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Exhibit R-2, RDT&E Budget Item Justification: PB 2013 Chemical and Biological Defense Program **DATE:** February 2012

APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 3: <i>Advanced Technology Development (ATD)</i>				R-1 ITEM NOMENCLATURE PE 0603384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>							
COST (\$ in Millions)	FY 2011	FY 2012	FY 2013 Base	FY 2013 OCO	FY 2013 Total	FY 2014	FY 2015	FY 2016	FY 2017	Cost To Complete	Total Cost
Total Program Element	218.323	229.200	234.280	-	234.280	220.606	197.471	185.286	185.286	Continuing	Continuing
CB3: <i>CHEMICAL BIOLOGICAL DEFENSE (ATD)</i>	21.219	23.818	20.034	-	20.034	18.343	18.893	17.357	17.357	Continuing	Continuing
NT3: <i>TECHBASE NON-TRADITIONAL AGENTS DEFENSE (ATD)</i>	-	-	31.916	-	31.916	30.864	30.927	31.603	31.603	Continuing	Continuing
TB3: <i>MEDICAL BIOLOGICAL DEFENSE (ATD)</i>	153.437	172.394	-	-	-	-	-	-	-	0.000	325.831
TC3: <i>MEDICAL CHEMICAL DEFENSE (ATD)</i>	25.486	21.789	-	-	-	-	-	-	-	0.000	47.275
TE3: <i>TEST & EVALUATION (ATD)</i>	11.346	11.199	-	-	-	-	-	-	-	0.000	22.545
TM3: <i>TECHBASE MED DEFENSE (ATD)</i>	-	-	182.330	-	182.330	171.399	147.651	136.326	136.326	Continuing	Continuing
TR3: <i>MEDICAL RADIOLOGICAL DEFENSE (ATD)</i>	2.402	-	-	-	-	-	-	-	-	0.000	2.402
TT3: <i>TECHBASE TECHNOLOGY TRANSITION</i>	4.433	-	-	-	-	-	-	-	-	0.000	4.433

A. Mission Description and Budget Item Justification

This program element (PE) demonstrates technologies that enhance the ability of U.S. forces to deter, defend against, and survive Chemical, Biological, and Radiological (CBR) warfare. This program element (PE) funds advanced technology development for Joint Service and Service-specific requirements in both medical and physical sciences CBR defense areas. The medical program aims to produce drugs, vaccines and medical devices as countermeasures for CBR threat agents. Specific areas of medical investigation include: prophylaxis, pretreatment, antidotes and therapeutics, personnel and patient decontamination, and medical management of casualties. In the physical sciences area, the focus is on demonstrations of CB defense technologies, including biological detection, chemical detection, protection, and decontamination. This PE also provides for the conduct of advanced technology development in the areas of real-time sensing, accelerated biological warfare operational awareness, and the restoration of operations following a biological warfare or chemical warfare attack. This program is dedicated to conducting proof-of-principle field demonstrations, test of system-specific technologies to meet specific military needs. Work conducted under this PE transitions to and provides risk reduction for System Integration/Demonstration (PE 0603884BP/PE 0604384BP) activities.

In FY13, all NTA-dedicated research (both medical and non-medical) is re-aligned to Project NT3 - Techbase Non-Traditional Agents Defense (ATD). Also all non-NTA Medical Biological and Medical Chemical Defense efforts (Projects TB3 and TC3) are re-aligned to Project TM3 - Techbase Medical Defense (ATD).

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APPROPRIATION/BUDGET ACTIVITY		R-1 ITEM NOMENCLATURE			
0400: Research, Development, Test & Evaluation, Defense-Wide		PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)			
BA 3: Advanced Technology Development (ATD)					
B. Program Change Summary (\$ in Millions)	FY 2011	FY 2012	FY 2013 Base	FY 2013 OCO	FY 2013 Total
Previous President's Budget	177.113	229.235	244.608	-	244.608
Current President's Budget	218.323	229.200	234.280	-	234.280
Total Adjustments	41.210	-0.035	-10.328	-	-10.328
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-0.518	-			
• SBIR/STTR Transfer	-2.667	-			
• Other Adjustments	44.395	-0.035	-10.328	-	-10.328
Change Summary Explanation					
Funding: FY11					
-\$1.207M Congressional General Reductions					
(-\$1.132M) Section 8117 (CB3 -\$159K; TB3 -\$681K; TC3 -\$125K; TE3 -\$97K; TR3 -\$33K; TT3 -\$37K)					
(-\$.075M) FFRDC (TE3 -\$75K)					
+\$45.600M Congressional Directed Transfer (TB3 +\$45,600K) Medical Realignment from BA5					
-\$0.516M Reprogrammings (CB3 +\$6,344K; TB3 -\$5,107K; TC3 -\$3,228K; TE3 -\$132K; TR3 +\$1,554K; TT3 +\$53K)					
-\$2.667M SBIR Transfers (CB3 -\$376K; TB3 -\$1,607K; TC3 -\$295K; TE3 -\$225K; TR3 -\$77K; TT3 -\$87K)					
-\$2.457M Other Adjustments (Efficiency Initiatives) (MB3 -\$2,288K; TE3 -\$167K)					
Schedule: N/A					
Technical: N/A					

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program	DATE: February 2012
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APPROPRIATION/BUDGET ACTIVITY				R-1 ITEM NOMENCLATURE				PROJECT			
0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 3: <i>Advanced Technology Development (ATD)</i>				PE 0603384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>				CB3: <i>CHEMICAL BIOLOGICAL DEFENSE (ATD)</i>			
COST (\$ in Millions)	FY 2011	FY 2012	FY 2013 Base	FY 2013 OCO	FY 2013 Total	FY 2014	FY 2015	FY 2016	FY 2017	Cost To Complete	Total Cost
CB3: <i>CHEMICAL BIOLOGICAL DEFENSE (ATD)</i>	21.219	23.818	20.034	-	20.034	18.343	18.893	17.357	17.357	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project (CB3) demonstrates technology advancements for joint service application in the areas of detection, information systems technology, protection/hazard mitigation, and technology transition efforts. These activities will speed maturing of advanced technologies to reduce risk in system-oriented integration/demonstration efforts. This project also includes efforts dedicated to developing capabilities to protect against Non-Traditional Agents (NTAs). Detection focuses on advanced development of technologies from applied research for standoff and point detection and identification of chemical and biological agents. Information systems advanced technology focuses on areas of advanced warning and reporting, hazard prediction and assessment, simulation analysis and planning, and systems performance modeling. Protection and Hazard Mitigation focuses on advanced development of technologies that protect and reduce the chemical/biological/radiological/nuclear threat or hazard to the Warfighter, weapons platforms, and structures. This project also funds advanced development of chemical and biological defense science and technology initiatives and transitions them to advanced development programs in Budget Activities 4 and 5, through prototypes that are evaluated in Advanced Technology Demonstration (ATDs) and Joint Warfighter Experimentation (JWE).

In FY13, all NTA-dedicated research from this Project is re-aligned to Project NT3 - Techbase Non-Traditional Agents Defense (ATD).

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

	FY 2011	FY 2012	FY 2013
Title: 1) Detection Description: Chemical and Biological Stand-off Technology: Focuses on the detection and identification of chemical and biological threats in near real time at a distance from the detector. Future programs focus on the improvement of algorithms, excitation sources, and detector elements to increase range, reduce false positives, increase sensitivity, and reduce cost. FY 2011 Accomplishments: Completed field trial validation of chemical signatures for chemical standoff detection and identification capabilities. Completed phase I validation of actual biological IR signatures in support of the Joint Biological Standoff Detection System Increment 2. Continued development of test methodology for next generation chemical standoff technology. Initiated the process of validating ground truth systems for field assessments. FY 2012 Plans: Close out development of test methodology for next generation chemical standoff technology. Begin processes of validating ground truth systems for point technologies (genomic and proteomic technology) field assessments. FY 2013 Plans:	0.502	7.642	5.852

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2011	FY 2012	FY 2013
Continue processes of validating ground truth systems for point technologies (genomic and proteomic technology) field assessments.					
Title: 2) Detection NTA Description: Detection NTA: Focuses on technologies to provide Non-Traditional Agents (NTA) detection capabilities. FY 2011 Accomplishments: Continued the supporting efforts necessary to provide the Initial Operating Capabilities for test facilities. The effort focused on detection and analytical methodologies to determine sensitivities/thresholds necessary to establish exposure standards needed to create standard operating procedures for the facility. FY 2012 Plans: Initiate the development of test methodology to validate signatures for chemical aerosols threat materials. In FY13, all research in this area is re-aligned to Project NT3 - Techbase Non-Med - Detection NTA.			4.083	7.346	-
Title: 3) Technology Transition Description: Technology Transition: Conduct competitive assessments of promising mature technology from outside the Chemical and Biological Defense Program (CBDP) and assist in transition of promising technology efforts. FY 2011 Accomplishments: Completed transition of the Integrated CB Agent Hazard Mitigation with systems and neutralization efficiency testing in an operational environment. Completed assessment and down-select to two or three best technologies that provides the highest enhancements to capabilities.			4.555	-	-
Title: 4) Information Systems Technology Description: Warning and Reporting Information and Analysis: Emphasis on developing science and technologies for collaborative information management, fusion of disparate information from multiple sources, environmental databases and modeling, fusion of syndromic/diseases surveillance data, and synthetic environments for model performance evaluation and acquisition decisions. FY 2011 Accomplishments: Transitioned next-generation outdoor Source Term Estimation (STE), Hazard Refinement (HR), and Sensor Placement Tool (SPT) to advanced development programs (Joint Effects Model (JEM) - see BA4 Project IS4). Transitioned first-generation false alarm			1.396	0.878	-

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2011	FY 2012	FY 2013
reduction capability and first generation rapid STE algorithms to advanced development program (Joint Warning and Reporting Network (JWARN)).				
FY 2012 Plans: Conduct Verification and Validation (V&V) of STE and HR algorithms for use in complex environments (e.g., variable terrain, urban, water, and building interiors). Transition report on the use of meteorological ensemble predictions in dispersion models to JEM.				
Title: 5) Information Systems Technology Description: Hazard Prediction & Information Analysis: Improve battlespace awareness by accurately predicting hazardous material releases, atmospheric transport and dispersion, and resulting human effects. Develop predictive capability for the source term of releases of chemical, biological, and industrial materials from weapons and accidents. FY 2011 Accomplishments: Continued to further refine the Geographic and Environmental Database Information System (GEDIS) data requirements tool. Completed optimization of methods to significantly improve performance of transport and dispersion hazard models for the Joint Effects Model (JEM). Continued development and implementation of a configuration management prototype for transition of project results to advanced development programs. Continued advanced development of JEM algorithms to portray and predict Non-Traditional Agent (NTA) hazards in operational environments. FY 2012 Plans: Continue development of the high altitude post-missile intercept effects model for eventual integration into hazard prediction and counterproliferation model frameworks by drawing upon existing modeling of other agencies and handling both successfully intercepted weapons as well as intentionally functioning weapons of a chemical, biological or nuclear payload. Continue work on configuration management prototype to implement standard module interfaces to comply with advanced development program requirements. Establish field transport and dispersion databases and websites for accessible permanent test archiving. FY 2013 Plans: Continue implementation of new numerical schemes for transport and dispersion models. Continue enhancement of urban transport and dispersion models which transitioned from CB2 efforts in FY12. Continue with work on configuration management prototype to establish upgraded capabilities listed as valid requirements for JEM. Complete development on the high altitude post-missile intercept effects model. Continue with field transport and dispersion databases and websites for accessible permanent test archiving. Continue implementation and testing of new numerical schemes for future establishment of 64-bit/multi-core capable models.		2.307	0.913	4.747
Title: 6) Information Systems Technology		0.427	1.412	-

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2011	FY 2012	FY 2013
<p>Description: Operations Planning & Information Analysis: Develop decision support tools and information management capabilities for planning and real-time analysis to determine and assess operational effects, risks, and impacts of CBRN incidents on decision making. Focus areas include consequence management, population modeling, and human knowledge management.</p> <p>FY 2011 Accomplishments: Transitioned decision support tools for CBRN to the Joint Warning and Reporting Network (JWARN). Transitioned refined secondary infection and contagious/infectious disease models to the Joint Effects Model (JEM). Transitioned updated and expanded human effects models. Transitioned Incident Management/Consequence Management (IM/CM) tools and capabilities in consequence systems. Transitioned a fully optimized sensor placement tool.</p> <p>FY 2012 Plans: Transition medical countermeasure models, to include: One Chemical Model: Organophosphate and Five Biological Models: Anthrax, Plague, Lassa Fever, Burkholderia Pseudomallei, and Tularemia models.</p>					
<p>Title: 7) Information Systems Technology</p> <p>Description: Systems Performance & Information Analysis: Develop Chemical, Biological, Radiological and Nuclear (CBRN) data sharing capabilities.</p> <p>FY 2012 Plans: Perform improvements in CBRN data management capabilities, with emphasis on enabling access to information for analysis within CBDP systems performance models. Enhance analysis toolset which provides the ability to evaluate decontaminants and decontamination systems.</p> <p>FY 2013 Plans: Continue to develop the Chemical and Biological Warfare Agent Effects Manual Number 1 (CB-1), an authoritative source capturing analytical methods for evaluating the effects of CB warfare agents on equipment, personnel, and operations, which was initiated in Information Systems Technology, Systems Performance & Information Analysis (CB2 - M&S). Conclude development of initial versions of systems performance models in collective protection, individual protection, contamination avoidance and decontamination. Initiate system performance model integration with advanced development for program-wide exploitation. A portion of this effort is funded in Test & Evaluation (TE3).</p>			-	0.750	1.985
<p>Title: 8) Information Systems Technology</p> <p>Description: Medical Surveillance & Information Analysis: Integrate existing disparate military and civilian datasets into advanced warning systems, and leverage and enhance epidemiological models and algorithms for disease prediction, impact and biological threat assessment. Contribute to the development of global, near real time, disease monitoring and surveillance systems that</p>			-	0.867	-

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2011	FY 2012	FY 2013
address secondary infection, fuse medical syndromic, environmental, and clinical data, and feed into agent-based epidemiological modeling, medical resource estimation and decision support tools. Focus areas include health/human effects modeling (casualty estimation, agent-based epidemiological modeling and fusion of disease surveillance data).					
FY 2012 Plans: Begin Validation and Verification (V&V) efforts for existing agent-based epidemiological models, to include underlying population data and disease spread algorithms, with regard to use in robust adaptive decision making. In FY13, all research in this area is realigned into Techbase Med Bio-Diagnostics (TM3).					
Title: 9) Protection & Hazard Mitigation Description: Lightweight Integrated Fabric: Demonstration of lightweight chemical and biological protective textiles that can be used as an integrated combat duty uniform. FY 2011 Accomplishments: Incorporated lessons from Individual Protection Advanced Technology Demonstration (IP Demo) and developed final data packages for transition to Uniform Integrated Protective Ensemble(UIPE) and/or Joint Service Lightweight Integrated Suit Technology (JSLIST) programs. Verified and transitioned CBART, a new methodology to assess agent resistance of material swatches that more closely simulates environmental conditions, significantly reduces experimental variability, and better supports assessment and comparison of new generations of materials compared to current methods. Completed and transitioned swatch reference materials to consistently baseline performance of new materials. Continued development and assessment of real-time Man-in-Simulant Test (MIST) sensor tags to support development and testing of future UIPE increments. FY 2012 Plans: Incorporate next phase of integrated textile systems into a complete second generation candidate ensemble for the Uniform Integrated Protective Ensemble (UIPE) Phase II program as well as other applicable Advanced Technology Demonstrations that may materialize. Provide a trade-space analysis of all government, industrial, and academic candidate materials for use in future UIPE phase initiations. Transition human performance initial tool set to Joint Program Manager (JPM) Protection that can be used in the optimization of protective ensemble design. FY 2013 Plans: Continue to integrate next phase of integrated textile systems into a complete second generation candidate ensemble for the Uniform Integrated Protective Ensemble (UIPE) Phase II program as well as other applicable Advanced Technology Demonstrations that may materialize. Continue the trade-space analysis of all government, industrial, and academic candidate			3.990	0.637	1.637

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2011	FY 2012	FY 2013
materials for use in future UIPE phase initiations. Continue to transition the human performance tool set to JPM Protection that can be used in the optimization of protective ensemble design.					
Title: 10) Protection & Hazard Mitigation Description: Low-Resistance, Low-Profile Filtration: Demonstration of novel filtration media into a lightweight, low-profile, and low-burden individual protective filter, which has enhanced performance against a broader range of challenges that includes toxic industrial chemicals. FY 2011 Accomplishments: Incorporated lessons from the IP Demo and develop final data packages for transition to advanced development programs such as the UIPE, Joint Service General Purpose Mask (JSGPM), and Joint Service Aircrew Mask (JSAM) (see BA5, Project IP5). Continued prototype development in support of Joint Expeditionary Collective Protection (JECF) and support of collective protection in vehicular/platform systems in Major Defense Acquisition Program (MDAP). Initiated advanced development of non-carbon adsorptive media ZZAT (Zirconium Oxide, Zinc, Silver and Triethylenediamine) with improved performance against toxic industrial chemicals in support of future generation JSGPM filters. FY 2012 Plans: Continue demonstration of novel filtration media into a lightweight, low-profile, and low-burden individual protective filter, which has enhanced performance against a broader range of challenges that includes toxic industrial chemicals. Transition these technologies to the JSGPM and JSAM programs. FY 2013 Plans: Continue the integration and demonstration of latest generation novel filtration media into a lightweight, low-profile, and low-burden individual protective filter, which has enhanced performance against a broader range of challenges that includes toxic industrial chemicals. Transition these technologies to the JSGPM and JSAM programs.			1.772	0.636	1.292
Title: 11) Protection & Hazard Mitigation Description: Low-Burden Air Purifying Respirator: Demonstration of design alternatives for chemical and biological air-purifying respirators to provide enhanced protection with lower physiological burden and improved interface with mission equipment. FY 2012 Plans: Advanced concept CBRN technologies will be integrated within the confines of the Chem/Bio protection component of the Helmet Electronics and Display System - Upgradable Protection (HEADS-UP) Army Technology Objective (ATO) program, which has multi-service participation for ground applications.			-	0.688	-
Title: 12) Protection & Hazard Mitigation			-	0.188	-

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2011	FY 2012	FY 2013
Description: Logistically Sustainable Air Purification for Collective Protection: Demonstration of chemical and biological air-purification alternative technologies that minimize or eliminate the need for expendable media within acceptable size, weight and power constraints. FY 2012 Plans: Demonstrate breadboard concepts of a residual life indicator (RLI) for collective filtration systems.					
Title: 13) Protection & Hazard Mitigation Description: Decontamination Family-of-Systems (DFoS): Demonstration of non-traditional decontamination technologies and approaches which gain significantly improved effectiveness by complementary application. FY 2011 Accomplishments: Completed additional data packages and technical assessments of technologies for transition to be into the Decontamination Family of Systems (DFoS) Program of Record. Continued advanced development of self-decontaminating and agent shedding coatings for aircraft. Initiated systems analysis studies that will better define technology objectives and integration issues with non-CB coatings requirements. Initiated development of Integrated Decontamination Test and Evaluation System (IDTES), a test fixture that will assess decontamination sub-scale processes on small-items and complex surfaces. FY 2012 Plans: Continue demonstration of non-traditional decontamination technologies and approaches which gain significantly improved effectiveness by complementary application. Integrate robust surface chemistry and decontamination process analysis using ultra high vacuum system into technology maturation process for hazard mitigation. Demonstrate IDTES live agent testing facility that allows scaled relevant environment evaluations. Pursue the optimization of reactive coatings (durable). Transition research efforts "Surfactant Technology for Surface Chemical/Biological Agent Removal" and "Decontamination Assurance Spray." FY 2013 Plans: Continue the development, demonstration, and transition of non-traditional decontamination technologies and approaches which gain significantly improved effectiveness by complementary application. Continue to integrate and demonstrate robust surface chemistry and decontamination process analysis using ultra high vacuum system into technology maturation process for hazard mitigation. Continue to develop coatings, innovative chemistries/processes, enzyme approaches to hazard mitigation, human remains decontamination processes, and radiological/nuclear decontamination/hazard mitigation capabilities. Transition quantitatively evaluated interim capability for radiological/nuclear decontamination/hazard mitigation.			1.183	1.173	0.397
Title: 14) Protection & Hazard Mitigation			1.004	0.334	-

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2011	FY 2012	FY 2013
Description: Innovative Systems Concepts and Analysis: Development and systems analysis of novel system concepts for chemical and biological protection of occupants of buildings and platforms that integrates emerging technologies. FY 2011 Accomplishments: Focused efforts on most promising approaches and initiate component development to support prototyping and demonstrations. Technologies included micro fine detoxifying aerosol fogs to facilitate entry and mitigate cross contamination into collective protection systems, internal self-detoxifying surfaces for walls and ductwork, expedient retrofit kits, self-detoxifying and expedient strippable coatings, rapid isolation and purge schemes, and novel and innovative air flow and re-circulation schemes. Completed testing and transitioned novel approach for a rapidly deployable Contamination Control Area (CCA)/Airlock (AL) for vehicular systems. System supports integrated collective protection in MDAP programs as well as enabling retrofits of legacy systems (vehicular or stand-alone). FY 2012 Plans: Transition research effort "Reactive Airlock for Armored Vehicles, Shipboard and Shelter Applications."					
Title: 15) Test and Evaluation (T&E) Description: Test and Evaluation, Information System Technology: Develop CBRN data sharing capabilities and simulation tools. FY 2013 Plans: Continue to develop the Test & Evaluation components of the Chemical and Biological Warfare Agent Effects Manual Number 1 (CB-1), an authoritative source capturing analytical methods for evaluating the effects of CB warfare agents on equipment, personnel, and operations. Conclude development of initial versions of systems performance models in collective protection, individual protection, contamination avoidance and decontamination. This project is being partially funded by CB3 Tech Base Non Med - Modeling and Simulation.			-	-	4.124
Title: 16) SBIR FY 2012 Plans: Small Business Innovative Research.			-	0.354	-
Accomplishments/Planned Programs Subtotals			21.219	23.818	20.034

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

<u>Line Item</u>	<u>FY 2011</u>	<u>FY 2012</u>	<u>FY 2013</u> <u>Base</u>	<u>FY 2013</u> <u>OCO</u>	<u>FY 2013</u> <u>Total</u>	<u>FY 2014</u>	<u>FY 2015</u>	<u>FY 2016</u>	<u>FY 2017</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• CB2: <i>CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	85.789	97.774	44.331		44.331	41.819	40.951	52.243	52.243	Continuing	Continuing
• TE3: <i>TEST & EVALUATION (ATD)</i>	11.346	11.199	0.000		0.000	0.000	0.000	0.000	0.000	0.000	22.545
• CA4: <i>CONTAMINATION AVOIDANCE (ACD&P)</i>	57.121	33.952	3.038		3.038	19.803	38.588	39.729	34.595	Continuing	Continuing
• DE4: <i>DECONTAMINATION SYSTEMS (ACD&P)</i>	6.933	24.749	12.374		12.374	10.247	9.779	12.751	6.083	Continuing	Continuing
• IS4: <i>INFORMATION SYSTEMS (ACD&P)</i>	11.032	7.420	13.831		13.831	5.672	10.496	0.260	0.000	0.000	48.711
• TE4: <i>TEST & EVALUATION (ACD&P)</i>	19.054	5.438	4.994		4.994	12.771	20.408	15.872	13.044	Continuing	Continuing
• TT4: <i>TECHBASE TECHNOLOGY TRANSITION (ACD&P)</i>	26.051	3.022	3.377		3.377	4.096	7.296	7.821	7.821	Continuing	Continuing

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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COST (\$ in Millions)	FY 2011	FY 2012	FY 2013 Base	FY 2013 OCO	FY 2013 Total	FY 2014	FY 2015	FY 2016	FY 2017	Cost To Complete	Total Cost
NT3: TECHBASE NON-TRADITIONAL AGENTS DEFENSE (ATD)	-	-	31.916	-	31.916	30.864	30.927	31.603	31.603	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project (NT3) develops future capabilities against emerging and novel threats and verifies current capabilities against Non-Traditional Agents (NTAs). This project focuses on demonstrating fast and agile scientific responses to enhance or develop capabilities that address emerging threats. Efforts in this project support an integrated approach to develop new or enhanced countermeasures against novel and emerging threats through innovative S&T solutions for detection, protection, decontamination and medical countermeasures (MCMs). Efforts supply test methodologies and supporting science to verify capabilities, develop protection and hazard mitigation options, expand hazard assessment tools, and develop MCMs against NTAs. This project is a comprehensive and focused effort for developing NTA defense capabilities, coordinated with specific interagency partners for doctrine, equipment, and training for the Warfighter and civilian population for defense against NTAs. This project funds advanced technology development of NTA defense science and technology initiatives and transitions them to Budget Activities 4 and 5.

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

	FY 2011	FY 2012	FY 2013
Title: 1) Techbase Medical Defense - NTA Diagnostics Description: Chem Diagnostics NTA: Focuses on state-of-the-art laboratory/fieldable methods that detect exposure to non-traditional agents in clinical samples. It also targets the identification of biomolecular targets that can be leveraged as analytical methodologies, as well as, laboratory and animal studies characterizing time-course and longevity of a particular analyte/ biomarker. FY 2013 Plans: Continue development of mature technologies that can quickly diagnose pre-symptomatic NTA exposure. Funding for this research area is realigned from Tech Base Med Defense - Diagnostics NTA (TC3).	-	-	0.404
Title: 2) Techbase Medical Defense - NTA Pretreatments Description: Chemical Medical Pretreatments NTA: Develop nerve agent enzyme pretreatments that provide protection against non-traditional agents. Enzymes should have the ability to rapidly bind and detoxify nerve agents, and have broad binding specificity and high catalytic efficiency for the destruction of agents. For enzyme approaches, one molecule of catalytic bioscavenger should be capable of detoxifying numerous molecules of nerve agents resulting in the capability for a small quantity of catalytic bioscavenger to protect against a large dose of nerve agent. FY 2013 Plans:	-	-	0.503

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program			DATE: February 2012		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 3: <i>Advanced Technology Development (ATD)</i>		R-1 ITEM NOMENCLATURE PE 0603384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>		PROJECT NT3: <i>TECHBASE NON-TRADITIONAL AGENTS DEFENSE (ATD)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2011	FY 2012	FY 2013
Continue exploitation of alternative expression systems for production of rBuChE. Complete study of use of plasma derived huBChE as prophylactic for all nerve agents. Funding for this research area is realigned from Tech Base Med Chem - Pretreatments NTA (TC3).					
Title: 3) Techbase Medical Defense - NTA Therapeutics Description: Chemical Medical Therapeutics NTA: Determine the toxic effects of agents by probable routes of field exposure and refine standard experimental routes. Physiological parameters and pathological assessment will be used to establish the general mode and mechanisms of toxicity. FY 2013 Plans: Continue formulation and stability studies. Begin safety studies in small animal model using selected formulation. Funding for this research area is realigned from Tech Base Med Chem - Therapeutics NTA (TC3).			-	-	10.055
Title: 4) Techbase Non-Medical - Detection Description: Detection NTA: Focuses on technologies to provide NTA detection capabilities. FY 2013 Plans: Continue the development of test methodology to validate signatures for chemical aerosol threat materials. Funding for this research area is realigned from Tech Base Non-Med Defense - Detection NTA (CB3).			-	-	13.373
Title: 5) Techbase Non-Medical - Protection & Hazard Mitigation Description: Protection & Hazard Mitigation - NTA Air Purification: Study and assessment of filter technologies. FY 2013 Plans: Continue development, verification and demonstration of novel materials to improve performance against NTAs. Transition these technologies to the Joint Service General Purpose Mask (JSGPM) and Joint Service Aircrew Mask (JSAM) programs. Funding for this research area is realigned from Tech Base Non-Med Defense - Protection & Hazard Mitigation NTA (CB3).			-	-	0.348
Title: 6) Techbase Non-Medical - Protection & Hazard Mitigation Description: Protection & Hazard Mitigation - NTA Percutaneous Protection: Study and assessment of protective technologies FY 2013 Plans:			-	-	0.349

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program									DATE: February 2012		
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)				R-1 ITEM NOMENCLATURE PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)				PROJECT NT3: TECHBASE NON-TRADITIONAL AGENTS DEFENSE (ATD)			
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2011	FY 2012	FY 2013
Continue verification, demonstration and transition of low burden technologies to improve overall protective clothing performance against NTAs. Funding for this research area is realigned from Tech Base Non-Med Defense - Protection & Hazard Mitigation NTA (CB3).											
Title: 7) Techbase Non-Medical - Protection & Hazard Mitigation Description: Protection & Hazard Mitigation - NTA Decontamination: Study and assessment of decontamination technologies. FY 2013 Plans: Continue verification, demonstration, and transition of decontamination technologies against NTAs. Continue to develop, demonstrate, and transition enzyme technology for low-impact decon of NTAs. Continue to enhance NTA related understanding and capabilities of current decontamination and hazard mitigation technologies and develop additional processes for NTA hazard mitigation. Funding for this research area is realigned from Tech Base Non-Med Defense - Protection & Hazard Mitigation NTA (CB3).									-	-	0.350
Title: 8) Techbase Non-Medical - Test & Evaluation Description: Test and Evaluation (T&E) NTA: Develops test and evaluation technologies and processes in support of NTA activities. FY 2013 Plans: Complete initial select agent testing, and continue further prioritized agent testing. Funding for this research area is realigned from Tech Base Non-Med Defense - Test & Evaluation NTA (TE3).									-	-	6.534
Accomplishments/Planned Programs Subtotals									-	-	31.916
C. Other Program Funding Summary (\$ in Millions)											
Line Item	FY 2011	FY 2012	FY 2013 Base	FY 2013 OCO	FY 2013 Total	FY 2014	FY 2015	FY 2016	FY 2017	Cost To Complete	Total Cost
• NT2: TECHBASE NON-TRADITIONAL AGENTS DEFENSE (APPLIED RESEARCH)	0.000	0.000	60.730		60.730	56.498	53.707	63.138	63.138	Continuing	Continuing
• CA4: CONTAMINATION AVOIDANCE (ACD&P)	57.121	33.952	3.038		3.038	19.803	38.588	39.729	34.595	Continuing	Continuing
• CO4: COLLECTIVE PROTECTION (ACD&P)	0.000	0.000	0.000		0.000	0.000	0.000	0.000	0.000	0.000	0.000

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program									DATE: February 2012		
APPROPRIATION/BUDGET ACTIVITY				R-1 ITEM NOMENCLATURE				PROJECT			
0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)				PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)				NT3: TECHBASE NON-TRADITIONAL AGENTS DEFENSE (ATD)			
C. Other Program Funding Summary (\$ in Millions)											
Line Item	FY 2011	FY 2012	FY 2013 Base	FY 2013 OCO	FY 2013 Total	FY 2014	FY 2015	FY 2016	FY 2017	Cost To Complete	Total Cost
• DE4: DECONTAMINATION SYSTEMS (ACD&P)	6.933	24.749	12.374		12.374	10.247	9.779	12.751	6.083	Continuing	Continuing
• IP4: INDIVIDUAL PROTECTION (ACD&P)	2.200	0.000	1.102		1.102	3.708	6.811	4.680	0.300	Continuing	Continuing
• MC4: MEDICAL CHEMICAL DEFENSE (ACD&P)	4.134	7.804	0.000		0.000	16.947	20.395	37.513	25.134	Continuing	Continuing
• TE4: TEST & EVALUATION (ACD&P)	19.054	5.438	4.994		4.994	12.771	20.408	15.872	13.044	Continuing	Continuing
D. Acquisition Strategy											
N/A											
E. Performance Metrics											
N/A											

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program **DATE:** February 2012

APPROPRIATION/BUDGET ACTIVITY				R-1 ITEM NOMENCLATURE				PROJECT			
0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 3: <i>Advanced Technology Development (ATD)</i>				PE 0603384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>				TB3: <i>MEDICAL BIOLOGICAL DEFENSE (ATD)</i>			
COST (\$ in Millions)	FY 2011	FY 2012	FY 2013 Base	FY 2013 OCO	FY 2013 Total	FY 2014	FY 2015	FY 2016	FY 2017	Cost To Complete	Total Cost
TB3: <i>MEDICAL BIOLOGICAL DEFENSE (ATD)</i>	153.437	172.394	-	-	-	-	-	-	-	0.000	325.831

A. Mission Description and Budget Item Justification

This project (TB3) supports preclinical and early phase clinical development of vaccines, therapeutic drugs, and diagnostic capabilities to provide safe and effective medical defense against validated biological threat agents or emerging infectious disease biothreats including bacteria, toxins, and viruses. Innovative biotechnology approaches to advance medical systems designed to rapidly identify, diagnose, prevent, and treat disease due to exposure to biological threat agents will be evaluated. Entry of candidate vaccines, therapeutics, and diagnostic technologies into advanced development is facilitated by the development of technical data packages that support the Food and Drug Administration (FDA) Investigational New Drug (IND) processes, DoD acquisition regulations, and the oversight of early phase clinical trials in accordance with FDA guidelines. Categories of this project include biological defense capability areas such as Pretreatments, Diagnostics, and Therapeutics. Pretreatment efforts conduct research and development (R&D) of promising vaccines, medications, and technologies provided prior to potential exposure to biological agents. The goal is to reduce or to entirely prevent adverse effects of exposure. Diagnostic efforts are aimed at screening procedures and analytical methods to verify exposure and determine the effects of exposure to biological warfare (BW) or other biothreat agents. Therapeutic efforts provide medical solutions to sustain and protect the Warfighter in biological environments. Specifically, therapeutic efforts are aimed at developing medical countermeasures to treat exposure to biological or emerging threats such as bacterial (plague, anthrax, glanders), viral (smallpox, encephalitic alphaviruses), and toxin (ricin, botulinum neurotoxin, staphylococcal enterotoxin) agents.

This project includes the Transformational Medical Technologies Initiative (TMTI). The program was launched to respond to the threat of emerging or intentionally engineered biological threats. TMT's mission is to protect the Warfighter from genetically engineered or emerging infectious disease 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 BW or emerging infectious disease 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 or emerging infectious disease agents (e.g. developing new and innovative ways to mass produce drugs in the event of a biological incident). Effective FY12 this effort is funded as the Transformational Medical Technologies (TMT) Program.

The Medical Countermeasures Initiative (MCMI) was established to coordinate inter-related advanced development and flexible manufacturing capabilities, based on public-private partnership agreements between the government and industry, providing a dedicated, cost-effective, reliable, and sustainable MCM process that meets the warfighter and national security needs. Specifically, the MCMI will provide the capability for the advanced development and flexible manufacturing of biological MCM (to include TMT developed MCMs) to address CBRN threats, including novel and previously unrecognized, naturally-occurring emerging infectious diseases. MCMI efforts within S&T are concentrated in three areas: 1) transition of novel platform/expression systems for MCMs, 2) transition advancement of regulatory science, and 3) integration of novel platforms with MCM advanced development and manufacturing.

In FY13, all research in this Project (TB3) is re-aligned to Project TM3 - Techbase Medical Defense (ATD).

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program		DATE: February 2012		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 3: <i>Advanced Technology Development (ATD)</i>	R-1 ITEM NOMENCLATURE PE 0603384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>	PROJECT TB3: <i>MEDICAL BIOLOGICAL DEFENSE (ATD)</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2011	FY 2012	FY 2013
Title: 1) Medical Countermeasures Initiative (MCMI) Description: The MCMI will integrate the regulatory science and manufacturing technologies and processes developed into the Technical Centers of Excellence (TCE) and advanced development and flexible manufacturing capability. FY 2012 Plans: Initiate and refine development of multi-product/multi-use MCM technology platforms for the advanced development of MCMs for CBRN threats and emerging infectious diseases. Evaluate and exploit the regulatory advantages of such systems, with the intent that regulatory approval of the platform for one product will simplify subsequent regulatory approvals of other products based on the same system. Initiate and refine development of new technologies and approaches that facilitate and accelerate the development and regulatory review of medical products. In FY13, all research in this area is re-aligned into Techbase Med Defense - Medical Countermeasures Initiative (TM3).		-	27.172	-
Title: 2) Diagnostics (Biosurveillance) Description: Diagnostic Technologies: Development and verification of rapid, sensitive and specific tests for the identification of Biological Warfare Agents (BWAs) and their expressed toxins in biological fluids of Warfighters for the diagnosis of exposure/infection. Discovery of biomarkers of response to exposure. Evaluation of next generation diagnostic technologies including portable instrument platforms, highly parallel and informative testing formats, and nanotechnology applications. FY 2011 Accomplishments: Transitioned two Technology Readiness Reviews on candidate diagnostic platforms to advanced development programs. Developed atlas/database of phenotypic and genotypic characteristics of relevant BWA bacterial strains. Demonstrated the utility of high informatic content screen-characterized affinity reagents in the discovery of novel biomarkers as targets for assay development. Developed standard methods/protocols for rapid sequencing directly from clinical matrices. Applied bioinformatic and computational methods to verify the utility of host response signatures for pre-symptomatic diagnostic assays. Transitioned candidate transport media/preservatives and protocols for clinical sample processing. Evaluated global-virus and global-microbial microarrays for promising multiplexing and identification of BWAs. Developed and verified production scale-up protocols for single domain biosynthetic (recombinant) antibodies to bacterial and viral BWA targets. FY 2012 Plans: Validate and submit pre-EUA (Emergency Use Authorization) data to FDA for high priority BWA and emerging threat assays to preposition for biopreparedness. Transition portable sequence based genetic analyzer and verify assays for top ten priority agents. Transition technology watch report and mature candidate platform technologies of sufficient utility for advanced development as Next Generation Diagnostics System and/or Biosurveillance platform. Transition data packages for detection of antibiotic (Cipro) resistance. Validate and transition scale-up protocols for single domain biosynthetic (recombinant) antibodies		9.068	10.197	-

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program		DATE: February 2012	
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 3: <i>Advanced Technology Development (ATD)</i>	R-1 ITEM NOMENCLATURE PE 0603384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>	PROJECT TB3: <i>MEDICAL BIOLOGICAL DEFENSE (ATD)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2011	FY 2012
to bacterial and viral BWA targets for use in austere environments. Supplement/continue accrual of geographically/genetically representative strain collection and transfer to repository; develop quantitative cell culture for an additional emerging threat agent of high genetic variability. Transition atlas/database of phenotypic and genotypic characteristics of relevant BWA bacterial strains to advanced developer. In FY13, all research in this area is re-aligned into Project TM3 - Techbase Med Bio - Diagnostics.			FY 2013
Title: 3) Pretreatments Description: Bacterial/Toxin Vaccines: Evaluates the best single agent bacterial and toxin vaccines for effectiveness against aerosol challenge in large animal models. FY 2011 Accomplishments: Completed the Phase I clinical trial with the Ricin Vaccine. FY 2012 Plans: Perform final analysis of data from Phase I Clinical trial. Assemble final Ricin vaccine data package. In FY13, all research in this area is re-aligned into Project TM3 - Techbase Med Bio - Pretreatments.		0.881	0.799
Title: 4) Pretreatments Description: Viral Vaccines: Evaluates the best vaccine candidates for Alphaviruses and Filoviruses for effectiveness and duration of protective immune response against aerosol challenge in large animal models. Animal models will be developed to support FDA licensure of mature vaccine candidates. The purpose of developing these animal models is to support pivotal animal studies under the "animal rule". FY 2011 Accomplishments: Completed duration studies with the vaccine components against Marburg. Continued aerosol efficacy studies for the Ebola Zaire and Ebola Sudan vaccine components in non-human primates. Transitioned the Ebola vaccine components to the advanced development program to combine with the Marburg vaccine component. Determined duration of protection elicited by the Ebola vaccine components. Optimized the dose and immunization schedule to ensure effectiveness of the individual components of the filovirus vaccine when co-administered as a mixture. Completed aerosol efficacy studies of DNA-based vaccines and chemically inactivated/attenuated vaccines against the alphaviruses. Optimized dosing regimens to ensure effectiveness when co-administering the alphavirus vaccine components. Continued the development of animals models for alphaviruses (EEE and WEE), and filoviruses (Ebola Sudan, Ebola Zaire, Ebola Bundibugyo, and Marburg), to fulfill future FDA animal rule requirements necessary for vaccine licensure. For Alphaviruses, determined the median lethal dose of VEE, EEE, and WEE in a distinct type of non-human primate, and tested the alphavirus vaccines for immune stimulation capability and efficacy against challenge in		10.687	19.681
			-
			-

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program		DATE: February 2012	
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 3: <i>Advanced Technology Development (ATD)</i>	R-1 ITEM NOMENCLATURE PE 0603384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>	PROJECT TB3: <i>MEDICAL BIOLOGICAL DEFENSE (ATD)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2011	FY 2012
<p>this new animal model. For filoviruses, determined the median lethal dose of Ebola Bundibugyo in a distinct type of non-human primate, and began natural history studies for Ebola Bundibugyo, Ebola Sudan, Ebola Zaire, and Marburg.</p> <p>FY 2012 Plans:</p> <p>Complete remaining aerosol efficacy studies for the Ebola Zaire and Ebola Sudan vaccine components in non-human primates. Conduct formulation studies of Ebola and Marburg vaccine components. Initiate the development of Filovirus and Alphavirus immunological assays to support advanced development. Coordinate with the advanced developer to fulfill S&T needs in support of the filovirus vaccine transition. For Alphavirus DNA vaccines, complete an Investigational New Drug (IND) package for the VEE component, submit the IND package to the FDA and initiate a Phase I clinical trial. As a part of this trial, assess alternative methodologies for vaccine delivery (i.e., electroporation) via intra-muscular or intra-dermal administration, Manufacture clinical grade (sufficient quality to be administered to humans in a Phase I clinical trial) lots of the EEE and WEE DNA components. Conduct pre-clinical studies on a trivalent VEE, EEE, WEE DNA formulation. For the Alphavirus replicon vaccine, conduct pre-clinical studies. Continue the development of animals models for alphaviruses (EEE and WEE), and filoviruses (Ebola Sudan, Ebola Zaire, Ebola Bundibugyo, and Marburg), to fulfill future FDA animal rule requirements necessary for vaccine licensure. Although the Filovirus vaccines are transitioning in FY11, work will continue on the selected candidate(s) to fill knowledge gaps. In FY13, all research in this area is re-aligned into Project TM3 - Techbase Med Bio - Pretreatments.</p>			
<p>Title: 5) Pretreatments</p> <p>Description: Vaccine Platforms and Research Tools: Conducts studies to determine potential immune interference between lead vaccine candidates, the effect of alternative vaccine delivery methods and thermo-stabilization technologies on the efficacy of lead vaccine candidates. Identifies correlates of protection in humans, and predicts the success of lead vaccine candidates in humans. Work conducted under Vaccine Platforms and Research Tools are distinct from those performed under Viral Vaccines because the focus is on the use of novel technologies to support vaccine candidates, not on the vaccine candidates themselves. Vaccine Platforms and Research Tools utilize novel technologies to stabilize advanced vaccine candidates as well as alternative delivery modalities.</p> <p>FY 2011 Accomplishments:</p> <p>Examined the efficacy of a mature filovirus vaccine in animals previously vaccinated with a mature alphavirus vaccine that was constructed using the same platform technology, to reveal potential immune interference in order to determine whether multiple vaccines using the same platform technologies can be used together. Analyzed blood samples collected from individuals in the Former Soviet Union (i.e., vaccinated laboratory workers and/or individuals infected with bio-defense agents endemic to the region) in laboratory assays to determine the antibody and cell-based immune responses elicited by vaccines and/or pathogens of interest, and compare those results to animal studies. Evaluated the safety and immune stimulating capability of mature Filovirus and Alphavirus vaccine candidates in humans by using the Modular Immune In-Vitro Constructs (MIMIC) technology, to support</p>		4.056	4.903
			-

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program			DATE: February 2012		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 3: <i>Advanced Technology Development (ATD)</i>		R-1 ITEM NOMENCLATURE PE 0603384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>		PROJECT TB3: <i>MEDICAL BIOLOGICAL DEFENSE (ATD)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2011	FY 2012	FY 2013
these candidates moving forward into phase I clinical studies by the advanced development program. Conducted pre-formulation studies to produce a thermo-stable, spray-dried formulation of the virus-like particle based Marburg vaccine candidate. FY 2012 Plans: Continue evaluation of the safety and immune stimulating capability of mature Filovirus and Alphavirus vaccine candidates in humans by using the MIMIC technology. Continue formulation studies to produce a thermo-stable, spray-dried formulation of an advanced vaccine candidate. Evaluate additional stabilization technologies that provide thermal stability to multiple classes of vaccines such as viral vectored vaccines and subunit protein vaccines. Test alternative (needle-free) vaccine delivery technologies such as inhalers or skin patches for the delivery of mature vaccine candidates. Evaluate clinical samples from filovirus and alphavirus outbreaks in multiple international locations to determine human immune responses. In FY13, all research in this area is re-aligned into Project TM3 - Techbase Med Bio - Pretreatments.					
Title: 6) Therapeutics Description: Viral Therapeutics: Identifies, optimizes and evaluates potential therapeutic candidates effective against designated viral threat agents. FY 2011 Accomplishments: Conducted remaining non-human primate studies required for licensure of ST-246, a low-molecular-weight compound that is active against multiple orthopoxviruses. Conducted toxicology studies and analyze efficacy of optimized lead compounds against alphavirus infection in murine and non-human primate challenge models. Characterized the clinical manifestations and virologic/immunologic parameters of human monkeypox. Determined the effectiveness of pan-alphavirus capsid assembly inhibitors in animal models. FY 2012 Plans: Evaluate immunotherapies for filoviruses in non-human primate models. Continue evaluation of optimized lead compounds against alphaviruses in animal models of infection. Continue evaluation of filovirus vaccines as treatments for post-exposure filovirus infection. Evaluate FDA approved drug combinations for efficacy against alphaviruses in animal models of infection. Initiate a screening program to determine efficacy of FDA approved compounds against emerging infectious diseases (i.e. alphavirus, filovirus, flavivirus, arenavirus, bunyavirus). In FY13, all research in this area is re-aligned to Project TM3 - Techbase Med Bio-Therapeutics (ATD).			9.351	2.898	-
Title: 7) Therapeutics Description: Bacterial Therapeutics: Identifies, optimizes, and evaluates potential therapeutic compounds effective against bacterial threat agents. FY 2011 Accomplishments:			2.700	2.000	-

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program		DATE: February 2012		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 3: <i>Advanced Technology Development (ATD)</i>	R-1 ITEM NOMENCLATURE PE 0603384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>	PROJECT TB3: <i>MEDICAL BIOLOGICAL DEFENSE (ATD)</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2011	FY 2012	FY 2013
Determined the effectiveness of commercially available antibiotics against Francisella tularensis in relevant animal infection models. FY 2012 Plans: Evaluate Protein Design Process optimized anthrax capsule depolymerase (CapD) in murine challenge models of anthrax infection. Transition data package demonstrating efficacy of FDA approved compounds against lethal challenge of aerosolized Y. pestis in nonhuman primate models. Conduct studies to determine efficacy against FDA approved compounds against Burkholderia, Francisella tularensis in murine animal models. Evaluate small molecule inhibitors targeting Y. pestis ATPase enzyme in small animal models. In FY13, all research in this area is re-aligned to Project TM3 - Techbase Med Bio-Therapeutics (ATD).				
Title: 8) Therapeutics Description: Toxin Therapeutics: Identifies, optimizes and evaluates potential therapeutic candidates effective against biological toxin threat agents. FY 2011 Accomplishments: Tested and evaluated FDA approved immunomodulating drugs against exposure to Staphylococcal Enterotoxin B (SEB). Developed and determined the therapeutic window of opportunity for novel inhibitors of SEB pathogenesis. Determined initial safety profile and conduct genotoxicity studies for BoNT inhibitors with the goal of improving physiochemical properties and mitigating product liabilities through the use of medicinal chemistry. Conducted pre- and post-challenge of efficacy studies of optimized BoNT inhibitors in mice. Evaluated efficacy of BoNT lead inhibitors using a targeted delivery system in mice. FY 2012 Plans: Continue evaluation of FDA approved immunomodulating agents to treat SEB. Initiate a screening program to determine efficacy of FDA approved compounds against BoNT intoxication. Continue evaluation of novel optimized SEB and BoNT inhibitors in small animal models of infection. In FY13, all research in this area is re-aligned to Project TM3 - Techbase Med Bio-Therapeutics (ATD).		1.500	2.184	-
Title: 9) Transformational Medical Technologies Description: Multiagent (Broad Spectrum) Medical Countermeasures: Continues efforts previously funded under the Transformational Medical Technologies Initiative to develop candidate countermeasures for HFV and IBP. Focuses on the initiation and completion of preclinical studies for candidate countermeasures, to include safety, toxicity, efficacy, and scalability work in accordance with the product's intended use. The ability to formulate Good Manufacturing Practices (GMP), pilot lots and further mature promising drug candidates will be the focus of activities in this capability area. The preclinical drug discovery		-	66.768	-

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program		DATE: February 2012		
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)	R-1 ITEM NOMENCLATURE PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)	PROJECT TB3: MEDICAL BIOLOGICAL DEFENSE (ATD)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2011	FY 2012	FY 2013
process culminates in the submission of an Investigational New Drug (IND) application to the Food and Drug Administration (FDA), to determine if candidate countermeasures are suitable for safety evaluation in humans. FY 2012 Plans: Continue pre-clinical research required to submit IND applications to the FDA for additional products or additional product indications to refresh the Hemorrhagic Fever Virus (HFV), Intracellular Bacterial Pathogen (IBP) and EID product pipelines. Continue planning for Phase 1 clinical trials and additional studies for INDs as required by the FDA prior to safety evaluation in humans. Continue the development of animal models for future advanced development of MCMs currently in the S&T phase of development, incorporating feedback from the FDA and Services into requirements. In FY13, all research in this area is re-aligned to Project TM3 - Techbase Med-Bio Therapeutics.				
Title: 10) Transformational Medical Technologies Description: Development of Platform Technologies: Continues efforts previously funded under the Transformational Medical Technologies Initiative. Platform Technologies are stand alone enabling technologies that support MCM development and when strategically aligned, provide a system of systems response capability to an adverse biological event - from the identification of an unknown pathogen to the development of an approved countermeasure ready for delivery to the Warfighter and the nation. The enabling technologies are divided into five platform areas: Pathogen Characterization, Target Identification, Countermeasure Discovery, Countermeasure Evaluation, and Bioinformatics. Efforts focus on advanced technology and development activities for Platform Technologies to include the maturation of components that will begin the process of integrating a countermeasure response pipeline. Off-the-shelf technologies will be identified, evaluated, and refined to demonstrate the ability to provide drug development capabilities. Advanced manufacturing platforms will continue to mature and the technology application will focus on the type of specific therapeutics under development. FY 2012 Plans: Investment to fund Bio-Surveillance efforts and integrate stand-alone platforms into system-wide capabilities. Continue development of rapid drug discovery and development platform technologies, and build upon early success to fully integrate the entire system using robust bioinformatics capabilities, validating the integrated bioinformatics platform. Increase investment to mature and accelerate manufacturing platform technologies for biological drugs to comply with regulatory guidelines. Support compliance and quality measures that are mandatory for future FDA submissions. Fully integrate pathogen characterization, target identification, countermeasure discovery and countermeasure evaluation platform areas into a rapid response capability supported by a centralized bioinformatics capability that link geographically separated performers from government agencies, industry and academia. In FY13, all research in this area is re-aligned to Project TM3 - Techbase Med-Bio Therapeutics.		-	33.585	-
Title: 11) Transformational Medical Technologies Initiative		66.929	-	-

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program			DATE: February 2012		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 3: <i>Advanced Technology Development (ATD)</i>		R-1 ITEM NOMENCLATURE PE 0603384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>		PROJECT TB3: <i>MEDICAL BIOLOGICAL DEFENSE (ATD)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2011	FY 2012	FY 2013
<p>Description: Multiagent (Broad Spectrum) Medical Countermeasures: Focuses on the initiation and completion of multiple preclinical studies for each new drug, to include safety, toxicity, efficacy, and scalability work in accordance with the product's intended use. The ability to formulate good manufacturing pilot lots and further mature promising drug candidates will be the focus of activities in this capability area. The preclinical drug discovery process culminates in the submission of an Investigational New Drug (IND) application to the Food and Drug Administration (FDA), which conducts reviews and approves new drug candidates. Estimated attrition from preclinical phase to Phase I clinical studies is approximately 50%, thus not all drugs will survive the transition between preclinical development and Phase I studies.</p> <p>FY 2011 Accomplishments: Completed pre-clinical research required to submit IND applications to the FDA for additional products or additional product indications. As MCMs effective as post-exposure prophylaxis and treatment against IBP are matured, an initial DoD Milestone A decision took place for the IBP Group of MCMs. Initiated planning for Phase 1 clinical trials and additional studies for INDs as required by the FDA prior to safety evaluation in humans. Continued the development of animal models for future advanced development of MCMs currently in the S&T phase of development. This included exploratory research and identification of products supported in the Technologies Portfolio; mitigation of risk associated with seeking in vivo potency and efficacy critical to the likely product development path; determining dose-response and the optimal route of administration and timing/schedule of administration of product in relevant animal efficacy models.</p>					
<p>Title: 12) Transformational Medical Technologies Initiative</p> <p>Description: Development of Platform Technologies: Platform Technologies are standalone enabling technologies that support MCM development and when strategically aligned, provide a system of systems response capability to an adverse biological event - from the identification of an unknown pathogen to the development of an approved countermeasure ready for delivery to the Warfighter and the nation. The enabling technologies are divided into five platform areas: Pathogen Characterization, Target Identification, Countermeasure Discovery, Countermeasure Evaluation, and Bioinformatics. Efforts focus on advanced technology and development activities for Platform Technologies to include the maturation of components that will begin the process of integrating a countermeasure response pipeline. Off-the-shelf technologies will be identified, evaluated, and refined to demonstrate the ability to provide drug development capabilities. Advanced manufacturing platforms will continue to mature and the technology application will focus on the type of specific therapeutics under development.</p> <p>FY 2011 Accomplishments: Continued integration of standalone platforms into capabilities that can be demonstrated as a system. Continued the development of rapid drug discovery and development platform technologies. Integrated the entire system using a robust bioinformatics capability, and validated the integrated bioinformatics platform. Continued to mature and accelerate manufacturing platform technologies for biological drugs to comply with regulatory guidelines. Supported compliance and quality measures</p>			48.265	-	-

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program									DATE: February 2012		
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)				R-1 ITEM NOMENCLATURE PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)				PROJECT TB3: MEDICAL BIOLOGICAL DEFENSE (ATD)			
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2011	FY 2012	FY 2013
that are mandatory for future FDA submissions. Continued to integrate pathogen characterization, target identification, countermeasure discovery and countermeasure evaluation platform areas into a rapid response capability supported by a centralized bioinformatics capability that ties together geographically separated performers from government agencies, industry and academia.											
Title: 13) SBIR									-	2.207	-
FY 2012 Plans: Small Business Innovative Research.											
Accomplishments/Planned Programs Subtotals									153.437	172.394	-
C. Other Program Funding Summary (\$ in Millions)											
Line Item	FY 2011	FY 2012	FY 2013 Base	FY 2013 OCO	FY 2013 Total	FY 2014	FY 2015	FY 2016	FY 2017	Cost To Complete	Total Cost
• TM3: TECHBASE MED DEFENSE (ATD)	0.000	0.000	182.330		182.330	171.399	147.651	136.326	136.326	Continuing	Continuing
• MB4: MEDICAL BIOLOGICAL DEFENSE (ACD&P)	129.682	116.653	133.254		133.254	194.502	155.024	81.188	23.593	Continuing	Continuing
• MB5: MEDICAL BIOLOGICAL DEFENSE (SDD)	75.657	216.715	214.056		214.056	246.295	187.101	213.001	238.653	Continuing	Continuing
• MB7: MEDICAL BIOLOGICAL DEFENSE (OP SYS DEV)	0.000	5.448	0.498		0.498	0.499	3.266	0.496	9.355	Continuing	Continuing
D. Acquisition Strategy											
N/A											
E. Performance Metrics											
N/A											

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program	DATE: February 2012
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APPROPRIATION/BUDGET ACTIVITY				R-1 ITEM NOMENCLATURE				PROJECT			
0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 3: <i>Advanced Technology Development (ATD)</i>				PE 0603384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>				TC3: <i>MEDICAL CHEMICAL DEFENSE (ATD)</i>			
COST (\$ in Millions)	FY 2011	FY 2012	FY 2013 Base	FY 2013 OCO	FY 2013 Total	FY 2014	FY 2015	FY 2016	FY 2017	Cost To Complete	Total Cost
TC3: <i>MEDICAL CHEMICAL DEFENSE (ATD)</i>	25.486	21.789	-	-	-	-	-	-	-	0.000	47.275

A. Mission Description and Budget Item Justification

This project (TC3) supports the advanced development of medical countermeasures to include prophylaxes, pretreatments, antidotes, skin decontaminants and therapeutic drugs against identified and emerging chemical warfare threat agents. Analytical stability studies, safety and efficacy screening, and preclinical toxicology studies are performed prior to full-scale development of promising pretreatment or treatment drug compounds. Entry of candidate pretreatment/prophylaxes, therapeutics, and diagnostic technologies into advanced development (i.e., efforts funded in Budget Activities 4 and 5) is facilitated by the development of technical data packages that support the Food and Drug Administration (FDA) Investigational New Drug (IND) application and licensure processes, as well as Department of Defense (DoD) acquisition regulations. Categories for this project include Pretreatments, Diagnostics, and Therapeutics to address Chemical Warfare Agent (CWA) and Non-Traditional Agents (NTAs) exposure.

In FY13, all non-NTA research in this Project (TC3) is re-aligned to Project TM3 - Techbase Medical Defense (ATD). All NTA-dedicated research in this Project is re-aligned to Project NT3 - Techbase Non-Traditional Agents Defense (ATD).

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

	FY 2011	FY 2012	FY 2013
Title: 1) Diagnostics Description: Diagnostic Technologies: Focuses on state-of-the-art laboratory/fieldable methods that detect exposure to chemical warfare agents (CWA) (e.g., nerve agents and vesicants) in clinical samples. It also targets the identification of biomolecular targets that can be leveraged as analytical methodologies, as well as laboratory and animal studies characterizing time-course and longevity of a particular analyte/biomarker. FY 2011 Accomplishments: Optimized the methodology for solvent free extraction of CWA mixtures. Completed blood and urine assay development for CWA exposure. Completed validation of fluoride regeneration method in plasma/blood/RBCs with solid phase extraction for nerve agents. FY 2012 Plans: Expand the current set of analytical methods to more sensitive analytical platforms for the detection of CWAs. In FY13, all research in this area is re-aligned to Project TM3 - Techbase Med Chem - Diagnostics.	1.297	0.467	-
Title: 2) Chem Diagnostics NTA Description: Chem Diagnostics NTA: Focuses on state-of-the-art laboratory/fieldable methods that detect exposure to non-traditional agents in clinical samples. It also targets the identification of biomolecular targets that can be leveraged as analytical	0.390	0.591	-

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program		DATE: February 2012		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 3: <i>Advanced Technology Development (ATD)</i>	R-1 ITEM NOMENCLATURE PE 0603384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>	PROJECT TC3: <i>MEDICAL CHEMICAL DEFENSE (ATD)</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2011	FY 2012	FY 2013
methodologies, as well as, laboratory and animal studies characterizing time-course and longevity of a particular analyte/ biomarker.				
FY 2011 Accomplishments: Continued evaluation of mature technologies that could quickly diagnose NTA exposure before symptoms appear and determine the type of agent. Developed a fluoride regeneration method for NTAs.				
FY 2012 Plans: Continue evaluation of mature technologies that can quickly diagnose pre-symptomatic NTA exposure. In FY13, all research in this area is re-aligned to Project NT3 - Techbase Med Defense - NTA Diagnostics.				
Title: 3) Pretreatments		4.189	1.843	-
Description: Nerve Agent, Pretreatments: Develop pretreatments that provide protection against all organophosphorous nerve agents. The enzymes should have the ability to rapidly bind and detoxify nerve agents, and have broad binding specificity and high enzymatic efficiency for the destruction of agents. For enzyme approaches, one molecule of catalytic bioscavenger should be capable of detoxifying numerous molecules nerve agents resulting in the capability for a small quantity of catalytic bioscavenger to protect against a large dose of nerve agent.				
FY 2011 Accomplishments: Applied physiologically based pharmacokinetics (PBPK) models to improved catalytic bioscavengers. Continued to test improved catalytic bioscavenger delivery methods and retention systems in animal models. Continued to develop binding proteins in animal models for safety and efficacy, using animal testing to down-select candidates for further development.				
FY 2012 Plans: Refine methods and expression systems for large-scale production and purification of enzymes. Continue testing of improved pretreatment delivery methods and retention approaches in animal models, including physiologically based pharmacokinetics (PBPK). Develop binding proteins in animal models for safety and efficacy. In FY13, all research in this area is re-aligned to Project TM3 - Techbase Medical Defense - Pretreatments.				
Title: 4) Chem Pretreatments NTA		-	0.982	-
Description: Chem Pretreatments NTA: Develop nerve agent enzyme pretreatments that provide protection against non-traditional agents. Enzymes should have the ability to rapidly bind and detoxify nerve agents, and have broad binding specificity and high catalytic efficiency for the destruction of agents. For enzyme approaches, one molecule of catalytic bioscavenger should be capable of detoxifying numerous molecules nerve agents resulting in the capability for a small quantity of catalytic bioscavenger to protect against a large dose of nerve agent.				

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program		DATE: February 2012	
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 3: <i>Advanced Technology Development (ATD)</i>	R-1 ITEM NOMENCLATURE PE 0603384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>	PROJECT TC3: <i>MEDICAL CHEMICAL DEFENSE (ATD)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2011	FY 2012
FY 2012 Plans: Further test improved nerve agent enzyme pretreatment delivery methods and retention approaches in animal models, including physiologically based pharmacokinetics. Further develop binding proteins in animal models for safety and efficacy. In FY13, all research in this area is re-aligned to Project NT3 - Techbase Medical Defense - NTA Pretreatments.			
Title: 5) Therapeutics Description: Cutaneous and Ocular: Focuses on minimizing injuries to dermal and ocular tissues resulting from exposure to chemical warfare agents (CWA). This work is designed to support eventual Food and Drug Administration (FDA) licensure of new compounds or new indications for licensed products for use in the treatment of chemical warfare casualties. FY 2011 Accomplishments: Continued to evaluate the effectiveness of various cell-based approaches to facilitate blister agent wound healing in skin and eyes. Began advanced studies focused on down-selecting wound healing products found to be most effective for transition. Continued to assess in animals whether bioengineering and molecular biology approaches may be used to treat blister agent skin and eye injury. Initiated the development of an approach to decontaminate CWAs in penetrating wounds. FY 2012 Plans: Determine the most effective cell-based approaches to facilitate healing of skin and eye wounds due to sulfur mustard exposure. Complete evaluation of potential wound healing products for advanced development. Evaluate candidate approaches to decontaminate penetrating wounds that have been exposed to CWAs. Continue to assess molecular biology approaches in animal models to treat skin and eye injuries as a result of sulfur mustard exposure. In FY13, all research in this area is re-aligned to Project TM3 - Techbase Med Chem - Therapeutics.		3.689	3.645
Title: 6) Therapeutics Description: Neurologic: Focuses on therapeutic strategies to effectively minimize neurologic injuries resulting from exposure to chemical warfare agents (CWA). This effort involves the development of neuroprotectants, anticonvulsants, and improved neurotransmitter restorers. Supports eventual Food and Drug Administration (FDA) licensure of new compounds or new indications for licensed products for use in the treatment of chemical warfare casualties. FY 2011 Accomplishments: Continued to evaluate, in animals, novel compounds and FDA-approved drugs not yet evaluated for efficacy against nerve agents. These potential compounds included anticholinergics, neuroprotectants, anticonvulsants, and improved reactivators. Continued		12.025	4.168

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program		DATE: February 2012		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 3: <i>Advanced Technology Development (ATD)</i>	R-1 ITEM NOMENCLATURE PE 0603384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>	PROJECT TC3: <i>MEDICAL CHEMICAL DEFENSE (ATD)</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2011	FY 2012	FY 2013
efficacy testing on candidates that are designed to support eventual FDA licensure. Continued development of animal models related to nerve exposure with emphasis on FDA animal rule approval. FY 2012 Plans: Continue animal model evaluation of novel and/or FDA approved drugs not yet tested for treatment of nerve agent exposure. Transition Centrally Active Nerve Agent Therapeutic (scopolamine). Continue development of animal models related to nerve agent exposure. Maintain core capabilities for standardization of in vitro and in vivo testing of therapeutic candidates. In FY13, all research in this area is re-aligned to Project TM3 - Techbase Medical Chemical - Therapeutics.				
Title: 7) Therapeutics Description: Respiratory and Systemic: Supports investigation of the systemic host response to chemical warfare agent (CWA) injury via all routes of exposure, with emphasis on the respiratory system and chronic effects of exposure. Develops effective practical field and clinic management strategies, and physical and pharmacological interventions to treat the injury processes. Designed to support eventual Food and Drug Administration (FDA) licensure of new compounds or new indications for licensed products for use in the treatment of chemical warfare casualties. FY 2011 Accomplishments: Evaluated previously identified lead candidate countermeasures for future transition to advanced development. Investigated novel delivery systems for potential inhalational therapeutics against CWA. Investigated efficacy of commercially available aerosol bronchodilators as supportive therapy following pulmonary exposure to CWAs.		1.442	-	-
Title: 8) Therapeutics Description: Non Traditional Agents (NTAs): Determines the toxic effects of agents by probable routes of field exposure and refines standard experimental routes. Physiological parameters and pathological assessment will be used to establish the general mode and mechanisms of toxicity. FY 2011 Accomplishments: Completed characterization of a novel therapeutic for manufacturability and pharmacology. Established formulation for safety testing and stability. In FY12, all NTA-related efforts have been re-aligned to Chemical Therapeutics NTA within this Project.		2.454	-	-
Title: 9) Chem Therapeutics NTA Description: Non-Traditional Agents (NTA): Determine the toxic effects of agents by probable routes of field exposure and refine standard experimental routes. Physiological parameters and pathological assessment will be used to establish the general mode and mechanisms of toxicity.		-	9.793	-

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program										DATE: February 2012		
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)				R-1 ITEM NOMENCLATURE PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)				PROJECT TC3: MEDICAL CHEMICAL DEFENSE (ATD)				
B. Accomplishments/Planned Programs (\$ in Millions)										FY 2011	FY 2012	FY 2013
FY 2012 Plans: Complete characterization of a novel therapeutic for manufacturability and pharmacology. Establish formulation for safety testing and stability. This work continues efforts initiated in prior years within the Project TC3 - Chemical Therapeutics capability area. In FY13, all research in this area is re-aligned to Project NT3 - Techbase Medical Defense - NTA Therapeutics.												
Title: 10) SBIR FY 2012 Plans: Small Business Innovative Research.										-	0.300	-
Accomplishments/Planned Programs Subtotals										25.486	21.789	-
C. Other Program Funding Summary (\$ in Millions)												
Line Item	FY 2011	FY 2012	FY 2013 Base	FY 2013 OCO	FY 2013 Total	FY 2014	FY 2015	FY 2016	FY 2017	Cost To Complete	Total Cost	
• TM2: TECHBASE MED DEFENSE (APPLIED RESEARCH)	0.000	0.000	118.208		118.208	110.294	97.308	130.654	130.654	Continuing	Continuing	
• TM3: TECHBASE MED DEFENSE (ATD)	0.000	0.000	182.330		182.330	171.399	147.651	136.326	136.326	Continuing	Continuing	
• MC4: MEDICAL CHEMICAL DEFENSE (ACD&P)	4.134	7.804	0.000		0.000	16.947	20.395	37.513	25.134	Continuing	Continuing	
• MC5: MEDICAL CHEMICAL DEFENSE (SDD)	3.801	2.407	9.642		9.642	41.257	45.477	50.862	58.935	Continuing	Continuing	
D. Acquisition Strategy N/A												
E. Performance Metrics N/A												

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program									DATE: February 2012		
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)				R-1 ITEM NOMENCLATURE PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)				PROJECT TE3: TEST & EVALUATION (ATD)			
COST (\$ in Millions)	FY 2011	FY 2012	FY 2013 Base	FY 2013 OCO	FY 2013 Total	FY 2014	FY 2015	FY 2016	FY 2017	Cost To Complete	Total Cost
TE3: TEST & EVALUATION (ATD)	11.346	11.199	-	-	-	-	-	-	-	0.000	22.545

A. Mission Description and Budget Item Justification

This project (TE3) supports the development of test and evaluation methodologies and protocols as new science and technology efforts are discovered and transitioned to advanced development programs. It includes methodology development for chemical and biological defense test and evaluation capabilities, with an emphasis on Non Traditional Agents (NTAs). These methodologies support development testing and operational testing with regard to advanced development programs that have unique chemical and biological defense requirements. These new methodologies and testing capabilities include the development of protocol and standards for use of chemical and biological simulants.

In FY13, all NTA-dedicated research is re-aligned to Project NT3 - Techbase Non-Traditional Agents Defense (ATD). All non-NTA related T&E efforts will be completed in FY12.

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

	FY 2011	FY 2012	FY 2013
Title: 1) Test and Evaluation (T&E) Description: Test and Evaluation, Detection: Develop, test, and evaluate technologies and processes in support of detection capability testing. FY 2011 Accomplishments: Completed development of methodologies and capabilities for test and evaluation of technologies currently in early stages of technology development.	2.625	-	-
Title: 2) Test and Evaluation (T&E) Description: Test and Evaluation, Threat Agent Science: Develop test and evaluation technologies and processes in support of Threat Agent Science activities. FY 2011 Accomplishments: Developed methodology and established the relationship of simulants used in field trials to agents for each CWA detection technology; included determination of quantity of simulants required to mimic the detector response to agent as well as how interferences and environmental factors impact both simulant and agent. Identified and developed simulants that enabled decontamination processes to be monitored to determine its/their progression and efficiency. Developed methodologies that disperse or deposit currently available simulants as if they were agents, which could include adding thickeners or surfactants.	1.322	-	-
Title: 3) Test and Evaluation (T&E)	5.357	4.668	-

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program			DATE: February 2012		
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)		R-1 ITEM NOMENCLATURE PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)	PROJECT TE3: TEST & EVALUATION (ATD)		
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2011	FY 2012	FY 2013
Description: Test and Evaluation, Information System Technology: Develop test and evaluation technologies and processes in support of Information System Technology activities. FY 2011 Accomplishments: Constructed a plan for development of the Chemical and Biological Warfare Agent Effects Manual Number 1 (CB-1), an authoritative source capturing analytical methods for evaluating the effects of CB warfare agents on equipment, personnel, and operations. Demonstrated initial versions of Systems Performance Models. Continued to develop collective protection, individual protection, contamination avoidance and decontamination models for test and evaluation. Continued to build requirements for system performance model integration and program-wide exploitation. FY 2012 Plans: Continue the development of CBRN data management capabilities for test and evaluation, with emphasis on enabling access to information for analysis within CBDP systems performance models. Enhance ability to evaluate decontaminants and decontamination systems by continuing to develop simulation capabilities for decontamination processes.					
Title: 4) Test and Evaluation (T&E) Description: Test and Evaluation, Protection and Hazard Mitigation: Develop test and evaluation technologies and processes in support of Protect and Hazard Mitigation activities. FY 2011 Accomplishments: Continued development of methodology/source data effort to simulate IP durability in laboratory and relationship to field durability.			0.100	-	-
Title: 5) Test and Evaluation (T&E) NTA Description: Develops test and evaluation technologies and processes in support of NTA activities. FY 2011 Accomplishments: Conducted facility design efforts by conducting large particle dissemination development and proof of principle tests with several agents. Completed testing regarding the safety of unprotected personnel using the chamber after decontamination. FY 2012 Plans: Complete facility design efforts by conducting large particle dissemination development and proof of principle tests with several agents. Initiate select agent testing. In FY13, all research in this area is re-aligned to Project NT3 - Techbase Non-Med Test & Evaluation (NTA).			1.942	6.362	-
Title: 6) SBIR FY 2012 Plans:			-	0.169	-

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program			DATE: February 2012
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 3: <i>Advanced Technology Development (ATD)</i>	R-1 ITEM NOMENCLATURE PE 0603384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>	PROJECT TE3: <i>TEST & EVALUATION (ATD)</i>	

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2011	FY 2012	FY 2013
Small Business Innovative Research.			
Accomplishments/Planned Programs Subtotals	11.346	11.199	-

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

Line Item	FY 2011	FY 2012	FY 2013 Base	FY 2013 OCO	FY 2013 Total	FY 2014	FY 2015	FY 2016	FY 2017	Cost To Complete	Total Cost
• CB3: <i>CHEMICAL BIOLOGICAL DEFENSE (ATD)</i>	21.219	23.818	20.034		20.034	18.343	18.893	17.357	17.357	Continuing	Continuing
• TE4: <i>TEST & EVALUATION (ACD&P)</i>	19.054	5.438	4.994		4.994	12.771	20.408	15.872	13.044	Continuing	Continuing
• TE5: <i>TEST & EVALUATION (SDD)</i>	30.653	11.043	6.394		6.394	20.202	12.033	14.200	14.200	Continuing	Continuing
• TE7: <i>TEST & EVALUATION (OP SYS DEV)</i>	4.732	3.597	4.156		4.156	3.690	3.642	2.846	2.846	Continuing	Continuing

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program **DATE:** February 2012

APPROPRIATION/BUDGET ACTIVITY				R-1 ITEM NOMENCLATURE				PROJECT			
0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 3: <i>Advanced Technology Development (ATD)</i>				PE 0603384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>				TM3: <i>TECHBASE MED DEFENSE (ATD)</i>			
COST (\$ in Millions)	FY 2011	FY 2012	FY 2013 Base	FY 2013 OCO	FY 2013 Total	FY 2014	FY 2015	FY 2016	FY 2017	Cost To Complete	Total Cost
TM3: <i>TECHBASE MED DEFENSE (ATD)</i>	-	-	182.330	-	182.330	171.399	147.651	136.326	136.326	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project (TM3) funds preclinical and early phase clinical development of vaccines, therapeutic drugs, and diagnostic capabilities to provide safe and effective medical defense against validated biological threat agents or emerging infectious disease biothreats including bacteria, toxins, and viruses. Innovative biotechnology approaches to advance medical systems designed to rapidly identify, diagnose, prevent, and treat disease due to exposure to biological threat agents will be evaluated. In addition this project supports the advanced development of medical countermeasures to include prophylaxes, pretreatments, antidotes, skin decontaminants and therapeutic drugs against identified and emerging chemical warfare threat agents. Entry of candidate vaccines, therapeutics, and diagnostic technologies into advanced development is facilitated by the development of technical data packages that support the Food and Drug Administration (FDA) Investigational New Drug (IND) processes, DoD acquisition regulations, and the oversight of early phase clinical trials in accordance with FDA guidelines. This project also supports the advanced development of medical countermeasures to protect the Warfighter against radiological/nuclear exposure.

This project also includes efforts such as the Transformational Medical Technologies Program (TMT). TMT's focus is to protect the Warfighter from genetically engineered or emerging infectious disease threats by providing a rapid response capability from identification of pathogens to the delivery of medical countermeasures.

The Medical Countermeasures Initiative (MCMI) was established to coordinate inter-related advanced development and flexible manufacturing capabilities, providing a dedicated, cost-effective, reliable, and sustainable MCM process that meets the warfighter and national security needs. MCMI efforts within S&T are concentrated in two areas: 1) advancement of regulatory science and 2) advancements in flexible manufacturing technologies for MCMs.

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

	FY 2011	FY 2012	FY 2013
Title: 1) Techbase Med Defense - Medical Countermeasures Initiative	-	-	19.237
Description: Medical Countermeasures Initiative (MCMI): The MCMI will integrate the regulatory science and manufacturing technologies and processes developed into the Advanced Development and Manufacturing Center of Excellence (ADM COE) as enablers of the advanced development and flexible manufacturing capability.			
FY 2013 Plans: Further the development of human in vitro immune mimetic assays for FDA acceptance to enable rapid and accurate prediction of the human response to experimental vaccines and other MCMs. Continue to develop and make practical improvements to existing agile, flexible, manufacturing bioprocesses for the purpose of accelerating access to biodefense MCMs. Continue the			

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program		DATE: February 2012	
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 3: <i>Advanced Technology Development (ATD)</i>	R-1 ITEM NOMENCLATURE PE 0603384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>	PROJECT TM3: <i>TECHBASE MED DEFENSE (ATD)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2011	FY 2012
development of a plant-based virus-like particle (VLP) vaccine. Identify additional ex-vivo cell/tissue mimetics such as precision cut tissue slices to serve as predictive surrogates for accelerated MCM efficacy and safety evaluation.			FY 2013
Title: 2) Techbase Med Bio - Diagnostics Description: Disease Surveillance/Epidemiological and Predictive Modeling: Integrate existing disparate military and civilian data sets into advanced warning systems, and leverage and enhance epidemiological models and algorithms for disease prediction, impact and biological threat assessment. Contribute to the development of global, near real time, disease monitoring and surveillance systems that address secondary infection, fuse medical syndromic, environmental, and clinical data, and feed into agent-based epidemiological modeling, medical resource estimation and decision support tools. Focus on agent-based epidemiological modeling and fusion of disease surveillance data. FY 2013 Plans: Continue effort initiated in Project CB3 (M&S) - Information Systems Technology, Medical Surveillance - of Verification and Validation (V&V) of existing agent-based epidemiological models, to include underlying population data and disease spread algorithms, along with biosurveillance data fusion, for use in robust adaptive decision making. Funding for this research area is realigned from Tech Base Non-Med Defense - Modeling & Simulation (CB3).		-	1.550
Title: 3) Techbase Med Bio - Diagnostics Description: Biological Diagnostic Technologies: Development and verification of rapid, sensitive, and specific tests for the identification of Biological Warfare Agents (BWAs) and their expressed pathogens and toxins in clinical specimens from Warfighters for the diagnosis of exposure/infection. Discovery of host biomarkers generated in response to exposure to biological threat agents. FY 2013 Plans: Translate laboratory, data fusion informatic methodologies and specimen pipelines into robust and well-characterized signatures required to identify and bio-type emerging, re-emerging, and synthetic threat agent strains, identify antibiotic resistant mutations and phenotypes, and therapeutic and vaccine response markers. Develop and transition thermostable reagents/scale-up protocols to advanced development for use in austere biosurveillance environments. Transition agent characterization dossiers to developers of: Medical Counter Measures, microbial forensics capabilities, and assays developers to augment existing biosurveillance infrastructure performing vector surveys, zoonotic epidemiology and provide a direct link between medical diagnostic, disease surveillance and MCM development. Submit pre-Emergency Use application data packages to FDA Office for in vitro diagnostics. Funding for this research area is realigned from Tech Base Med Bio - Diagnostics (TB3) and Techbase Med Bio - TMT Platform Technologies (TB3).		-	32.649
Title: 4) Techbase Med Bio - Diagnostics		-	14.770

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program			DATE: February 2012		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 3: <i>Advanced Technology Development (ATD)</i>		R-1 ITEM NOMENCLATURE PE 0603384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>		PROJECT TM3: <i>TECHBASE MED DEFENSE (ATD)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2011	FY 2012	FY 2013
Description: Next Generation Technologies: Development of next generation diagnostic technologies including portable diagnostic platforms, highly parallel and informative testing formats, and nanotechnology applications. Development of novel assay formats and hardware solutions to enable point of need diagnostic capabilities, allowing for rapid guidance of medical decisions. FY 2013 Plans: Perform pre-clinical validation studies in relevant animal models and human/zoonotic disease states to stratify pre-symptomatic biomarker panel positive and negative predictive values. Funding for this research area is realigned from Tech Base Med Bio - Diagnostics (TB3) and Techbase Med Bio - TMT Platform Technologies (TB3).					
Title: 5) Techbase Med Bio - Diagnostics Description: Biological Diagnostic Devices: Diagnostic device development to include systems able to harness next generation technologies to revolutionize clinical diagnostics in care facilities and in hospital laboratories. This investment will incorporate capabilities such as next generation sequencing and advanced biomolecular methods to harness both host and pathogen biomarkers in a threat agnostic approach that will serve all echelons of military medical care. FY 2013 Plans: Provide documented assessments of candidate devices potential for transition to advanced developers to support the deployment of point of care diagnostic capabilities. Verify clinical utility of host and pathogen biomarkers and integrate onto diagnostic platform prototype(s) that confers the ability to identify and type novel infectious agents as a function of their relationship to previously characterized pathologies. Funding for this research area is realigned from Tech Base Med Bio - Diagnostics (TB3) and Techbase Med Bio - TMT Platform Technologies (TB3).			-	-	17.880
Title: 6) Techbase Med Bio - Pretreatments Description: Pretreatments - Bacterial/Toxin Vaccines: Evaluates the best single agent bacterial and toxin vaccines for effectiveness against aerosol challenge in large animal models. FY 2013 Plans: Deliver final data package for Ricin vaccine. Funding for this research area is realigned from Tech Base Med Bio - Pretreatments (TB3).			-	-	0.510
Title: 7) Techbase Med Bio - Pretreatments Description: Pretreatments - Viral Vaccines: Evaluates the best vaccine candidates for Alphaviruses and Filoviruses for effectiveness and duration of protective immune response against aerosol challenge in large animal models. Animal models			-	-	19.038

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program		DATE: February 2012	
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 3: <i>Advanced Technology Development (ATD)</i>	R-1 ITEM NOMENCLATURE PE 0603384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>	PROJECT TM3: <i>TECHBASE MED DEFENSE (ATD)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2011	FY 2012
will be developed to support FDA licensure of mature vaccine candidates. The purpose of developing these animal models is to support pivotal animal studies under the "animal rule".			
FY 2013 Plans: Coordinate with the advanced developer to fulfill S&T needs in support of the Filovirus vaccine transition. Continue development of Filovirus and Alphavirus immunological assays to support product development. Complete Phase I clinical trial of VEE DNA vaccine delivered by in vivo electroporation via intra-muscular or intra-dermal administration. Complete pre-clinical studies on a trivalent VEE, EEE, WEE DNA formulation. Continue to conduct pre-clinical studies of the Alphavirus replicon vaccine in coordination with the advanced developer. Continue the development of animals models for alphaviruses (EEE and WEE), and filoviruses (Ebola Sudan, Ebola Zaire, Ebola Bundibugyo, and Marburg), to fulfill future FDA animal rule requirements necessary for vaccine licensure. Although the Filovirus vaccines are transitioning in FY11, work will continue on the selected candidate(s) to fill knowledge gaps. Funding for this research area is realigned from Tech Base Med Bio - Pretreatments (TB3).			
Title: 8) Techbase Med Bio - Pretreatments Description: Pretreatments - Vaccine Platforms and Research Tools: Conducts studies to determine potential immune interference between lead vaccine candidates, the effect of alternative vaccine delivery methods and thermo-stabilization technologies on the efficacy of lead vaccine candidates. Identifies correlates of protection in humans, and predicts the success of lead vaccine candidates in humans. Work conducted under Vaccine Platforms and Research Tools are distinct from those performed under Viral Vaccines because the focus is on the use of novel technologies to support vaccine candidates, not on the vaccine candidates themselves. Vaccine Platforms and Research Tools utilize novel technologies to stabilize advanced vaccine candidates as well as alternative delivery modalities. FY 2013 Plans: Continue formulation studies to produce a thermo-stable, spray-dried formulation of an advanced vaccine candidate. Continue to evaluate stabilization technologies that provide thermal stability to multiple classes of vaccines such as viral vectored vaccines and subunit protein vaccines. Continue to evaluate alternative (needle-free) vaccine delivery technologies such as inhalers or skin patches for the delivery of mature vaccine candidates. Utilize clinical samples from filovirus or alphavirus outbreaks in multiple international locations to help define clinically relevant correlates of immunity. Funding for this research area is realigned from Tech Base Med Bio - Pretreatments (TB3).		-	-
			3.200
Title: 9) Techbase Med Bio - Therapeutics Description: Viral Therapeutics: Identify, optimize and evaluate potential therapeutic candidates effective against designated viral threat agents. FY 2013 Plans:		-	-
			6.100

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program		DATE: February 2012	
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 3: <i>Advanced Technology Development (ATD)</i>	R-1 ITEM NOMENCLATURE PE 0603384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>	PROJECT TM3: <i>TECHBASE MED DEFENSE (ATD)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2011	FY 2012
Continue evaluation of immunotherapies for filoviruses in non-human primate models. Develop immune modulators for the treatment of filovirus infection. Continue screening program to determine efficacy of FDA approved compounds against emerging infectious diseases (i.e. alphavirus, filovirus, flavivirus, arenavirus, bunyavirus). Continue pre-clinical research required to submit IND applications to the FDA for additional products or additional product indications to refresh the viral therapeutics product pipeline. Funding for this research area is realigned from Tech Base Med Bio - Therapeutics (TB3).			
Title: 10) Techbase Med Bio - Therapeutics Description: Bacterial Therapeutics: Identify, optimize and evaluate potential therapeutic compounds effective against bacterial threat agents. FY 2013 Plans: Evaluate FDA approved compounds for efficacy in non-human primate models against aerosolized challenge of Y. pestis and F. tularensis. Develop small molecule inhibitors of the electron transport chain and the ATP synthase bacterial biothreat agents. Perform pharmacokinetic studies of humanized CapD in mouse models. Continue pre-clinical research required to submit IND applications to the FDA for additional products or additional product indications to refresh the bacterial therapeutics product pipeline. Funding for this research area is realigned from Tech Base Med Bio - Therapeutics (TB3).		-	5.100
Title: 11) Techbase Med Bio - Therapeutics Description: Toxin Therapeutics: Identify, optimize and evaluate potential therapeutic candidates effective against biological toxin threat agents. FY 2013 Plans: Evaluate small molecule non-peptidic inhibitors for pharmacokinetic and toxicology profiles. Test novel small molecule inhibitors in mouse model of BoNT A intoxication for efficacy. Funding for this research area is realigned from Tech Base Med Bio - Therapeutics (TB3).		-	1.645
Title: 12) Techbase Med Bio - Therapeutics Description: Multiagent (Broad Spectrum) Medical Countermeasures: Continues efforts previously funded under the Transformational Medical Technologies Initiative to develop candidate countermeasures for HFV and IBP. Focuses on the initiation and completion of preclinical studies for candidate countermeasures, to include safety, toxicity, efficacy, and scalability work in accordance with the product's intended use. The ability to formulate Good Manufacturing Practices (GMP), pilot lots and further mature promising drug candidates will be the focus of activities in this capability area. The preclinical drug discovery process culminates in the submission of an Investigational New Drug (IND) application to the Food and Drug Administration (FDA), to determine if candidate countermeasures are suitable for safety evaluation in humans.		-	48.225

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program			DATE: February 2012		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 3: <i>Advanced Technology Development (ATD)</i>		R-1 ITEM NOMENCLATURE PE 0603384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>		PROJECT TM3: <i>TECHBASE MED DEFENSE (ATD)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2011	FY 2012	FY 2013
FY 2013 Plans: Continue pre-clinical research required to submit IND applications to the FDA for additional products or additional product indications to refresh the Hemorrhagic Fever Virus (HFV), Intracellular Bacterial Pathogen (IBP) and EID product pipelines. Continue planning for Phase 1 clinical trials and additional studies for INDs as required by the FDA prior to safety evaluation in humans. Continue the development of animal models for future advanced development of MCMs currently in the S&T phase of development, incorporating feedback from the FDA and Services into requirements. Funding for this research area is realigned from Tech Base Med Bio - Transformational Medical Technologies (TB3).					
Title: 13) Techbase Med Chem - Diagnostics Description: Chemical Diagnostics: Focuses on state-of-the-art laboratory/fieldable methods that detect exposure to chemical warfare agents (CWA) (e.g., nerve agents and vesicants) in clinical samples. It also targets the identification of biomolecular targets that can be leveraged as analytical methodologies, as well as laboratory and animal studies characterizing time-course and longevity of a particular analyte/biomarker. FY 2013 Plans: Expand the current set of analytical methods to more sensitive analytical platforms for the detection of CWAs. Funding for this research area is realigned from Tech Base Med Chem - Diagnostics (TC3).			-	-	0.469
Title: 14) Techbase Med Chem - Pretreatments Description: Chemical Medical Pretreatments - Nerve Agent, Pretreatments: Develop pretreatments that provide protection against all organophosphorous nerve agents. The enzymes should have the ability to rapidly bind and detoxify nerve agents, and have broad binding specificity and high enzymatic efficiency for the destruction of agents. For enzyme approaches, one molecule of catalytic bioscavenger should be capable of detoxifying numerous molecules nerve agents resulting in the capability for a small quantity of catalytic bioscavenger to protect against a large dose of nerve agent. FY 2013 Plans: Continue characterization of rHuBChE bioscavenger product of selected alternative expression systems. Funding for this research area is realigned from Tech Base Med Chem - Pretreatments (TC3).			-	-	4.122
Title: 15) Techbase Med Chem - Therapeutics Description: Chemical Medical Therapeutics - Neurologic: Focuses on therapeutic strategies to effectively minimize neurologic injuries resulting from exposure to chemical warfare agents (CWA). This effort involves the development of neuroprotectants, anticonvulsants, and improved neurotransmitter restorers. Supports eventual Food and Drug Administration (FDA) licensure of new compounds or new indications for licensed products for use in the treatment of chemical warfare casualties.			-	-	7.633

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program										DATE: February 2012		
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)				R-1 ITEM NOMENCLATURE PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)				PROJECT TM3: TECHBASE MED DEFENSE (ATD)				
B. Accomplishments/Planned Programs (\$ in Millions)										FY 2011	FY 2012	FY 2013
FY 2013 Plans: Complete studies developing appropriate animal models. Maintain core capability for in vitro and in vivo testing. This core capability for product testing, using standardized methodologies under well-controlled laboratory conditions (e.g., GLP), is needed to ensure quality and consistency of study test data submitted in applications to FDA in support of regulatory actions. Funding for this research area is realigned from Tech Base Med Chem - Therapeutics (TC3).												
Title: 16) Techbase Med Defense - Rad CM Description: Radiological Medical Countermeasures: Develops medical countermeasures to protect the Warfighter against radiological/nuclear exposure. The Department of Defense is the only governmental agency currently developing medical prophylaxis to protect Warfighters or other responders in the event of a radiological incident. FY 2013 Plans: Further explore the development of a biodosimetry hand-held diagnostic device that is minimally invasive, accurate, rapid, high-throughput and suitable for medical triage. Funding for this research area is realigned from Tech Base Med Rad - Radiation Countermeasures (TR3).										-	-	0.202
Accomplishments/Planned Programs Subtotals										-	-	182.330
C. Other Program Funding Summary (\$ in Millions)												
Line Item	FY 2011	FY 2012	FY 2013 Base	FY 2013 OCO	FY 2013 Total	FY 2014	FY 2015	FY 2016	FY 2017	Cost To Complete	Total Cost	
• TM2: TECHBASE MED DEFENSE (APPLIED RESEARCH)	0.000	0.000	118.208		118.208	110.294	97.308	130.654	130.654	Continuing	Continuing	
• MB4: MEDICAL BIOLOGICAL DEFENSE (ACD&P)	129.682	116.653	133.254		133.254	194.502	155.024	81.188	23.593	Continuing	Continuing	
• MC4: MEDICAL CHEMICAL DEFENSE (ACD&P)	4.134	7.804	0.000		0.000	16.947	20.395	37.513	25.134	Continuing	Continuing	
• MB5: MEDICAL BIOLOGICAL DEFENSE (SDD)	75.657	216.715	214.056		214.056	246.295	187.101	213.001	238.653	Continuing	Continuing	
• MC5: MEDICAL CHEMICAL DEFENSE (SDD)	3.801	2.407	9.642		9.642	41.257	45.477	50.862	58.935	Continuing	Continuing	
• MB7: MEDICAL BIOLOGICAL DEFENSE (OP SYS DEV)	0.000	5.448	0.498		0.498	0.499	3.266	0.496	9.355	Continuing	Continuing	

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program		DATE: February 2012
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 3: <i>Advanced Technology Development (ATD)</i>	R-1 ITEM NOMENCLATURE PE 0603384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>	PROJECT TM3: <i>TECHBASE MED DEFENSE (ATD)</i>
<u>D. Acquisition Strategy</u> N/A		
<u>E. Performance Metrics</u> N/A		

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program	DATE: February 2012
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APPROPRIATION/BUDGET ACTIVITY				R-1 ITEM NOMENCLATURE				PROJECT			
0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 3: <i>Advanced Technology Development (ATD)</i>				PE 0603384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>				TR3: <i>MEDICAL RADIOLOGICAL DEFENSE (ATD)</i>			
COST (\$ in Millions)	FY 2011	FY 2012	FY 2013 Base	FY 2013 OCO	FY 2013 Total	FY 2014	FY 2015	FY 2016	FY 2017	Cost To Complete	Total Cost
TR3: <i>MEDICAL RADIOLOGICAL DEFENSE (ATD)</i>	2.402	-	-	-	-	-	-	-	-	0.000	2.402

A. Mission Description and Budget Item Justification

This project (TR3) funds advanced technology development of medical countermeasures against radiological exposure. Specifically, innovative technical approaches will be used to develop, refine, and transition promising products to advanced development efforts to mitigate health consequences resulting from Acute Radiation Exposure (ARS) and Delayed Effects of Acute Radiation Exposure (DEARE). Promising products and pertinent science and technology data will be used to support Investigational New Drug (IND) applications and Food and Drug Administration (FDA) licensure processes, with an emphasis on the development of pretreatments to protect military responders in the event of a radiological incident. Research efforts and data are collaboratively shared with other government agencies so that more mature and promising product candidates will be quickly transitioned to advanced development efforts.

In FY13, all research in this Project (TR3) is realigned to Project TM3 - Techbase Medical Defense (ATD).

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

	FY 2011	FY 2012	FY 2013
Title: 1) Radiological Medical Countermeasures Description: Radiation Medical Countermeasures: Develops medical countermeasures to protect the Warfighter against radiological/nuclear exposure. The Department of Defense is the only governmental agency currently developing medical prophylaxis to protect Warfighters or other responders in the event of a radiological incident. FY 2011 Accomplishments: Continued to investigate relatively mature candidates for advanced development as medical countermeasures to prevent and treat exposure to radiation. Continued to evaluate diagnostic biodosimetry biomarkers that could be used to potentially screen mass casualties. Continued to explore the development of a biodosimetry hand-held diagnostic device that is minimally invasive, accurate, rapid, high-throughput, and suitable for medical triage. Continued development of animal models for radiation exposures useful to support FDA licensure. In FY13, all research in this area is re-aligned to Project TM3 - Techbase Medical Defense - Rad CM.	2.402	-	-
Accomplishments/Planned Programs Subtotals	2.402	-	-

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program									DATE: February 2012			
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)				R-1 ITEM NOMENCLATURE PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)				PROJECT TR3: MEDICAL RADIOLOGICAL DEFENSE (ATD)				
C. Other Program Funding Summary (\$ in Millions)												
Line Item	FY 2011	FY 2012	FY 2013 Base	FY 2013 OCO	FY 2013 Total	FY 2014	FY 2015	FY 2016	FY 2017	Cost To Complete	Total Cost	
• TM2: TECHBASE MED DEFENSE (APPLIED RESEARCH)	0.000	0.000	118.208		118.208	110.294	97.308	130.654	130.654	Continuing	Continuing	
• TR2: MEDICAL RADIOLOGICAL DEFENSE (APPLIED RESEARCH)	2.083	0.806	0.000		0.000	0.000	0.000	0.000	0.000	0.000	2.889	
• TM3: TECHBASE MED DEFENSE (ATD)	0.000	0.000	182.330		182.330	171.399	147.651	136.326	136.326	Continuing	Continuing	
• MR4: MEDICAL RADIOLOGICAL DEFENSE (ACD&P)	1.129	0.000	4.050		4.050	0.000	0.000	0.000	0.000	0.000	5.179	
• MR5: MEDICAL RADIOLOGICAL DEFENSE (SDD)	0.000	0.000	2.027		2.027	16.610	18.103	6.101	7.115	Continuing	Continuing	
D. Acquisition Strategy N/A												
E. Performance Metrics N/A												

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program	DATE: February 2012
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APPROPRIATION/BUDGET ACTIVITY				R-1 ITEM NOMENCLATURE				PROJECT			
0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 3: <i>Advanced Technology Development (ATD)</i>				PE 0603384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>				TT3: <i>TECHBASE TECHNOLOGY TRANSITION</i>			
COST (\$ in Millions)	FY 2011	FY 2012	FY 2013 Base	FY 2013 OCO	FY 2013 Total	FY 2014	FY 2015	FY 2016	FY 2017	Cost To Complete	Total Cost
TT3: <i>TECHBASE TECHNOLOGY TRANSITION</i>	4.433	-	-	-	-	-	-	-	-	0.000	4.433

A. Mission Description and Budget Item Justification

This project (TT3) supports technology transition, technology experimentation and demonstration efforts, and technology readiness assessments in support of unique chemical and biological Advanced Technology Demonstrations (ATDs) and Joint Capability Technology Demonstrations (JCTDs). Within this project are two primary capability areas: 1) Experiment and Technology Demonstrations; and 2) Technology Readiness Assessment. The Experiment and Technology Demonstrations capability area focuses on integration, testing, and assessing candidate ATDs and JCTDs and includes three thrust areas (two of which are new sub-thrust areas that consolidate legacy systems and are annotated as such below): Advanced Remediation Technologies (ART), Early Warning Military Application in Reconnaissance Systems (EW-MARS), and Comprehensive Innovative Protection (CIP). The ART addresses Chemical, Biological, and Radiological (CBR) remediation and decontamination processes and demonstrates technologies and methods to restore assets such as mobile equipment, fixed sites, critical infrastructures, personnel, and equipment to operational status as a result of having reduced or eliminated CBR contamination. The EW-MARS achieves enhanced command and control decision making capabilities as a result of a combined and orchestrated family of chemical and biological defense systems deployed on various platforms in remote locations. The CIP transitions mature technologies to improve individual and collective protection capabilities. The Technology Readiness Assessment capability area focuses on completing manufacturing readiness assessments, technology readiness evaluations, and assessing maturity levels before transitioning ATDs and JCTDs to advanced development efforts located in Budget Activity 4 (Project TT4).

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

	FY 2011	FY 2012	FY 2013
Title: 1) Experiment & Technology Demonstrations FY 2011 Accomplishments: ART Thrust Area Performed technical assessments for the ART Hazard Mitigation, Material, and Equipment Restoration (HaMMER) ATD. Incorporated results into HaMMER from testing and transition of solid oxidant and green surfactant and the Decontamination of Family Systems from the Protection and Hazard Mitigation capability area (see BA2, Project CB2, Protection and Hazard Mitigation - Lightweight Integrated Fabric). EW Thrust Area. Conducted surety testing, technical demonstrations, and down selects for the RASR ATD. CIP Thrust Area	2.168	-	-

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Exhibit R-2A, RDT&E Project Justification: PB 2013 Chemical and Biological Defense Program										DATE: February 2012		
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)				R-1 ITEM NOMENCLATURE PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)				PROJECT TT3: TECHBASE TECHNOLOGY TRANSITION				
B. Accomplishments/Planned Programs (\$ in Millions)										FY 2011	FY 2012	FY 2013
Developed lessons learned from the IP Demo and inform the Protection and Hazard Mitigation capability area for future development (see BA2, Project CB2, Protection and Hazard Mitigation).												
Title: 2) Technology Readiness Assessment										2.265	-	-
FY 2011 Accomplishments: Completed Technology Readiness Evaluations in support of the EW MARS-JFP ATD. Initiated Technology Readiness Evaluation for the CIP thrust area in preparation for a new ATD. Assessed emerging innovations associated with orchestrating the response and capabilities of both individual and collective protection measures within the framework of smart networks and smart materials.												
Accomplishments/Planned Programs Subtotals										4.433	-	-
C. Other Program Funding Summary (\$ in Millions)												
Line Item	FY 2011	FY 2012	FY 2013 Base	FY 2013 OCO	FY 2013 Total	FY 2014	FY 2015	FY 2016	FY 2017	Cost To Complete	Total Cost	
• CB2: CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)	85.789	97.774	44.331		44.331	41.819	40.951	52.243	52.243	Continuing	Continuing	
• CB3: CHEMICAL BIOLOGICAL DEFENSE (ATD)	21.219	23.818	20.034		20.034	18.343	18.893	17.357	17.357	Continuing	Continuing	
• TT4: TECHBASE TECHNOLOGY TRANSITION (ACD&P)	26.051	3.022	3.377		3.377	4.096	7.296	7.821	7.821	Continuing	Continuing	
D. Acquisition Strategy N/A												
E. Performance Metrics N/A												