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Exhibit R-2, RDT&E Budget Item Justification: PB 2011 Chemical and Biological Defense Program **DATE:** February 2010

APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 1: <i>Basic Research</i>	R-1 ITEM NOMENCLATURE PE 0601384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)</i>
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COST (\$ in Millions)	FY 2009 Actual	FY 2010 Estimate	FY 2011 Base Estimate	FY 2011 OCO Estimate	FY 2011 Total Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
Total Program Element	60.355	78.764	49.508	0.000	49.508	52.024	54.543	55.018	56.107	Continuing	Continuing
CB1: <i>CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)</i>	23.871	35.475	31.041	0.000	31.041	32.670	36.744	37.688	38.458	Continuing	Continuing
C11: <i>CONGRESSIONAL INTEREST ITEMS (BASIC RESEARCH)</i>	8.090	20.036	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
TB1: <i>MEDICAL BIOLOGICAL DEFENSE (BASIC RESEARCH)</i>	15.086	16.782	14.352	0.000	14.352	15.499	14.845	14.402	14.672	Continuing	Continuing
TC1: <i>MEDICAL CHEMICAL DEFENSE (BASIC RESEARCH)</i>	13.308	5.496	3.144	0.000	3.144	2.889	2.954	2.928	2.977	Continuing	Continuing
TR1: <i>MEDICAL RADIOLOGICAL DEFENSE (BASIC RESEARCH)</i>	0.000	0.975	0.971	0.000	0.971	0.966	0.000	0.000	0.000	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. 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.

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

B. Program Change Summary (\$ in Millions)

	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011 Base</u>	<u>FY 2011 OCO</u>	<u>FY 2011 Total</u>
Previous President's Budget	61.194	58.974	0.000	0.000	0.000
Current President's Budget	60.355	78.764	49.508	0.000	49.508
Total Adjustments	-0.839	19.790	49.508	0.000	49.508
• Congressional General Reductions		-0.330			
• Congressional Directed Reductions		0.000			
• Congressional Rescissions	0.000	0.000			
• Congressional Adds		20.120			
• Congressional Directed Transfers		0.000			
• Reprogrammings	0.000	0.000			
• SBIR/STTR Transfer	-0.839	0.000			
• Other Adjustments	0.000	0.000	49.508	0.000	49.508

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

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

Congressional Add: *Garden State Cancer Center Vaccine Development Program -*

Congressional Add: *DNA Safeguard -*

Congressional Add: *In Vitro Models for Biodefense Vaccine -*

Congressional Add: *Superstructural Particle Evaluation and Characterization with Targeted Reaction Analysis (SPECTRA) -*

Congressional Add: *Defense Through Early Containment -*

Congressional Add: *Protection from Oxidative Stress -*

Congressional Add: *Research on a Molecular Approach to Hazardous Materials Decontamination -*

Congressional Add: *Synchotron Beamline and Experimental Station*

Congressional Add: *Advanced Development of Antiviral Prophylactics and Therapeutics*

Congressional Add: *Countermeasures to Chemical/Biological Control-Rapid Response*

Congressional Add: *MEMS Sensors for Real-Time Sensing of Weaponized Pathogens*

	<u>FY 2009</u>	<u>FY 2010</u>
	0.789	0.000
	1.184	0.000
	0.987	1.514
	1.184	0.000
	1.184	0.000
	1.579	0.000
	1.183	0.000
	0.000	3.187
	0.000	2.987
	0.000	2.788
	0.000	1.992

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APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 1: <i>Basic Research</i>	R-1 ITEM NOMENCLATURE PE 0601384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)</i>
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<u>Congressional Add Details (\$ in Millions, and Includes General Reductions)</u>	FY 2009	FY 2010
Congressional Add: <i>Mismatch Repair Derived Antibody to Treat Staph Derived Bioweapon</i>	0.000	0.996
Congressional Add: <i>Portable Rapid Bacterial Warfare Detection</i>	0.000	3.983
Congressional Add: <i>Potent Human Monocolonal Antibodies Against BoNT, A, B and E Suited for Mass Production</i>	0.000	0.996
Congressional Add: <i>High Speed and High Volume Laboratory Network for Infectious Diseases</i>	0.000	1.593
Congressional Add Subtotals for Project: CI1	8.090	20.036
Congressional Add Totals for all Projects	8.090	20.036

Change Summary Explanation

Funding: N/A - Adjustments less than 10% of total program.

Schedule: N/A

Technical: N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Chemical and Biological Defense Program **DATE:** February 2010

APPROPRIATION/BUDGET ACTIVITY			R-1 ITEM NOMENCLATURE				PROJECT				
0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 1: <i>Basic Research</i>			PE 0601384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)</i>				CB1: <i>CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)</i>				
COST (\$ in Millions)	FY 2009 Actual	FY 2010 Estimate	FY 2011 Base Estimate	FY 2011 OCO Estimate	FY 2011 Total Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
CB1: <i>CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)</i>	23.871	35.475	31.041	0.000	31.041	32.670	36.744	37.688	38.458	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, and bio-inspired sciences; surface and signature sciences (with an emphasis on non-traditional agents (NTAs); and information 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, molecular motors, and nanometer imaging) may 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. This will 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 NTAs, that seek 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 duration period, from conception to completion, of three to five years. Promising basic research efforts will be further exploited for their application to chemical and biological defense in Budget Activity 2 (Applied Science). The basic research program promotes cross-pollination between government and academia, as well as sponsors world class scientists while promoting the development of young researchers.

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

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
1) SBIR	0.000	0.584	0.000	0.000	0.000

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APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 1: <i>Basic Research</i>	R-1 ITEM NOMENCLATURE PE 0601384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)</i>	PROJECT CB1: <i>CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)</i>				
B. Accomplishments/Planned Program (\$ in Millions)						
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
<i>FY 2010 Plans:</i> Small Business Innovative Research.						
2) Basic Research Core Nano-Scale Sciences: Improve understanding of nano-scale materials (scale of 1-100 nanometers in length) for use in chemical and biological defense. <i>FY 2009 Accomplishments:</i> Completed efforts investigating new types of materials for potential use in decontamination and protection, and shared information on new techniques for detection of chemical agents through novel applications of physics and chemistry. Continued study of compounds which mimic biological organisms and nano-scale sensing technologies for identification of agents. Continued 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 studied interfaces between nano-materials and living cells, and systems found in nature for creative solutions for future protection concepts. <i>FY 2010 Plans:</i> 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. Continue the study of 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.		5.572	9.009	8.700	0.000	8.700

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B. Accomplishments/Planned Program (\$ in Millions)						
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
<p>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 chemical and biological defense.</p> <p><i>FY 2011 Base Plans:</i> Continue developing novel tools to investigate cells and cell mechanisms. Continue to investigate and leverage developments in bioscience, bio-inspired science, and chemical sciences to support and improve fundamental scientific understanding. Leverage and merge developments with other basic research areas such as information sciences and surface and signature sciences. Initiate efforts in response to identified science gaps.</p>						
<p>4) Basic Research Core</p> <p>Information Science: Leverages new developments in information and computation to impact modeling and other chemical and biological defense efforts.</p> <p><i>FY 2009 Accomplishments:</i> Continued research on projects initiated in FY08. Initiated 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><i>FY 2010 Plans:</i> 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</p>		5.925	5.876	6.000	0.000	6.000

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B. Accomplishments/Planned Program (\$ in Millions)						
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
will leverage advances in physics, mathematics, biology, and other relevant sciences to improve informational and decision making tools. <i>FY 2011 Base Plans:</i> Continue investigating genetic algorithms and studying effects of heightened sensory input during chemical biological warfare events. Utilize efforts in information sciences to inform other areas of core chemical and biological defense programs, such as modeling and computational efforts.						
5) Basic Research Core Cognitive Science: Focuses on thinking and decision making to impact support tools for CB defense. <i>FY 2009 Accomplishments:</i> Continued research on projects initiated in FY08. Initiated efforts to investigate the presentation of risk and uncertainty for chemical and biological defense decision making. <i>FY 2010 Plans:</i> All Cognitive Science efforts are re-aligned to Information Science.		3.463	0.000	0.000	0.000	0.000
6) Basic Research Core 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. <i>FY 2009 Accomplishments:</i> Completed research on projects initiated in FY08, and transitioned relevant information to various physical applied research projects located in Budget Activity 2.		4.111	0.000	0.000	0.000	0.000
7) Basic Research Core		0.000	8.488	8.000	0.000	8.000

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B. Accomplishments/Planned Program (\$ in Millions)											
							FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
<p>Surface and Signature Sciences: A new study area established to focus on the study of physical and chemical properties that seeks to improve physical capabilities, such as, detection and decontamination.</p> <p><i>FY 2010 Plans:</i> Identify and exploit 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 to protect, detect, decontaminate, or otherwise counter chemical (to include NTAs) and biological threats. Study interactions of chemical and biological agents with biological and environmental matrices.</p> <p><i>FY 2011 Base Plans:</i> Continue studying interactions of chemical and biological agents with biological and environmental matrices, and develop novel tools to investigate surface and signature sciences to address capability gaps. Study signature sciences and surface interactions.</p>											
Accomplishments/Planned Programs Subtotals							23.871	35.475	31.041	0.000	31.041
C. Other Program Funding Summary (\$ in Millions)											
Line Item	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total	FY 2012	FY 2013	FY 2014	FY 2015	Cost To Complete	Total Cost
• CB2: <i>CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	102.599	110.955	88.897		88.897	100.243	97.979	90.686	91.554	Continuing	Continuing
• CB3: <i>CHEMICAL BIOLOGICAL DEFENSE (ATD)</i>	19.567	25.297	15.410		15.410	21.450	26.120	36.775	37.148	Continuing	Continuing
D. Acquisition Strategy											
N/A											

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APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE	PROJECT
0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 1: <i>Basic Research</i>	PE 0601384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)</i>	CB1: <i>CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)</i>

E. Performance Metrics

N/A

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COST (\$ in Millions)	FY 2009 Actual	FY 2010 Estimate	FY 2011 Base Estimate	FY 2011 OCO Estimate	FY 2011 Total Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
C11: <i>CONGRESSIONAL INTEREST ITEMS (BASIC RESEARCH)</i>	8.090	20.036	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

The efforts listed in this project include congressional interest programs for FY09 and FY10.

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

	FY 2009	FY 2010
Congressional Add: Garden State Cancer Center Vaccine Development Program - <i>FY 2009 Accomplishments:</i> Continued 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	0.000
Congressional Add: DNA Safeguard - <i>FY 2009 Accomplishments:</i> Continued 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.	1.184	0.000
Congressional Add: In Vitro Models for Biodefense Vaccine -	0.987	1.514

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B. Accomplishments/Planned Program (\$ in Millions)		
	FY 2009	FY 2010
<i>FY 2009 Accomplishments:</i> Conducted basic research for the use of In Vitro models in vaccine development.		
<i>FY 2010 Plans:</i> Continuation of FY09 research		
Congressional Add: Superstructural Particle Evaluation and Characterization with Targeted Reaction Analysis (SPECTRA) - <i>FY 2009 Accomplishments:</i> Continued basic research on superstructural particle evaluation and characterization with targeted reaction analysis begun in FY06.	1.184	0.000
Congressional Add: Defense Through Early Containment - <i>FY 2009 Accomplishments:</i> Conducted basic research focused on containment of agents following an incident.	1.184	0.000
Congressional Add: Protection from Oxidative Stress - <i>FY 2009 Accomplishments:</i> Conducted basic research focused on protection technologies.	1.579	0.000
Congressional Add: Research on a Molecular Approach to Hazardous Materials Decontamination - <i>FY 2009 Accomplishments:</i> Continued research on molecular approach to decontamination in collaboration with the Naval Surface Warfare Center (NSWC) begun in FY06.	1.183	0.000

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B. Accomplishments/Planned Program (\$ in Millions)		
	FY 2009	FY 2010
Congressional Add: Synchrotron Beamline and Experimental Station <i>FY 2010 Plans:</i> Build an experimental end-station at National Synchrotron Light Source-II for the purpose of conducting basic research on the structure and processes of pathogens, toxins and their antidotes.	0.000	3.187
Congressional Add: Advanced Development of Antiviral Prophylactics and Therapeutics <i>FY 2010 Plans:</i> Apply knowledge of the discovery of a new class of antiviral drugs to develop medical countermeasures against viral biowarfare agents and for therapies against other viral diseases such as Hepatitis C, HIV and Influenza. Explore chemical modifications of previously identified broadly active compounds to target proteins involved in additional viruses of interest. Demonstrate efficacy of active compounds via in vitro and animal trials.	0.000	2.987
Congressional Add: Countermeasures to Chemical/Biological Control-Rapid Response <i>FY 2010 Plans:</i> Research Support of Biodefense and emerging infectious disease.	0.000	2.788
Congressional Add: MEMS Sensors for Real-Time Sensing of Weaponized Pathogens <i>FY 2010 Plans:</i> Develop a wearable sensor to detect weaponized pathogens utilizing the unique properties of diamond and enable a new class of compact, wearable chemical and biological point sensors, with unprecedented sensitivity, stability, and reproducibility.	0.000	1.992
	0.000	0.996

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B. Accomplishments/Planned Program (\$ in Millions)		
	FY 2009	FY 2010
Congressional Add: Mismatch Repair Derived Antibody to Treat Staph Derived Bioweapon <i>FY 2010 Plans:</i> Develop fully human anti-Staphylococcus enterotoxin B (SEB) monoclonal antibodies (mAbs) that can neutralize >1000 times the human LD50 of the toxin.		
Congressional Add: Portable Rapid Bacterial Warfare Detection <i>FY 2010 Plans:</i> Develop a field deployable system based on InfraRed spectroscopy.	0.000	3.983
Congressional Add: Potent Human Monocolonal Antibodies Against BoNT, A, B and E Suited for Mass Production <i>FY 2010 Plans:</i> Develop Potent Human Monocolonal Antibodies Against BoNT, A, B and E Suited for Mass Production	0.000	0.996
Congressional Add: High Speed and High Volume Laboratory Network for Infectious Diseases <i>FY 2010 Plans:</i> Develop an expanded capability to include other biothreat agents, including bacterial and/or viruses (dual-use).	0.000	1.593
Congressional Adds Subtotals	8.090	20.036

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

<u>Line Item</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011</u> <u>Base</u>	<u>FY 2011</u> <u>OCO</u>	<u>FY 2011</u> <u>Total</u>	<u>FY 2012</u>	<u>FY 2013</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• C12: <i>CONGRESSIONAL INTEREST ITEMS (APPLIED RESEARCH)</i>	42.714	16.630	0.000		0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
• C13: <i>CONGRESSIONAL INTEREST ITEMS (ATD)</i>	46.971	18.622	0.000		0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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COST (\$ in Millions)	FY 2009 Actual	FY 2010 Estimate	FY 2011 Base Estimate	FY 2011 OCO Estimate	FY 2011 Total Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
TB1: <i>MEDICAL BIOLOGICAL DEFENSE (BASIC RESEARCH)</i>	15.086	16.782	14.352	0.000	14.352	15.499	14.845	14.402	14.672	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. Advance innovative biotechnology approaches with the potential to rapidly identify, diagnose, prevent, and treat disease due to exposure to biological threat agents. Project categories 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 single capability area called Biological Based Basic Research.

This project also includes efforts such as the Transformational Medical Technologies Initiative (TMTI). The TMTI was launched 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)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
1) SBIR <i>FY 2010 Plans:</i> Small Business Innovative Research.	0.000	0.270	0.000	0.000	0.000
2) Diagnostics Pursue technologies that enable medical elements to determine exposure or infection of forces by a biological warfare agent and assist in appropriate lifesaving treatment.	3.026	0.000	0.000	0.000	0.000

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Chemical and Biological Defense Program				DATE: February 2010		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 1: <i>Basic Research</i>	R-1 ITEM NOMENCLATURE PE 0601384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)</i>	PROJECT TB1: <i>MEDICAL BIOLOGICAL DEFENSE (BASIC RESEARCH)</i>				
B. Accomplishments/Planned Program (\$ in Millions)						
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
<p><i>FY 2009 Accomplishments:</i> Continued to seek novel avenues for assay design and application. Investigated cutting edge technologies as new genomic techniques become available. Accelerated identification of novel biomarkers of biological warfare agent (BWA) infection and applied to assay development.</p> <p><i>FY 2010 Plans:</i> Efforts re-aligned to Biological Based Basic Research.</p>						
<p>3) Pretreatments</p> <p>Multiagent Vaccines: Research vaccines that protect against multiple agents.</p> <p><i>FY 2009 Accomplishments:</i> Utilized novel technologies to define target antigens for different bio-threat pathogens. Explored DNA-based vaccine formulations against multiple agents. Incorporated novel adjuvants and/or delivery systems in the design of a multi-agent vaccine.</p> <p><i>FY 2010 Plans:</i> Efforts re-aligned to Biological Based Basic Research.</p>		0.315	0.000	0.000	0.000	0.000
<p>4) Pretreatments</p> <p>Vaccine Research Support: Research human immune response and pathogenicity of biological agents.</p> <p><i>FY 2009 Accomplishments:</i> Conducted basic pathogenicity studies of selected biothreat agents. Developed and refined in vitro correlates of immunity for new antigen in relation to vaccines under development. Pursued the identification and evaluation of novel target antigens for intracellular pathogens by studying the innate and adaptive immune responses to pathogens. Optimized epitope mapping of lead antigen candidates.</p>		2.937	0.000	0.000	0.000	0.000

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B. Accomplishments/Planned Program (\$ in Millions)						
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
<i>FY 2010 Plans:</i> Efforts re-aligned to Biological Based Basic Research.						
5) Therapeutics Viral Therapeutics: Research understanding of viral infection. <i>FY 2009 Accomplishments:</i> Delineated the mechanisms of pathogenesis of conventional threats to support the progression of therapeutics to advanced development. Compared the host response of well characterized threats with that of poorly characterized category A and B threats to identify new therapeutic targets. <i>FY 2010 Plans:</i> Effort re-aligned to Biological Based Basic Research.		0.435	0.000	0.000	0.000	0.000
6) Therapeutics Toxin Therapeutics: Research efforts to enhance understanding of toxins and their effects on the host. <i>FY 2009 Accomplishments:</i> Improved in silico, in vitro, and in vivo modeling systems that will assist in defining responses to threat agent toxins. Completed development of a mouse model for inhalational exposure to staphylococcal enterotoxin B (SEB) using microinstillation technology. Characterized the process of intracellular targeting of BoNT, and initiated intracellular assay model development. Defined the cellular factors responsible for Botulinum Neurotoxin (BoNT) translocation inside cells. Determined the structural requirements of potential restorative therapeutics for neuromuscular paralysis following BoNT intoxication. <i>FY 2010 Plans:</i> Efforts re-aligned to Biological Based Basic Research.		2.606	0.000	0.000	0.000	0.000

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B. Accomplishments/Planned Program (\$ in Millions)						
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
7) Therapeutics Bacterial Therapeutics: Research efforts to enhance understanding of bacterial pathogens. <i>FY 2009 Accomplishments:</i> Characterized new potential targets for therapeutic countermeasures, focusing on those identified for poorly characterized threats. <i>FY 2010 Plans:</i> Efforts re-aligned to Biological Based Basic Research.		0.653	0.000	0.000	0.000	0.000
8) Biological Based Basic Research Research to understand biological agents of interest, their pathways, virulence, immunization factors and identification. <i>FY 2010 Plans:</i> Determine mechanisms of pathogenesis for viral and bacterial biothreat agents and toxins. Define immune responses and mechanisms that confer protection against biothreat agents. 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. <i>FY 2011 Base Plans:</i> Conduct studies of pathogenic mechanisms for viral and bacterial biothreat agents and toxins. Clarify mechanisms of host-pathogen interaction to identify mechanisms of pathogenesis and/or correlates of protective immunity against biothreat agents. Define novel and/or shared antigens from viral and bacterial threat agents to be used in the design of future treatment options. Define the contribution		0.000	9.160	8.899	0.000	8.899

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B. Accomplishments/Planned Program (\$ in Millions)								
				FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
of post-translational modification to the structure and biology of BoNT. Research novel constructs for affinity reagents for the identification of biological warfare agents and biomarkers.								
9) Transformational Medical Technologies Initiative Multiagent (Broad Spectrum) Medical Countermeasures: Basic research efforts focused on the early drug discovery phase of drug development. Active monitoring of scientific literature to generate hypotheses for research. Review scientific findings and assess a foundation for characterizing new therapeutics. Identify and develop brand new compounds that could lead to successful therapeutic candidates. Scientific studies to generate research ideas, hypotheses, and experimental designs for addressing the development of therapeutics against Biological Warfare (BW) agents. Use computer simulation or other virtual platforms to test hypotheses. Begin research, data collection, and analysis to test hypothesis. Explore alternative concepts, identify and evaluate critical technologies and components, and begin characterization of candidates. Demonstrate preliminary efficacy. <i>FY 2009 Accomplishments:</i> Continued drug discovery research for broad-spectrum countermeasures with new candidates. Continued basic research to identify new candidates for molecular targets for broad-spectrum countermeasures. Continued to evaluate new thrust areas in genomics, proteomics, bioinformatics, and other relevant systems biology research. Focused efforts on promising intervention points for broad-spectrum therapeutic approaches based on results from drug design collaborations. Developed 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. Continued to study changes in host response to infection. Initiated study of biomarkers for intracellular bacterial (ICB) and hemorrhagic fever virus (HFV) agents. <i>FY 2010 Plans:</i> 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				5.114	5.471	0.000	0.000	0.000

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B. Accomplishments/Planned Program (\$ in Millions)						
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
<p>rational drug design. Initiate investigation of technological advancements in genetic sequencing and drugs based on protein-to-protein interactions.</p> <p><i>FY 2011 Base Plans:</i> All successful and promising efforts will transition to BA2 during FY11.</p>						
<p>10) Transformational Medical Technologies Initiative</p> <p>Development of Platform Technologies: Invest in components necessary to develop an integrated capability from pathogen identification and characterization to countermeasure delivery. In particular, basic research is needed to develop animal models for diseases caused by BW agents. Such animal models are required to demonstrate drug effectiveness 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 such as 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.</p> <p><i>FY 2010 Plans:</i> 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.</p> <p><i>FY 2011 Base Plans:</i> Continue to investigate new drug-based platforms which may be able to generate families of broad spectrum drugs to protect against bio-threat agents. Develop components to evaluate which</p>		0.000	1.881	5.453	0.000	5.453

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APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 1: <i>Basic Research</i>	R-1 ITEM NOMENCLATURE PE 0601384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)</i>	PROJECT TB1: <i>MEDICAL BIOLOGICAL DEFENSE (BASIC RESEARCH)</i>
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B. Accomplishments/Planned Program (\$ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
technologies are appropriate for each aspect of the countermeasure development. Continue to support discovery of conserved host and pathogen directed targets for the development of broad spectrum drugs against BW agents. Continue to develop leading edge technologies to assist in pathogen characterization, target identification, countermeasure discovery and countermeasure evaluation.					
Accomplishments/Planned Programs Subtotals	15.086	16.782	14.352	0.000	14.352

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

<u>Line Item</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011 Base</u>	<u>FY 2011 OCO</u>	<u>FY 2011 Total</u>	<u>FY 2012</u>	<u>FY 2013</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>Cost To Complete</u>	<u>Total Cost</u>
• TB2: <i>MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	50.485	53.930	43.858		43.858	50.866	51.077	51.051	51.959	Continuing	Continuing
• TB3: <i>MEDICAL BIOLOGICAL DEFENSE (ATD)</i>	180.425	203.723	115.233		115.233	125.666	109.737	115.049	117.289	Continuing	Continuing

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Chemical and Biological Defense Program								DATE: February 2010			
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 1: <i>Basic Research</i>				R-1 ITEM NOMENCLATURE PE 0601384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)</i>				PROJECT TC1: <i>MEDICAL CHEMICAL DEFENSE (BASIC RESEARCH)</i>			
COST (\$ in Millions)	FY 2009 Actual	FY 2010 Estimate	FY 2011 Base Estimate	FY 2011 OCO Estimate	FY 2011 Total Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
TC1: <i>MEDICAL CHEMICAL DEFENSE (BASIC RESEARCH)</i>	13.308	5.496	3.144	0.000	3.144	2.889	2.954	2.928	2.977	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project (TC1) emphasizes the understanding of the basic action mechanisms of nerve, blister, blood, and respiratory agents within the body. Basic studies are performed to delineate biological mechanisms for identified and emerging chemical threats to generate required information for initial design and synthesis of chemical 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 new capability area termed Chemical Based Basic Research.

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

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
1) SBIR <i>FY 2010 Plans:</i> Small Business Innovative Research.	0.000	0.093	0.000	0.000	0.000
2) Therapeutics Respiratory and Systemic: Research efforts that define pathways of injury and therapeutic targets against chemical agent exposure through inhalation. <i>FY 2009 Accomplishments:</i> Expanded efforts to elucidate common injury pathways due to multiple agents and routes of exposure, to maximize application to the development of broad-based therapeutics. Established definitive correlation between simulants and live agent effects at the molecular level. <i>FY 2010 Plans:</i> Efforts re-aligned to Chemical Based Basic Research.	5.133	0.000	0.000	0.000	0.000

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Chemical and Biological Defense Program				DATE: February 2010		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 1: <i>Basic Research</i>	R-1 ITEM NOMENCLATURE PE 0601384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)</i>	PROJECT TC1: <i>MEDICAL CHEMICAL DEFENSE (BASIC RESEARCH)</i>				
B. Accomplishments/Planned Program (\$ in Millions)						
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
3) Therapeutics Cutaneous and Ocular: Research efforts that define pathways of injury and therapeutic targets for chemical agent exposure through skin and eye exposure. <i>FY 2009 Accomplishments:</i> Extrapolated the results of genotoxicity studies to the development of cancerous conditions using the appropriate in vivo models. Investigated the effects of solvent vehicles on percutaneous transmission to normalize past, present, and future research endeavors. Investigated new tissue engineering technologies to reduce reliance on grafts. <i>FY 2010 Plans:</i> Efforts re-aligned to Chemical Based Basic Research.		2.541	0.000	0.000	0.000	0.000
4) Therapeutics Neurologic: Research efforts that aim to improve understanding of nerve agents. <i>FY 2009 Accomplishments:</i> Researched mechanisms of action of nerve agents and therapeutic interventions using whole animal models, with a focus on data required to support FDA submissions. Initiated research into the development of nerve agent therapeutic alternatives with reduced impact on visual performance. <i>FY 2010 Plans:</i> Efforts re-aligned to Chemical Based Basic Research.		1.703	0.000	0.000	0.000	0.000
5) Therapeutics Medical Toxicology: Research Non Traditional Agents (NTAs) and other agents to improve understanding of NTA exposure.		3.931	0.000	0.000	0.000	0.000

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Chemical and Biological Defense Program				DATE: February 2010		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 1: <i>Basic Research</i>	R-1 ITEM NOMENCLATURE PE 0601384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)</i>	PROJECT TC1: <i>MEDICAL CHEMICAL DEFENSE (BASIC RESEARCH)</i>				
B. Accomplishments/Planned Program (\$ in Millions)						
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
<p><i>FY 2009 Accomplishments:</i> Demonstrated the biological equivalency of NTA toxicity mechanisms across relevant species.</p> <p><i>FY 2010 Plans:</i> Efforts re-aligned to Chemical Based Basic Research.</p>						
<p>6) Chemical Based Basic Research (CBBR)</p> <p>Research focuses on understanding chemical agents, their mechanism of action, toxicity, cellular injury, and identification.</p> <p><i>FY 2010 Plans:</i> 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.</p> <p><i>FY 2011 Base Plans:</i> Research pathways of molecular mechanisms of injury associated with chemical warfare agents. Conduct mechanistic studies using appropriate in vitro models to identify the biochemical cascade of effects following chemical agent exposure. Based on these studies, generate basic information for initial design and synthesis of medical countermeasures, located in Budget Activity 2, Project TC2.</p>		0.000	5.403	3.144	0.000	3.144
Accomplishments/Planned Programs Subtotals		13.308	5.496	3.144	0.000	3.144

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Chemical and Biological Defense Program		DATE: February 2010
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 1: <i>Basic Research</i>	R-1 ITEM NOMENCLATURE PE 0601384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)</i>	PROJECT TC1: <i>MEDICAL CHEMICAL DEFENSE (BASIC RESEARCH)</i>

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

<u>Line Item</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011</u> <u>Base</u>	<u>FY 2011</u> <u>OCO</u>	<u>FY 2011</u> <u>Total</u>	<u>FY 2012</u>	<u>FY 2013</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• TC2: <i>MEDICAL CHEMICAL DEFENSE (APPLIED RESEARCH)</i>	35.008	40.418	33.648		33.648	36.327	36.500	37.475	38.150	Continuing	Continuing
• TC3: <i>MEDICAL CHEMICAL DEFENSE (ATD)</i>	21.641	28.971	29.134		29.134	30.401	30.546	31.356	31.877	Continuing	Continuing

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Chemical and Biological Defense Program **DATE:** February 2010

APPROPRIATION/BUDGET ACTIVITY			R-1 ITEM NOMENCLATURE				PROJECT				
0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 1: <i>Basic Research</i>			PE 0601384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)</i>				TR1: <i>MEDICAL RADIOLOGICAL DEFENSE (BASIC RESEARCH)</i>				
COST (\$ in Millions)	FY 2009 Actual	FY 2010 Estimate	FY 2011 Base Estimate	FY 2011 OCO Estimate	FY 2011 Total Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
TR1: <i>MEDICAL RADIOLOGICAL DEFENSE (BASIC RESEARCH)</i>	0.000	0.975	0.971	0.000	0.971	0.966	0.000	0.000	0.000	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 identifies the basic action mechanisms of Acute Radiation Syndrome (ARS) and Delayed Effects of Acute Radiation Exposure (DEARE), as well as, develops 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)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
1) Medical Radiological Defense Research focuses on understanding mechanisms of injury from radiation exposure. <i>FY 2010 Plans:</i> 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. <i>FY 2011 Base Plans:</i> Continue projects begun in FY10 to understand cellular and molecular responses to ionizing radiation and identify biomarkers of radiation exposure.	0.000	0.959	0.971	0.000	0.971
2) SBIR	0.000	0.016	0.000	0.000	0.000

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Exhibit R-2A, RDT&E Project Justification: PB 2011 Chemical and Biological Defense Program **DATE:** February 2010

APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 1: <i>Basic Research</i>	R-1 ITEM NOMENCLATURE PE 0601384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)</i>	PROJECT TR1: <i>MEDICAL RADIOLOGICAL DEFENSE (BASIC RESEARCH)</i>
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B. Accomplishments/Planned Program (\$ in Millions)

	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
<i>FY 2010 Plans:</i> Small Business Innovative Research.					
Accomplishments/Planned Programs Subtotals	0.000	0.975	0.971	0.000	0.971

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

<u>Line Item</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011 Base</u>	<u>FY 2011 OCO</u>	<u>FY 2011 Total</u>	<u>FY 2012</u>	<u>FY 2013</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>Cost To Complete</u>	<u>Total Cost</u>
• TR2: <i>MEDICAL RADIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	0.525	2.897	2.884		2.884	1.904	2.855	1.913	1.903	Continuing	Continuing
• TR3: <i>MEDICAL RADIOLOGICAL DEFENSE (ATD)</i>	4.859	2.403	0.957		0.957	0.966	1.922	2.901	2.927	Continuing	Continuing

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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