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**Exhibit R-2, PB 2010 Chemical and Biological Defense Program RDT&E Budget Item Justification** **DATE:** April 2009

<b>APPROPRIATION/BUDGET ACTIVITY</b> 0400 - Research, Development, Test & Evaluation, Defense-Wide/BA 1 - Basic Research	<b>R-1 ITEM NOMENCLATURE</b> PE 0601384BP CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)
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COST (\$ in Millions)	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
Total Program Element	82.399	61.194	58.974						Continuing	Continuing
CB1: CHEMICAL/ BIOLOGICAL DEFENSE (BASIC RESEARCH)	20.344	24.332	35.624						Continuing	Continuing
CI1: CONGRESSIONAL INTEREST ITEMS (BASIC RESEARCH)	16.718	8.200	0.000						Continuing	Continuing
TB1: MEDICAL BIOLOGICAL DEFENSE (BASIC RESEARCH)	33.173	16.329	16.852						Continuing	Continuing
TC1: MEDICAL CHEMICAL DEFENSE (BASIC RESEARCH)	12.164	12.333	5.519						Continuing	Continuing
TR1: MEDICAL RADIOLOGICAL DEFENSE (BASIC RESEARCH)	0.000	0.000	0.979						Continuing	Continuing

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

This program element funds the Joint Service fundamental research program for (medical and physical sciences) Chemical, Biological, and Radiological (CBR) defense. The objective of the basic research program is to advance fundamental knowledge and understanding of the sciences with an emphasis in exploring new and innovative research for combating or countering chemical, biological and radiological weapons. Moreover, basic research supports a Joint Force concept of a lethal, integrated, supportable, highly mobile force with enhanced capability by the individual service member. Specifically, the program promotes theoretical and experimental research and studies in the chemical, biological, radiological, medical and related sciences.

Research areas are aligned and prioritized to meet Joint Service needs as stated in mission area analyses, joint operational requirements and to take advantage of scientific opportunities. Basic research is executed by government laboratories, industry, and academia to include Historically Black Colleges and Universities and Minority Institutions (HBCU/MIs). Funds directed to these laboratories and research organizations capitalize on scientific talent, specialized facilities, and technological breakthroughs. The work in this program element is consistent with the Chemical Biological Defense Program Research, Development and Acquisition (RDA) Plan.

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<b>APPROPRIATION/BUDGET ACTIVITY</b>	<b>R-1 ITEM NOMENCLATURE</b>
0400 - Research, Development, Test & Evaluation, Defense-Wide/BA 1 - Basic Research	PE 0601384BP CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)

Knowledge and technologies resulting from basic research efforts are expeditiously transitioned to the applied research (PE 0602384BP) and advanced technology development (PE 0603384BP) activities. This project also covers the conduct of basic research efforts in the areas of real-time sensing and immediate biological countermeasures. The projects in this PE are placed in BA1, because they are basic research efforts directed towards non-specific or non-unique military applications.

**B. Program Change Summary (\$ in Millions)**

	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011</u>
Previous President's Budget	83.132	53.191	55.484	
Current BES/President's Budget	82.399	61.194	58.974	
Total Adjustments	-0.733	8.003	3.490	
Congressional Program Reductions	0.000	-0.197		
Congressional Rescissions				
Total Congressional Increases	0.000	8.200		
Total Reprogrammings	0.294	0.000		
SBIR/STTR Transfer	-1.027	0.000		
Other Adjustments	0.000	0.000	3.490	

**Congressional Increase Details (\$ in Millions)**

**Project:** CI1, CONGRESSIONAL INTEREST ITEMS (BASIC RESEARCH)

<b>FY 2008</b>	<b>FY 2009</b>
0.000	8.200

**Change Summary Explanation**

Funding: FY09 - Congressional increases to enhance projects within the science and technology base (+\$8,200K CI1); Congressional general reductions and other adjustments (-\$92K CB1; -\$59K TB1; -\$46K TC1).

Schedule: N/A

Technical: N/A

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<b>Exhibit R-2a, PB 2010 Chemical and Biological Defense Program RDT&amp;E Project Justification</b>								<b>DATE:</b> April 2009		
<b>APPROPRIATION/BUDGET ACTIVITY</b> 0400 - Research, Development, Test & Evaluation, Defense-Wide/BA 1 - Basic Research				<b>R-1 ITEM NOMENCLATURE</b> PE 0601384BP CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)					<b>PROJECT NUMBER</b> CB1	
<b>COST (\$ in Millions)</b>	<b>FY 2008 Actual</b>	<b>FY 2009 Estimate</b>	<b>FY 2010 Estimate</b>	<b>FY 2011 Estimate</b>	<b>FY 2012 Estimate</b>	<b>FY 2013 Estimate</b>	<b>FY 2014 Estimate</b>	<b>FY 2015 Estimate</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
CB1: CHEMICAL/ BIOLOGICAL DEFENSE (BASIC RESEARCH)	20.344	24.332	35.624						Continuing	Continuing

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

This project (CB1) supports basic research efforts in fundamental science phenomenology to include: Life Sciences; Physical Sciences; Environmental Sciences; Mathematics; Psychology and Social Sciences; and Engineering. The objective of the Basic Research program is to successfully support the advancement of fundamental knowledge and understanding of the sciences with an emphasis on exploring new and innovative research for Chemical and Biological (CB) Defense. It includes new study areas, such as: Nanoscale Sciences; Chemical, Biological & Bio-Inspired Sciences; Surface & Signature Sciences (with an emphasis on Non-Traditional Agents (NTA's); and Informational Sciences. The aim is to promote innovative concepts and directions of research, which could lead to transformational capabilities to enhance the performance and ensure the safety of the warfighter. Research in Nanoscale Sciences (nanoelectromechanical systems, carbon nanotubes, molecular motors, and nanometer imaging) can bring about improvements in protection, decontamination and other core CB defense fields. Research in Chemical, Biological & Bio-Inspired Sciences includes research in concepts, such as, synthetic biology, biomimetics, and other emerging areas of science to build a foundation for developing novel smart materials, which combine multiple functionalities into a common autonomous unit or network. Surface and Signature sciences focuses on the study of physical and chemical properties, especially with regard to Non Traditional Agents (NTA's), that seeks to improve physical capabilities such as detection and decontamination. Informational Sciences includes research in understanding cognitive and physiological effects on human decision-making, behavior and performance, and modeling and simulation of CB threats. Breakthroughs and advances in functional capabilities gained from these scientific disciplines could impact the entire chemical and biological defense science and technology program. Basic Research activities described in this budget justification leverage existing research programs and activities within the DoD and other government agencies to accelerate transformational breakthroughs, which may be transitioned to applied research or advanced development initiatives. Due to the exploratory, academic, and theoretical nature of Basic Research efforts, projects described in this justification typically have a short duration time from conception to completion (one to three years). Promising techniques will transition to both technology development and system level programs. The basic research program will continue to promote cross-pollination between government and academia, as well as, sponsor world class scientists while promoting the development of young researchers.

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

	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
Nano-Scale Sciences: Aims to improve understanding of nanoparticles (scale of 1-100 nanometers in length) for use in chemical and biological defense.	4.912	5.572	9.198	

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<b>Exhibit R-2a, PB 2010 Chemical and Biological Defense Program RDT&amp;E Project Justification</b>			<b>DATE:</b> April 2009	
<b>APPROPRIATION/BUDGET ACTIVITY</b> 0400 - Research, Development, Test & Evaluation, Defense-Wide/BA 1 - Basic Research	<b>R-1 ITEM NOMENCLATURE</b> PE 0601384BP CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)		<b>PROJECT NUMBER</b> CB1	
<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
<p>FY08 - Continued efforts investigating new types of materials (with molecular scale porosity) for potential use in decontamination and protection, as well as, new techniques for detection of chemical agents through novel applications of physics and chemistry. Explored compounds which mimic biological organisms and nano-scale sensing technologies for identification of agents. Initiated studies developing new materials through nanotechnology for improvements to protective equipment.</p> <p>FY09 - Complete efforts investigating new types of materials (with porosity in the nanometers) for potential use in decontamination and protection, and share information on new techniques for detection of chemical agents through novel applications of physics and chemistry. Continue study of compounds which mimic biological organisms and nano-scale sensing technologies for identification of agents. Continue studies of new materials being developed through nanotechnology for protective equipment, while initiating new efforts into new textiles with a higher resistance to oily substances or with adjustable porosity. Other new efforts will study interfaces between nano-materials and living cells, and systems found in nature for creative solutions for future protection concepts.</p> <p>FY10 - Complete study of some compounds which mimic biological organisms and nano-scale sensing technologies for identification of agents. Continue efforts into new textiles with a higher resistance to oily substances or with adjustable porosity, as well, as efforts studying interfaces between nano-materials and living cells, and studying systems found in nature for creative solutions for future protection concepts. Continue to identify new topics for investments in basic research to support the fundamental scientific phenomena in nano-scale science technology. Investigate new concepts in nano-scale chemical and biological sensing/detection. Initiate new studies to develop nano-scaled porous materials. Identify/leverage state-of-the-art breakthroughs to fill capability gaps. Advancements made in Nano-scale Sciences may apply to and be leveraged by other Basic Research areas such as Biosciences &amp; Bio-inspired Sciences, Surface and Signature Science, Informational Science, and Threat Agent Science (TAS) activities located in Budget Activity 2.</p>				
SBIR - FY09 - Small Business Innovative Research.	0.000	0.336	0.000	
Chemical, Biological, and Bio-Inspired Science: Focuses on discovering fundamental phenomena that could impact Chemical and biological defense.	3.860	4.800	11.760	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
<p>FY08 - Continued to leverage previous Basic Research efforts in fundamental phenomena that reflect recent advances in bioscience. Investigated novel materials for biomolecular adsorption and cell signaling to better understand the effects of Chem-Bio agents, as well as, new hybrid nanomaterials that bridge nanoparticle and metallic surfaces to make biological interfaces. Studied real-time changes in bacterial sizes during growth of biological agent simulants, and immobilized antimicrobial activities in non-biological and antibacterial materials and coatings. Examined biophysical fluid dynamics near surfaces and interaction of bio-aerosols with shock blast waves on the dispersion, activation, and destruction of airborne threats.</p> <p>FY09 - Continue research on projects initiated in FY08, such as novel materials for biomolecular adsorption and cell signaling to mitigate effects of Chem-Bio Agents, as well as, new hybrid nanomaterials that bridge nanoparticle and metallic surfaces to make biological interfaces. Initiate efforts to investigate reactions of certain chemical compounds in alcohol media for possible decontaminant applications, and new peptide structures for alternative active sites on the molecule for recognition and decontamination. Investigate new approaches for the classification of biological agents and specifically engineered genetics</p> <p>FY10 - Continue previous FY08/FY09 projects related to Bioscience. Continue research to investigate new hybrid nanomaterials that bridge nanoparticle and metallic surfaces to make biological interfaces, which will allow for improved understanding of cellular reactions and responses to chemical and biological agents. Continue to characterize new mechanisms of reaction for these new materials. Begin developing novel tools to investigate cells and cell mechanisms. Characterize NTA toxicokinetic properties and mechanisms of toxicity for NTAs. Assess effectiveness of developmental general purpose decontaminants, as well as explore new formulations. Maintain visibility of relevant research which could be leveraged for the benefit of the program.</p>				
<p>Information Science: Leverages new developments in information and computation to impact modeling and other chemical and biological efforts.</p> <p>FY08 - Initiated and continued to leverage previous Basic Research efforts in fundamental phenomena to address opportunities to leverage advances in information science. Investigated the use of dynamic combinatorial chemistry that enables new host-guest combinations that may result in new approaches in detection, protection, or decontamination. Studied the physics of molecules adhered to surfaces under conditions of flow. Investigated the dynamics of bacterial germination and migration within the body, infection</p>	4.680	5.925	6.000	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
<p>of target tissues and modeled the results. Analyzed atmospheric behavior by deriving basic mathematical and physical relationships such as momentum and energy exchanges. Studied the fundamental relationships between models and data for moisture in soil, variability in clouds, and characteristics of the wind and turbulence at the boundary layer.</p> <p>FY09 - Continue research on projects initiated in FY08. Initiate efforts to investigate genetic algorithms to identify optimal material arrangements, quantification and reduction of uncertainty for dispersion models via meteorological predictions through computer experimentation, calculations of the complete electromagnetic response of large macromolecules, and new molecular recognition signatures in the electromagnetic spectrum.</p> <p>FY10 - Continue FY08/FY09 projects. Initiate efforts to support and investigate genetic algorithms. Seek to understand cognitive effects of heightened sensory input. Research conducted will draw from many disciplines, including: cognitive psychology; neuroscience; linguistics; medical sciences; and will leverage advances in physics, mathematics, biology, and other relevant sciences to improve informational and decision making tools.</p>				
<p>Cognitive Science: Focuses on thinking and decision making to impact support tools for CB defense.</p> <p>FY08 - Initiated efforts in fundamental phenomena to address opportunities to leverage advances in cognitive science to support chemical and biological defense program requirements. Conducted research in cognitive science that draws from many disciplines including: cognitive psychology; neuroscience; linguistics; computer science; physics; mathematics; and biology. Initiated research on imaging methods (e.g., modern optical microscopy, functional brain mapping) and their applications to the affects of chemical and biological agents. Leveraged data gathered during the study of human cognitive, sense and motor processes. Conducted cause and effect research to fill the gap between psychological processes and brain functions as a result of exposure to chemical and biological agents.</p> <p>FY09 - Continue research on projects initiated in FY08. Initiate efforts to investigate the presentation of risk and uncertainty for chemical and biological defense decision making.</p> <p>FY10 - All Cognitive Science efforts will be re-aligned to Information Science.</p>	3.174	4.199	0.000	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
<p>Integration of Basic Research Science: Focuses on basic research for chemical and biological defense and reaches out to a varied performer base for the best innovations and programs.</p> <p>FY08 - Initiated a multi-faceted, integrated, and cross-cutting effort involving DoD laboratories, industry, academia, and federally funded research efforts to determine best basic research investment strategies and approach integration of CB basic research findings into applied research.</p> <p>FY09 - Complete research on projects initiated in FY08, and transition relevant information to various physical applied research projects located in Budget Activity 2.</p>	3.718	3.500	0.000	
<p>Surface &amp; Signature Sciences: A new study area that focuses on the study of physical and chemical properties, especially with regard to Non Traditional Agents (NTA's), that seeks to improve physical capabilities, such as, detection and decontamination.</p> <p>FY10 - Develop novel tools to investigate surface and signature sciences to inform capability gaps in fields such as detection and decontamination. Initiate and combine the efforts that improve the phenomenology needed for and to protect, detect, decontaminate, or otherwise counter chemical (to include NTA's) and biological threats. Study interactions of Chemical and Biological agents with biological and environmental matrices.</p>	0.000	0.000	8.666	

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<b>C. Other Program Funding Summary (\$ in Millions)</b>										
	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011</u>	<u>FY 2012</u>	<u>FY 2013</u>	<u>FY 2014</u>	<u>FY 2015</u>	<b>Cost To Complete</b>	<b>Total Cost</b>
CB2/CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)	93.629	110.615	111.420						Continuing	Continuing
CB3/CHEMICAL BIOLOGICAL DEFENSE (ATD)	18.839	19.183	25.403						Continuing	Continuing
TT3/TECHBASE TECHNOLOGY TRANSITION	9.239	8.214	7.388						Continuing	Continuing
<b>D. Acquisition Strategy</b>										
N/A										
<b>E. Performance Metrics</b>										
N/A										

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<b>COST (\$ in Millions)</b>	<b>FY 2008 Actual</b>	<b>FY 2009 Estimate</b>	<b>FY 2010 Estimate</b>	<b>FY 2011 Estimate</b>	<b>FY 2012 Estimate</b>	<b>FY 2013 Estimate</b>	<b>FY 2014 Estimate</b>	<b>FY 2015 Estimate</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
CI1: CONGRESSIONAL INTEREST ITEMS (BASIC RESEARCH)	16.718	8.200	0.000						Continuing	Continuing

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

The efforts listed in Section B of this justification include congressional interest programs for FY08 and FY09.

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

	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
<p>CBDP Initiative Fund Basic Research: The CBDIF goal was to fund new and innovative chemical and biological science and technology projects across a wide range of military operations. Established in FY2003, it is congressionally directed with the intent to provide funds via a competitive acquisition to non-Government entities.</p> <p>FY08 - Solicited proposals from degree-granting universities, nonprofit organizations, and commercial concerns, to include small businesses, in support of the CBDP to explore new and innovative ideas to fill identified knowledge gaps. Upon technical evaluation and selection of proposals, provided a report detailing the number of projects funded and areas of research.</p>	3.943	0.000	0.000	
<p>SBIR - FY09 - Small Business Innovative Research.</p>	0.000	0.110	0.000	
<p>Detection of Biological Agents in Water -</p> <p>FY08 - Conducted research to develop a highly sensitive and selective acoustic wave biosensor arrays with signal analysis system to provide a fingerprint for the real-time identification and quantification of a wide array of bacterial pathogens and environmental health hazards.</p>	1.972	0.000	0.000	
<p>Diamond Microelectronic Machined Sized (MEMS) Sensors for Real-Time Sensing of Weaponized Pathogens -</p> <p>FY08 - Researched and developed a new class of compact, wearable, real-time chemical and biological point sensors using the unique properties of diamond.</p>	0.986	0.000	0.000	
<p>Portable Continuous Monitor for Biodetection -</p>	1.577	0.000	0.000	

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<b>APPROPRIATION/BUDGET ACTIVITY</b> 0400 - Research, Development, Test & Evaluation, Defense-Wide/BA 1 - Basic Research	<b>R-1 ITEM NOMENCLATURE</b> PE 0601384BP CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)		<b>PROJECT NUMBER</b> C11	
<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
FY08 - Conducted research to develop a platform capable of performing multiple bioassays for live organisms and toxins simultaneously, efficiently, accurately and extremely fast.				
Rapid Response Database Systems Initiative -  FY08 - Conducted research to develop an exercise system (that can be implemented and replicated throughout the military, guard and the world) that most effectively ensures a rapid response to All Hazards whether natural or man-made.	0.986	0.000	0.000	
Garden State Cancer Center Vaccine Development Program -  FY08 - Conducted research to continue the development of a safe vaccine against smallpox that does not require whole or live virus, thereby eliminating the danger of vaccine-associated side effects and transmission for viral infections to immunocompromised individuals.  FY09 - Continue research to continue the development of a safe vaccine against smallpox that does not require whole or live virus, thereby eliminating the danger of vaccine-associated side effects and transmission for viral infections to immunocompromised individuals.	0.789	0.789	0.000	
DNA Safeguard -  FY08 - Conducted research to develop a stable, DNA-based chemical marker (DNA Barcode) capable of encoding information that can be added to any DNA sample in order to label the sample and guarantee its integrity.  FY09 - Continue development of a stable, DNA-based chemical marker (DNA Barcode) capable of encoding information that can be added to any DNA sample in order to label the sample and guarantee its integrity.	1.341	1.184	0.000	
PhotoScrub -  FY08 - Conducted research using PhotoScrub to break down chemical and biological threats into simpler, non-hazardous molecules such as carbon dioxide and water.	1.578	0.000	0.000	

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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>			<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>
Initiative for Defense Against Bio-Warfare and Bio-Terrorism -  FY08 - Researched and developed pharmaceutical drugs with a broad spectrum of action against a range of Categories A and B bacterial pathogens, and emerging drug-resistant bacteria that cause serious, life-threatening infections in the community and health-care facilities.			1.576	0.000	0.000
Multisignal Nanosensors for Detections of IEDs -  FY08 - Conducted basic research in the use of nanosensors to detect IED.			1.970	0.000	0.000
Detection and Remediation Response to Bio/Chem Weapons -  FY08 - TBD.			0.000	0.000	0.000
In Vitro Models for Biodefense Vaccine -  FY09 - Conduct basic research for the use of In Vitro models in vaccine development.			0.000	0.987	0.000
Superstructural Partical Evaluation and Characterization with Targeted Reaction Aanlysis (SPECTRA) -  FY09 - Continuation of basic research on superstructural particle evaluation and characterization with targeted reaction analysis begun in FY06.			0.000	1.184	0.000
Defense Through Early Containment -  FY09 - TBD.			0.000	1.184	0.000
Protection from Oxidative Stress -  FY09 - Recipient TBD.			0.000	1.579	0.000
Research on a Molecular Approach to Hazardous Materials Decontamination -  FY09 - Continuation of research on molecular approach to decontamination in collaboration with NSWC begun in FY06.			0.000	1.183	0.000

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<b>C. Other Program Funding Summary (\$ in Millions)</b> N/A		
<b>D. Acquisition Strategy</b> N/A		
<b>E. Performance Metrics</b> N/A		

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<b>COST (\$ in Millions)</b>	<b>FY 2008 Actual</b>	<b>FY 2009 Estimate</b>	<b>FY 2010 Estimate</b>	<b>FY 2011 Estimate</b>	<b>FY 2012 Estimate</b>	<b>FY 2013 Estimate</b>	<b>FY 2014 Estimate</b>	<b>FY 2015 Estimate</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
TB1: MEDICAL BIOLOGICAL DEFENSE (BASIC RESEARCH)	33.173	16.329	16.852						Continuing	Continuing

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

This project (TB1) funds basic research of vaccines, diagnostic tools, and therapeutic drugs to provide effective medical defense against validated biological threat agents including: bacteria; toxins; and viruses. Innovative biotechnology approaches with the potential to rapidly identify, diagnose, prevent, and treat disease due to exposure to biological threat agents will be advanced. Categories of this project include core science efforts and technology programs areas in biological defense capability areas, such as, Pretreatments, Diagnostics, and Therapeutics. Starting in FY10, all efforts will be combined into a capability area termed Biological Based Basic Research in order to streamline the management of medical basic research activities.

This project also includes efforts such as the Transformational Medical Technologies Initiative (TMTI). The TMTI was launched in FY 2006 as a key Quadrennial Defense Review initiative to respond to the threat of emerging or intentionally bioengineered biological threats. TMTI's mission is to protect the Warfighter from genetically engineered biological threats by providing a rapid response capability from identification of pathogens to the delivery of medical countermeasures. This mission is accomplished through two main efforts: 1) developing broad spectrum (multi-agent) therapeutics against biological warfare (BW) agents (e.g, one drug that treats multiple agents); and 2) developing platform technologies to assist in the rapid development of medical countermeasures (MCMs) in response to BW agents (e.g, developing new and innovative ways to mass produce drugs in the event of a biological incident).

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

	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
Multiagent (Broad Spectrum) Medical Countermeasures - Basic research efforts are focused on the early drug discovery phase of drug development. Active monitoring of scientific literature takes place to generate hypotheses for research. Scientific findings are reviewed and assessed as a foundation for characterizing new therapeutics. Researchers try to identify and develop brand new compounds that could lead to successful therapeutic candidates. Scientific studies occur to generate research ideas, hypotheses, and experimental designs for addressing the development of therapeutics against Biological Warfare (BW) agents. Focus on practical applications based on basic principles observed. Use of computer simulation or other virtual platforms to test hypotheses. Begin research, data collection, and analysis in order to test hypothesis. Explore alternative concepts, identify and evaluate critical technologies and components, and begin characterization of	21.114	6.103	5.631	

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<b>Exhibit R-2a, PB 2010 Chemical and Biological Defense Program RDT&amp;E Project Justification</b>			<b>DATE:</b> April 2009	
<b>APPROPRIATION/BUDGET ACTIVITY</b> 0400 - Research, Development, Test & Evaluation, Defense-Wide/BA 1 - Basic Research	<b>R-1 ITEM NOMENCLATURE</b> PE 0601384BP CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)		<b>PROJECT NUMBER</b> TB1	
<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
<p>candidate(s). Preliminary efficacy demonstrated. Multiple performers will be initiating tests at various stages of preclinical development.</p> <p>FY08 - Conducted basic research drug discovery research to identify molecular targets for broad-spectrum countermeasures. Evaluated research in genomics, proteomics and other relevant bioinformatics research to aid in this effort. Initiated collaborations to support rational drug design. Studied host immune response to infections.</p> <p>FY09 - Continue drug discovery research for broad-spectrum countermeasures with new candidates. Continue basic research to identify new candidates for molecular targets for broad-spectrum countermeasures. Continue to evaluate new thrust areas in genomics, proteomics, bioinformatics, and other relevant systems biology research. Focus efforts on promising intervention points for broad-spectrum therapeutic approaches based on results from drug design collaborations. Develop computer models and other methodologies to support rational drug design by determining the three-dimensional structure of important molecules based on the genetic sequences of organisms. Continue to study changes in host response to infection. Initiate study of biomarkers for intracellular bacterial (ICB) and hemorrhagic fever virus (HFV) agents.</p> <p>FY10 - Initiate support for the discovery of conserved host and pathogen directed targets for the development of broad spectrum drugs against BW agents. Validate computer models and other methodologies for rational drug design. Initiate investigation of technological advancements in genetic sequencing and drugs based on protein-to-protein interactions.</p>				
<p>Viral Therapeutics: Research understanding of viral infection.</p> <p>FY08 - Delineated host cell alarm response to viral infection to enhance the current understanding of viral pathogenesis (mechanism of injury), in support of therapeutic development against viral threat agents. Focused on host cell responses common to infection with multiple viral threats.</p> <p>FY09 - Delineate the mechanisms of pathogenesis of conventional threats to support the progression of therapeutics to advanced development. Compare the host response of well characterized threats with that of poorly characterized category A and B threats to identify new therapeutic targets.</p>	0.495	0.435	0.000	

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<b>Exhibit R-2a, PB 2010 Chemical and Biological Defense Program RDT&amp;E Project Justification</b>			<b>DATE:</b> April 2009	
<b>APPROPRIATION/BUDGET ACTIVITY</b> 0400 - Research, Development, Test & Evaluation, Defense-Wide/BA 1 - Basic Research	<b>R-1 ITEM NOMENCLATURE</b> PE 0601384BP CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)		<b>PROJECT NUMBER</b> TB1	
<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
FY10 - Effort will be re-aligned to Biological Based Basic Research.				
Diagnostic Technologies: Pursue technologies to discover infection in the host.  FY08 - Explored new avenues for assay design and application, focusing on improving sensitivity and specificity. Validated a key component for automated sample preparation. Increased efforts for a novel method to produce improved reagents for diagnoses of disease. Assessed the applicability of novel technology platforms as new techniques became available in gene sequencing. Pursued identification of novel biomarkers identifying exposure to biological pathogens.  FY09 - Continue to seek novel avenues for assay design and application. Investigate cutting edge technologies as new genomic techniques become available. Accelerate identification of novel biomarkers of biological warfare agent (BWA) infection and apply to assay development.  FY10 - Efforts realigned to Biological Based Basic Research.	3.309	3.027	0.000	
Multiagent Vaccines: Researched stable genes for potential vaccine targets.  FY08 - Identified stable genes that could serve as potential targets in the design of multi-agent vaccines for intracellular pathogens considered potential biological threats.  FY09 - Utilize novel technologies to define target antigens for different bio-threat pathogens. Explore DNA-based vaccine formulations against multiple agents. Incorporate novel adjuvants and/or delivery systems in the design of a multi-agent vaccine.  FY10 - Efforts realigned to Biological Based Basic Research.	0.504	0.345	0.000	
Biologic Based Basic Research: Researches understanding of biological agents of interest, their pathways, virulence, immunization factors and identification.	0.000	0.000	9.340	

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<b>Exhibit R-2a, PB 2010 Chemical and Biological Defense Program RDT&amp;E Project Justification</b>			<b>DATE:</b> April 2009	
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<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
FY10 - Determine mechanisms of pathogenesis for viral and bacterial biothreat agents and toxins. Define immune responses and mechanisms that confer protection against biothreat agents of interest to DoD. Identify novel and/or shared antigens from viral and bacterial threat agents to be used in the design of future vaccine formulations. Determine the contribution of post-translational modification of Botulinum Neurotoxin (BoNT) to the intracellular biology of the toxin. Determine advanced pharmacokinetic models of BoNT intoxication to define the therapeutic window of opportunity.				
SBIR - FY09 - Small Business Innovative Research.	0.000	0.223	0.000	
Development of Platform Technologies - TMTI is investing in components to develop an integrated capability from pathogen identification and characterization to countermeasure delivery. In particular, basic research is needed in the development of animal models for diseases caused by BW agents. Such animal models are required to test drug effectiveness in order to generate the data required to file for licensure of BW drug countermeasures with the Food and Drug Administration (FDA). Efforts are also directed towards pathogen identification and characterization, using methods like genetic sequencing to generate high quality reference information. This data will be used in sophisticated analyses to delineate the exact nature of advanced or genetically engineered bio-threats.  FY10 - Initiate the development of host and pathogen based platforms, such as cell, animal and computer models to describe and predict drug interactions during treatment for BW agent exposure. Initiate projects to generate animal models to characterize BW agent disease and to compare human and animal model responses to infection for use in live biological agent testing. Explore pathogen identification and characterization capabilities, including genetic sequencing, integrate existing capabilities, assess future sequence and analysis needs to characterize advance threats. Determine bioinformatics infrastructure needs.	0.000	0.000	1.881	
Vaccine Technology Development: Identified common pathogenic mechanisms by agents to improve vaccine design.  FY08 - Identified some common pathogenic mechanisms of cell signaling by agents. Explored the manipulation of those cell signaling pathways to improve vaccine design for enhanced immunity.  FY09 - Efforts realigned to Vaccine Research Support.	1.496	0.000	0.000	

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<b>Exhibit R-2a, PB 2010 Chemical and Biological Defense Program RDT&amp;E Project Justification</b>			<b>DATE:</b> April 2009	
<b>APPROPRIATION/BUDGET ACTIVITY</b> 0400 - Research, Development, Test & Evaluation, Defense-Wide/BA 1 - Basic Research	<b>R-1 ITEM NOMENCLATURE</b> PE 0601384BP CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)		<b>PROJECT NUMBER</b> TB1	
<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
<p>Toxin Therapeutics: Research efforts to enhance understanding of toxins and their effects on the host.</p> <p>FY08 - Initiated studies to investigate the process of intracellular targeting of Botulinum Neurotoxin (BoNT), with application to the development of new assay systems for evaluating potential therapeutics. Investigated the restoration of nerve activity following paralysis from BoNT intoxication. Utilized computer modeling techniques and traditional assays to provide structural and molecular data to facilitate the design and development of therapeutic countermeasures against select toxins.</p> <p>FY09 - Improve in silico, in vitro, and in vivo modeling systems that will assist in defining responses to threat agent toxins. Complete development of a mouse model for inhalational exposure to staphylococcal enterotoxin B (SEB) using microinstillation technology. Characterize the process of intracellular targeting of BoNT, and initiate intracellular assay model development. Define the cellular factors responsible for the BoNT translocation inside cells. Determine the structural requirements of potential restorative therapeutics for neuroparalysis following BoNT intoxication.</p> <p>FY10 - Efforts will be re-aligned to Biological Based Basic Research.</p>	3.137	2.606	0.000	
<p>Vaccine Research Support: Researched human immune response and pathogenicity of biological agents.</p> <p>FY08 - Assessed human immune response to bacterial pathogens. Continued studying pathogenicity of bio-agents. Developed and refined laboratory parallel relationships of immunity for vaccines under development. Identified and evaluated new target antigens from intracellular pathogens.</p> <p>FY09 - Further conduct basic pathogenicity studies of selected biothreat agents. Develop and refine in vitro correlates of immunity for new antigen in relation to vaccines under development. Pursue the identification and evaluation of novel target antigens for intracellular pathogens by studying the innate and adaptive immune responses to pathogens. Optimize epitope mapping of lead antigen candidates.</p> <p>FY10 - Efforts re-aligned to Biological Based Basic Research.</p>	2.276	2.937	0.000	
<p>Bacterial Therapeutics: Research efforts to enhance understanding of bacterial pathogens.</p>	0.842	0.653	0.000	

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<b>Exhibit R-2a, PB 2010 Chemical and Biological Defense Program RDT&amp;E Project Justification</b>							<b>DATE:</b> April 2009			
<b>APPROPRIATION/BUDGET ACTIVITY</b> 0400 - Research, Development, Test & Evaluation, Defense-Wide/BA 1 - Basic Research			<b>R-1 ITEM NOMENCLATURE</b> PE 0601384BP CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)				<b>PROJECT NUMBER</b> TB1			
<b>B. Accomplishments/Planned Program (\$ in Millions)</b>							<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
FY08 - Delineated host cell response to bacterial pathogens to identify new therapeutic targets for broad spectrum therapeutics. Demonstrated and confirmed the role for selected common pathways and factors in bacterial virulence.										
FY09 - Characterize new potential targets for therapeutic countermeasures, focusing on those identified for poorly characterized threats.										
FY10 - Efforts will be re-aligned to Biological Based Basic Research.										
<b>C. Other Program Funding Summary (\$ in Millions)</b>										
	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>	<b>FY 2012</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
TB2/MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)	98.878	47.591	54.156						Continuing	Continuing
TB3/MEDICAL BIOLOGICAL DEFENSE (ATD)	95.996	188.748	204.576						Continuing	Continuing
<b>D. Acquisition Strategy</b>										
N/A										
<b>E. Performance Metrics</b>										
N/A										

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<b>Exhibit R-2a, PB 2010 Chemical and Biological Defense Program RDT&amp;E Project Justification</b>									<b>DATE:</b> April 2009	
<b>APPROPRIATION/BUDGET ACTIVITY</b> 0400 - Research, Development, Test & Evaluation, Defense-Wide/BA 1 - Basic Research				<b>R-1 ITEM NOMENCLATURE</b> PE 0601384BP CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)					<b>PROJECT NUMBER</b> TC1	
<b>COST (\$ in Millions)</b>	<b>FY 2008 Actual</b>	<b>FY 2009 Estimate</b>	<b>FY 2010 Estimate</b>	<b>FY 2011 Estimate</b>	<b>FY 2012 Estimate</b>	<b>FY 2013 Estimate</b>	<b>FY 2014 Estimate</b>	<b>FY 2015 Estimate</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
TC1: MEDICAL CHEMICAL DEFENSE (BASIC RESEARCH)	12.164	12.333	5.519						Continuing	Continuing

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

This project (TC1) emphasizes understanding of the basic action mechanisms of nerve, blister, blood, and respiratory agents. Basic studies are performed to delineate biological mechanisms and bodily sites of action of identified and emerging chemical threats to generate required information for initial design and synthesis of medical countermeasures. In addition, these studies are further designed to maintain and extend a science base. Starting in FY10, all efforts will be combined into a capability area termed Chemical Based Basic Research in order to streamline the management of medical basic research activities.

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

	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
Chemical Based Basic Research: Research focuses on understanding chemical agents, their mechanism of action, toxicity, cellular injury, and identification.  FY10 - Investigate new tissue engineering technologies to reduce reliance on skin grafts. Assess the results of genotoxicity studies. Research mechanisms of action of nerve agents and therapeutic interventions using whole animal models, with a focus on data required to support FDA submissions. Initiate research into the development for novel nerve agent therapeutics with reduced impact on visual performance. Initiate development of new animal models to characterize in vivo effects of NTAs. Demonstrate the biological equivalency of Non-Traditional Agent (NTA) toxicity mechanisms across relevant species.	0.000	0.000	5.519	
Respiratory and Systemic: Research efforts that define pathways of injury and therapeutic targets against chemical agent exposure through inhalation.  FY08 - Developed additional laboratory and other model systems to identify new therapeutic targets, based on findings from mechanism of injury studies, focusing on common injury pathways. Investigated long term effects of lung injury, collected toxicological, physiological, and biochemical data.	4.723	4.849	0.000	

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<b>Exhibit R-2a, PB 2010 Chemical and Biological Defense Program RDT&amp;E Project Justification</b>			<b>DATE:</b> April 2009	
<b>APPROPRIATION/BUDGET ACTIVITY</b> 0400 - Research, Development, Test & Evaluation, Defense-Wide/BA 1 - Basic Research	<b>R-1 ITEM NOMENCLATURE</b> PE 0601384BP CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)		<b>PROJECT NUMBER</b> TC1	
<b>B. Accomplishments/Planned Program (\$ in Millions)</b>	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
FY09 - Expand efforts to elucidate common injury pathways due to multiple agents and routes of exposure, to maximize application to the development of broad-based therapeutics. Establish definitive correlation between simulants and live agent effects at the molecular level.				
FY10 - Efforts re-aligned to Chemical Based Basic Research.				
SBIR - FY09 - Small Business Innovative Research.	0.000	0.170	0.000	
Cutaneous and Ocular: Research efforts that define pathways of injury and therapeutic targets for chemical agent exposure through skin and eye exposure.  FY08 - Optimized models for cutaneous, percutaneous and ocular exposure. Explored novel cellular biochemical pathways as potential targets for therapeutic intervention. Maximized strategies to extend "latency" period between exposure and injury. Expanded study of agent exposure to cutaneous cells through damage to cell genetic components.  FY09 - Extrapolate the results of genotoxicity studies to the development of cancerous conditions using the appropriate in vivo models. Investigate the effects of solvent vehicles on percutaneous transmission to normalize past, present, and future research endeavors. Investigate new tissue engineering technologies to reduce reliance on grafts.  FY10 - Efforts re-aligned to Chemical Based Basic Research.	2.446	2.400	0.000	
Neurologic: Research efforts that aim to improve understanding of nerve agents.  FY08 - Exploited data from structure activity relationship (SAR) studies to delineate commonality between known toxins and nerve agents. Delineated general mechanism of action for nerve reactivation (following exposure) as required to support Federal Drug Administration (FDA) submissions for improved nerve agent therapeutics.	1.286	1.200	0.000	

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<b>Exhibit R-2a, PB 2010 Chemical and Biological Defense Program RDT&amp;E Project Justification</b>							<b>DATE:</b> April 2009			
<b>APPROPRIATION/BUDGET ACTIVITY</b> 0400 - Research, Development, Test & Evaluation, Defense-Wide/BA 1 - Basic Research			<b>R-1 ITEM NOMENCLATURE</b> PE 0601384BP CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)				<b>PROJECT NUMBER</b> TC1			
<b>B. Accomplishments/Planned Program (\$ in Millions)</b>							<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
FY09 - Research mechanisms of action of nerve agents and therapeutic interventions using whole animal models, with a focus on data required to support FDA submissions. Initiate research into the development of nerve agent therapeutic alternatives with reduced impact on visual performance.										
FY10 - Efforts re-aligned to Chemical Based Basic Research.										
Medical Toxicology: Research Non Traditional Agents (NTAs) and other agents to improve understanding of NTA exposure.							3.709	3.714	0.000	
FY08 - Collected data derived from models after chemical agent exposure. Initiated exploratory studies to determine the mode/mechanism of action of Non-Traditional Agents (NTAs). Developed appropriate model systems for non-traditional modes of action and toxicity.										
FY09 - Demonstrate the biological equivalency of NTA toxicity mechanisms across relevant species.										
FY10 - Efforts re-aligned to Chemical Based Basic Research.										
<b>C. Other Program Funding Summary (\$ in Millions)</b>										
	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>	<b>FY 2012</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
TC2/MEDICAL CHEMICAL DEFENSE (APPLIED RESEARCH)	36.154	35.922	40.587						Continuing	Continuing
TC3/MEDICAL CHEMICAL DEFENSE (ATD)	24.183	26.482	29.092						Continuing	Continuing
<b>D. Acquisition Strategy</b>										
N/A										
<b>E. Performance Metrics</b>										
N/A										

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**Exhibit R-2a, PB 2010 Chemical and Biological Defense Program RDT&E Project Justification** **DATE:** April 2009

<b>APPROPRIATION/BUDGET ACTIVITY</b>				<b>R-1 ITEM NOMENCLATURE</b>					<b>PROJECT NUMBER</b>	
0400 - Research, Development, Test & Evaluation, Defense-Wide/BA 1 - Basic Research				PE 0601384BP CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)					TR1	
<b>COST (\$ in Millions)</b>	<b>FY 2008 Actual</b>	<b>FY 2009 Estimate</b>	<b>FY 2010 Estimate</b>	<b>FY 2011 Estimate</b>	<b>FY 2012 Estimate</b>	<b>FY 2013 Estimate</b>	<b>FY 2014 Estimate</b>	<b>FY 2015 Estimate</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
TR1: MEDICAL RADIOLOGICAL DEFENSE (BASIC RESEARCH)	0.000	0.000	0.979						Continuing	Continuing

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

This project (TR1) emphasizes the research and study of medical countermeasures to protect the warfighter against radiation exposure. Specifically, this project emphasizes the identification of basic action mechanisms of Acute Radiation Syndrome (ARS) and Delayed Effects of Acute Radiation Exposure (DEARE), as well as developing possible radioprotectants (Pretreatments), post-irradiation exposure treatments (Therapeutics), and the ability to identify exposure to radiation (Diagnostics). These Basic Research efforts advance promising technology with the potential to rapidly identify, diagnose, prevent, and mitigate ARS and/or DEARE in the event of a radiological incident.

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

	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
Medical Radiological Defense: Research focuses on mechanisms of injury from radiation exposure.	0.000	0.000	0.979	
FY10 - Initiate efforts to identify mechanisms of injury from acute radiation exposure and delayed health effects following radiation exposure. Explore novel assays to diagnose radiation injury, through studies of cellular science, metabolism, and bioregulators.				

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<b>Exhibit R-2a, PB 2010 Chemical and Biological Defense Program RDT&amp;E Project Justification</b>								<b>DATE:</b> April 2009		
<b>APPROPRIATION/BUDGET ACTIVITY</b> 0400 - Research, Development, Test & Evaluation, Defense-Wide/BA 1 - Basic Research				<b>R-1 ITEM NOMENCLATURE</b> PE 0601384BP CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)				<b>PROJECT NUMBER</b> TR1		
<b>C. Other Program Funding Summary (\$ in Millions)</b>										
	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011</u>	<u>FY 2012</u>	<u>FY 2013</u>	<u>FY 2014</u>	<u>FY 2015</u>	<b>Cost To Complete</b>	<b>Total Cost</b>
TR2/MEDICAL RADIOLOGICAL DEFENSE (APPLIED RESEARCH)	2.008	1.969	2.909						Continuing	Continuing
TR3/MEDICAL RADIOLOGICAL DEFENSE (ATD)	2.152	4.863	2.413						Continuing	Continuing
<b>D. Acquisition Strategy</b>										
N/A										
<b>E. Performance Metrics</b>										
N/A										

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