medical Products Support and Advanced Concept Development (GDF-MPSACD) | 0.000 | 193.065 | 160.168 | 170.481 | 146.814 | 106.175 | 77.927 |
| Biological Agent Identification and Diagnostic System (JBAIDS) (Army) | 0.000 | 7.800 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |

A. MISSION DESCRIPTION AND BUDGET ITEM JUSTIFICATION: Funding is provided for Advanced Component Development of medical products that are regulated by the U.S. Food and Drug Administration (FDA) and the accelerated transition of FDA licensed and unregulated products and medical practice guidelines to the military operational user through clinical and field validation studies. Research in this PE is designed to address

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areas of interest to the Secretary of Defense and to close medical capability gaps associated with the Joint Force Health Protection Concept of Operations (JFHP CONOPS) and derivative Joint Capability Documents (JCD). Program development and execution is peer-reviewed and fully coordinated with all Services and other agencies through the Expanded-Joint Technology Coordinating Groups under the Armed Services Biomedical Evaluation and Management (ASBREM) Committee to assure quality, relevance, and responsiveness to military operational needs, the needs of the Military Health System and the JFHP CONOPS and JCDs. Research includes trials for accelerated transition of modeling and simulation technology for medical training/education/treatment; trials for accelerated transition of medical technology to include the Joint Medical Information and Biotechnology support to the Warfighter under the JITC-Maui (\$34.3M), practice guidelines and standards; medical products - advanced component development; and medical information technology development.

The Army Medical Department received Congressional Special Interest (CSI) directed research programs for FY 2009. The strategy for Congressionally directed research is to stimulate innovative research through a competitive, peer reviewed research program, as well as focused medical research at selected Army sites. For FY 2009, CSI effort included Orthopedic Research and Traumatic Brain Injury/Psychological Health Research. Because of the CSI annual structure out-year funding is not programmed.

For FY 2010, the Army Medical Department received funding for Joint Biological Agent Identification and Diagnostic System (JBAIDS) research to explore H1N1 viral identification. Funding was appropriated in the Supplemental Appropriations Act, 2009, Title VIII (P.L. 111-32) and transferred from Department of Health and Human Services (DHHS) to Department of Defense for Pandemic Influenza Preparedness and Response.

For the Navy Medical Department, this research supports the product development efforts resulting from a previously initiated project for Hyperbaric Oxygenation for Chronic, Mild Traumatic Brain Injury. Clinical trials conducted by that project entail the development, initiation, operation, and analysis, including publication, from a multi-center, prospective, randomized controlled trial comparing multiple outcomes of enrolled subjects more than four months after mild hyperbaric chamber exposures. The project is comparing and assessing the long-term benefit of hyperbaric oxygen therapy on service members with mild traumatic brain injury. 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.

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B. PROGRAM CHANGE SUMMARY:

| | <u>2009</u> | <u>2010</u> | <u>2011</u> | <u>2012</u> |
|------------------------------|-------------|-------------|-------------|-------------|
| FY11 Budget Estimate RDT&E | 122.850 | 198.015 | 160.168 | 170.481 |
| CSI | 0.000 | 5.000 | 0.000 | 0.000 |
| Transfer | 0.000 | 7.800 | 0.000 | 0.000 |
| SBIR | 0.000 | -5.150 | 0.000 | 0.000 |
| FY11 Budget Submission RDT&E | 122.850 | 205.865 | 160.168 | 170.481 |

PROGRAM CHANGE SUMMARY EXPLANATION:

FY09:
 No Change.

FY10:
 Congressional Special Interest increase for CSI-Hawaii Federal Health Network (TMA) (PE 0604110) (+\$5.000 million)

Transfer from Health and Human Services (HHS) under Supplemental Appropriations Act, 2009, Title VIII (P.L. 111-32), for Pandemic Influenza Preparedness and Response, for Joint Biological Agent Identification and Diagnostic System (JBAIDS) Lab Testing to provide diagnostic capability at deployed and remote locations for influenza viruses (+\$7.800 million).

SBIR Transfer from DHP RDT&E Program Element 0604110-Medical Products Support and Advanced Concept Development to DHP RDT&E Program Element 0605502-Small Business Innovation Research (SBIR) (-\$4.950 million); and from Pandemic Influenza Preparedness and Response to DHP RDT&E Program Element 0605502-Small Business Innovation Research (SBIR) (-\$0.200 million).

FY11:
 No Change.

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FY12:
No Change.

C. OTHER PROGRAM FUNDING SUMMARY: None.

D. ACQUISITION STRATEGY: Not Required.

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.