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Exhibit R-2, RDT&E Budget Item Justification: PB 2014 Chemical and Biological Defense Program **DATE:** April 2013

APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>					R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>							
COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013[#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
Total Program Element	-	223.009	223.269	227.065	-	227.065	231.152	235.312	243.548	247.460	Continuing	Continuing
CB2: <i>CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	-	97.530	44.331	53.901	-	53.901	55.042	59.834	66.483	66.214	Continuing	Continuing
NT2: <i>TECHBASE NON-TRADITIONAL AGENTS DEFENSE (APPLIED RESEARCH)</i>	-	0.000	60.730	75.053	-	75.053	71.749	72.932	77.542	77.805	Continuing	Continuing
TB2: <i>MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	-	87.849	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	87.849
TC2: <i>MEDICAL CHEMICAL DEFENSE (APPLIED RESEARCH)</i>	-	36.695	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	36.695
TM2: <i>TECHBASE MED DEFENSE (APPLIED RESEARCH)</i>	-	0.000	118.208	98.111	-	98.111	104.361	102.546	99.523	103.441	Continuing	Continuing
TR2: <i>MEDICAL RADIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	-	0.935	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	0.935

[#] FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

^{##} The FY 2014 OCO Request will be submitted at a later date

A. Mission Description and Budget Item Justification

Funding under this program element (PE) sustains a robust defense program, which both reduces the danger of a Chemical, Biological, or Radiological (CBR) attack and enables U.S. forces to survive, and continue operations in a CBR environment. The medical program (was TB2, TC2, TR2, but in FY13 these continue within one project, TM2) focuses on the development of antidotes, drug treatments, disease surveillance and point-of-need diagnostic devices, patient decontamination and medical technologies management. The Medical Countermeasures Initiative (MCMi) (was in TB2, but it too continues in FY13 in TM2, consistent with consolidation of the medical program) was established to provide the capability for the advancement of regulatory science and flexible manufacturing of biological MCM to address CBR threats, including novel and previously unrecognized, naturally-occurring emerging infectious diseases. In the physical sciences area, the emphasis is on continuing improvements in CB defense materiel, including contamination avoidance, decontamination, and protection technologies, as well as biological weapon/agent

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surveillance. NT2 consolidated all efforts related to NTAs, including medical pretreatments, therapeutics, detection, threat agent science, modeling, and protection and hazard mitigation. Research efforts are planned to be initiated for CB defense technologies that will result from a strategic approach of converging nanotechnology, biotechnology, information technology and cognitive science. The PE also provides for applied research in the areas of real-time sensing and immediate biological countermeasures.

Key efforts within this PE are in support of the FY14 policy priorities for Countering Biological Threats. Approximately \$40.8M supports the priority to "Promote global health security efforts through building and improving international capacity to prevent, detect, and respond to infectious disease threats, whether caused by natural, accidental, or deliberate events." Approximately \$28.4M supports the priority to "Expand our capability to prevent, attribute, and apprehend those engaged in biological weapons proliferation or terrorism, with a focus on facilitating data sharing and knowledge discovery to improve integrated capabilities." Approximately \$56.9M supports the priority to "Leverage science, technology, and innovation through domestic and international partnerships and agreements to improve global capacity to respond to and recover from biological incidents."

Efforts under this PE will transition to or will provide risk reduction for Advanced Technology Development (PE: 0603384BP), Advanced Component Development and Prototypes (PE: 0603884BP) and System Development and Demonstration (PE: 0604384BP).

In FY13, all NTA efforts (both Medical and Non-Medical) within the PE were re-aligned to Project NT2 - Techbase Non-Traditional Agents Defense. Also in FY13, all Medical efforts formerly included in Project TB2 (Medical Biological Defense), Project TC2 (Medical Chemical Defense) and Project TR2 (Medical Radiological Defense), were re-aligned to Project TM2 (Techbase Med Defense). CB2 Physical Science Applied Research continues, and is the project in which biological threat agent surveillance (biosurveillance) research is pursued.

B. Program Change Summary (\$ in Millions)	<u>FY 2012</u>	<u>FY 2013</u>	<u>FY 2014 Base</u>	<u>FY 2014 OCO</u>	<u>FY 2014 Total</u>
Previous President's Budget	219.873	223.269	208.611	-	208.611
Current President's Budget	223.009	223.269	227.065	-	227.065
Total Adjustments	3.136	0.000	18.454	-	18.454
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	6.159	0.000			
• SBIR/STTR Transfer	-3.023	0.000			
• Other Adjustments	0.000	0.000	18.454	-	18.454

Change Summary Explanation

Funding: Adjustments less than 10% of total program.

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Schedule: N/A		
Technical: N/A		

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Biological Defense Program										DATE: April 2013		
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 2: Applied Research					R-1 ITEM NOMENCLATURE PE 0602384BP: CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)				PROJECT CB2: CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)			
COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 [#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
CB2: CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)	-	97.530	44.331	53.901	-	53.901	55.042	59.834	66.483	66.214	Continuing	Continuing
# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012												
## The FY 2014 OCO Request will be submitted at a later date												
A. Mission Description and Budget Item Justification												
This project (CB2) provides physical science applied research to develop future, multi-disciplinary, multi-functional capabilities in life sciences, physical sciences, environmental sciences, mathematics, cognitive sciences, and engineering. Efforts in this project support the seamless integration of state-of-the-art-technologies into a collection of systems across the spectrum of capabilities required to support chemical and biological defense missions. Capability areas in this project include: detection; Information systems technology; protection/hazard mitigation; and threat agent science. Detection focuses on developing technologies for standoff and point detection and identification of chemical and biological agents. Information systems technology focuses on advanced warning and reporting, hazard prediction and assessment, simulation analysis and planning, and systems performance modeling. Protection and hazard mitigation focuses on providing technologies that protect and reduce the chemical/biological threat or hazard to the Warfighter, weapons platforms, and structures. Threat agent science is devoted to characterizing threat agents and the hazards they present in terms of agent fate in the environment, toxicology, and pathogenicity. This project also supports biological threat agent surveillance (biosurveillance). This project focuses on horizontal integration of CB defensive technologies in support of the Joint Services. This project also supports applied biosurveillance research.												
Multiple projects and associated funding that had been reflected in FY12 with separate CB2 Applied Research project titles (Detection, Information Systems, Protection & Hazard Mitigation, Threat Agent Science) were re-aligned in FY13 into CB2 Techbase Non-Medical (TBNM) Physical Science Applied Research (PSAR), which pursues research on traditional agents. Further, all non-traditional agent (NTA)-dedicated research formerly in CB2 was re-aligned to Project NT2 - Techbase NTA Defense.												
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2012	FY 2013	FY 2014	
Title: 1) Detection									8.610	0.000	0.000	
Description: Chemical and Biological Point Detection Technology: Emphasis on the detection and identification of chemical and biological threats. Objectives include the development of nanoscale detector for sensing of chemical and biological agents, design for prototype whole pathogen genome sequencing system, and development of a portable point detector for chemical warfare (CW) detection in potable water.												
FY 2012 Accomplishments:												

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013
Continued concept development of nano-scale biological agent identification and sensing technologies. Continued feasibility studies of nanoscale detection systems. Continued integration studies for the Next Generation Chemical Detection (NGCD) based on micro-electromechanical systems (MEMS) components for gas chromatography (GC), Infrared (IR), and mass spectrometry (MS). Continued development of breadboard prototype for complete sequencing of entire pathogen genomes with automated sample preparation which also applies to biosurveillance. In FY13, all research in this area was re-aligned into Techbase Non-Med Defense - Physical Science Applied Research (PSAR) (CB2).			
Title: 2) Detection NTA Description: Primary focus is to assess the potential of optical technologies to meet the needs to detect the presence of NTAs. FY 2012 Accomplishments: Continued feasibility development of plant sentinel concept. Continued development from technology concepts and models to meet the needs to detect contamination on surfaces in pre- and post-decontamination application. Completed designs for chemical aerosols point detection system. Initiated integration studies for chemical aerosol detection into the Next Generation Chemical Detection (NGCD) system. In FY13, all research in this area was re-aligned into Techbase Non-Traditional Agents Defense Non-Medical (Applied Research) (NT2).		12.771	0.000
Title: 3) Information Systems Technology Description: Warning and Reporting Information & 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 2012 Accomplishments: Completed study on integration of biosurveillance data with disease spread models to enable early warning and reporting capabilities. Investigation included approaches and tools to automatically access, process and store biosurveillance data, architecture to search stored raw and processed biosurveillance data including adapting existing taxonomies or ontologies to facilitate interoperability, and approaches to facilitate using the architecture in near real-time to update disease spread models with new biosurveillance data. Completed advanced source term estimation (STE) and hazard refinement (HR) algorithms for use in complex environments (e.g., variable terrain, urban, water), based on results of field trial-based validation and verification (V&V) effort. Completed interior building transport and dispersion modeling effort to improve modeling of indoor-to-outdoor dispersion and to enhance the indoor modeling capabilities of advanced development programs. Continued to expand and improve data assimilation techniques for linking chemical, environmental, medical surveillance, and other disparate sensor data with computer based applications. Completed enhanced coupling between environmental parameters and advanced development programs.		5.951	0.000

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013
In FY13, all research in this area was re-aligned into Techbase Non-Med Defense - Physical Science Applied Research (PSAR) (CB2).			
Title: 4) Information Systems Technology Description: Hazard Prediction and 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 CB agents or industrial materials from CB attack or accidents. FY 2012 Accomplishments: Continued development of a waterborne transport tool by beginning investigation of transport methods for biological agents and other materials as well as beginning a feasibility study of waterborne inverse species transport module. Continued to develop a high altitude post-missile intercept hazard prediction model for eventual integration into the Joint Effects Model (JEM) supplemented by small scale testing for model validation. Initiated enhancement of urban dispersion models to include source characterization/backtracking for eventual integration into the Joint Effects Model. Initiated implementation and testing of new numerical schemes for future establishment of 64-bit/multi-core capable models. Transferred high-altitude post-missile intercept, urban transport and dispersion, and 64-bit/multi-core capable model development to CB3 Modeling and Simulation (M&S) funding in FY13. In FY13, all research in this area was re-aligned into Techbase Non-Med Defense - Physical Science Applied Research (PSAR) (CB2).		3.143	0.000
Title: 5) Information Systems Technology 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. FY 2012 Accomplishments: Continued development of CB operational effects in tactical and operational level models, continued development of IM/CM tools, capabilities that leverage and integrate existing early detection and disease surveillance data for inclusion into advanced development efforts. Initiated studies on social/cultural norms for application in agent based models. Initiated study of social reaction to disease and disease mitigation strategies to support biosurveillance. Initiated development of human cognitive models that incorporate the effects of chemical biological agent interaction with other battle stressors to facilitate operational decision making. Continued operational effects research and analysis efforts. In FY13, all research in this area was re-aligned into Techbase Non-Med Defense - Physical Science Applied Research (PSAR) (CB2).		4.597	0.000
Title: 6) Information Systems Technology		0.569	0.000

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013
Description: Systems Performance Information & Analysis: Develop Chemical, Biological, Radiological and Nuclear (CBRN) data sharing capabilities and simulation tools. FY 2012 Accomplishments: Initiated development of an authoritative manual capturing analytical methods for evaluating the effects of chemical and biological warfare on equipment, personnel, and operations. In FY13, all research in this area was re-aligned into Techbase Non-Med Defense - Physical Science Applied Research (PSAR) (CB2).			
Title: 7) Information Systems Technology 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 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 including casualty estimation, agent-based epidemiological modeling and fusion of disease surveillance data. FY 2012 Accomplishments: Continued effort on biosurveillance data stream evaluation and analysis. Initiated effort to devise structured expansion roadmap for agent-based epidemiological models for Outside Contiguous United States (OCONUS). Initiated research on agent-based modeling platforms and policy assessment. In FY13, all research in this area was re-aligned into Techbase Med Bio - Diagnostics (TM2).		3.154	0.000
Title: 8) Information Systems Technology NTA Description: Modeling & Simulation for Non-Traditional Agents (NTA): Provide modeling of NTA materials for hazard prediction. Develop NTA source term algorithms for predicting CBRN hazards from intentionally functioning weapons, counter-proliferation scenarios (bomb on target), and missile intercept. "Intentionally Functioning Weapons" refers to the case where a missile has released its chemical or biological payload as it was designed, rather than where the release was caused by missile interdiction. Investigate NTA agent fate for secondary effects, environmental/atmospheric chemistry, atmospheric and waterborne transport and dispersion, human effects, model validation and verification (V&V), scaled testing, casualty estimation, and supporting data management. FY 2012 Accomplishments: Established initial methodologies of defining NTA source terms for relevant scenarios. Began establishment of a classified database for linking NTA types to weapon system types for NTA source term modeling to be incorporated into the acquisition		2.003	0.000

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013	FY 2014
program of record (Joint Effects Model (JEM)). Expanded material file collection to include those NTAs on which there is sufficient initial data. Created initial priority list of remaining agents with data gaps. Initiated the establishment of capabilities for data collection on NTA data gaps. Initiated planning and implementation of small scale testing for NTA simulants for use in creating and verifying NTA modeling source terms, for defense against CBRN hazards. In FY13, all research in this area was re-aligned into Techbase Non-Traditional Agents Defense Non-Medical(Applied Research) (NT2).				
Title: 9) Protection & Hazard Mitigation 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 2012 Accomplishments: Completed Innovative Systems Concepts and Analysis projects from FY10.		0.475	0.000	0.000
Title: 10) Protection & Hazard Mitigation Description: Lightweight Integrated Fabric: Development of lightweight chemical and biological protective textiles that can be used as an integrated combat duty uniform. FY 2012 Accomplishments: Continued development work, fabrication, and testing of prototype integrated fabrics to determine protection, mechanical properties, and comfort characteristics (such as heat and water vapor transfer properties). Continued use of computational methods to assess and refine prototypes. Developed improved thermal modeling simulations. Developed and scaled an advanced adsorbent nanofiber/textile production technology and/or a "smart material" technology for possible transition to a Uniform Integrated Protective Ensemble (UIPE) program. Continued development of ensemble design conceptual work based on the lessons gathered in the human performance projects for transition to Joint Service Lightweight Integrated Suit Technology (JSLIST). In FY13, all research in this area was re-aligned into Techbase Non-Med Defense - Physical Science Applied Research (PSAR) (CB2).		2.553	0.000	0.000
Title: 11) Protection & Hazard Mitigation Description: Low-Resistance, Low-Profile Filtration: Development and integration 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 (TIC). FY 2012 Accomplishments: Continued development of low resistance/profile filtration. Continued effort to develop the next generation novel filtration media for individual protection from CB agents and TICs (NTAs are addressed in Protection & Hazard Mitigation NTA) and transitioned		5.380	0.000	0.000

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013	FY 2014
these media technologies to the Joint Service General Purpose Mask (JSGPM) and Joint Service Aircrew Mask (JSAM) programs. Integrated metal-organic frameworks and other novel adsorbent into "system" prototypes. Integrated nanofiber high-efficiency particulate air (HEPA) filters into system prototypes. Continued reactive hybrid approaches for individual protection filtration and evaluate performance. In FY13, all research in this area was re-aligned into Techbase Non-Med Defense - Physical Science Applied Research (PSAR) (CB2).				
Title: 12) Protection & Hazard Mitigation Description: Human Performance Prediction and Assessment: Analysis and modeling of human performance in chemical and biological protective ensembles in order to determine design priorities and trade-offs. FY 2012 Accomplishments: Finalized development of human performance prediction and assessment by investigating the interactive effects of competing burdens on human cognitive performance. Studies were conducted to quantify the cumulative effects of the two primary factors researched to date: thermal burden (via moisture vapor transport rate) and breathing resistance. Transitioned data on Human Performance Assessment that will allow the prediction and design of individual protective gear. Project was discontinued in FY13 due to availability of funding		0.667	0.000	0.000
Title: 13) Protection & Hazard Mitigation Description: Low-Burden Air Purifying Respirator: Development and analysis 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 Accomplishments: Continued development of a low-burden air purifying respirator. Advanced concept CBRN technologies were 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. Various levels of comfort versus protection were integrated into prototype helmets. Work was focused on revolutionary, innovative design concepts (such as a dual-cavity respirator) in the final design in order to support decisions to initiate future helmet/mask developmental programs. In FY13, all research in this area was re-aligned into Techbase Non-Med Defense - Physical Science Applied Research (PSAR) (CB2).		3.515	0.000	0.000
Title: 14) Protection & Hazard Mitigation		1.331	0.000	0.000

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2012	FY 2013	FY 2014
Description: Logistically Sustainable Air Purification for Collective Protection: Development 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 Accomplishments: Completed development of reactive membrane and regenerative post treatment media technologies for applications in building protection and vehicular/platform systems. In FY13, all research in this area was suspended at the end of FY12.					
Title: 15) Protection & Hazard Mitigation Description: General Purpose Formulations for Decontamination: Development and improvement of chemical and biological decontamination formulations that are compatible with the current family of decontamination systems. FY 2012 Accomplishments: Continued focused enzymatic decontamination development. Completed study and transitioned data on agent fate of contaminated human remains and also transitioned the Human Remains Decontamination System program. In FY13, all research in this decontamination area was consolidated into the "Decontamination Family-of-Systems" effort, and placed in the Techbase Non-Med Defense - Physical Science Applied Research (PSAR) (CB2).			2.151	0.000	0.000
Title: 16) Protection & Hazard Mitigation Description: Decontamination Family-of-Systems (DFoS): Development and analysis of non-traditional decontamination technologies and approaches which gain significantly improved effectiveness by complementary application. FY 2012 Accomplishments: Transitioned mature DFoS technologies including reactive coatings. Continued the optimization of decontamination applicators. Continued investigation of microwave interaction with coating embedded particles and functionalities for directed energy decontamination. Coatings efforts also examined durable and temporary coatings that pursue reactive and barrier options. Continued studies on effect of delivery and application methods on decontamination efficacy on complex surfaces. In FY13, all research in this area was re-aligned into Techbase Non-Med Defense - Physical Science Applied Research (PSAR) (CB2).			6.791	0.000	0.000
Title: 17) Protection & Hazard Mitigation Description: Smart Hazard Mitigation: Development of decontamination technologies that sense, respond (decontaminate) and signal in the presence of chemical and biological contamination. FY 2012 Accomplishments:			2.035	0.000	0.000

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2012	FY 2013	FY 2014
Continued development of molecular switches that respond and react to the presence of CB agents and signal results. Continued development of rotaxane chemistry as artificial tunable G and V receptors that sense and react to chemical and biological agents. Conducted comparative analysis/technology readiness assessment of smart system candidate technologies to select candidates for further development. In FY13, all research in this area was terminated due to limited resources and was used to inform "Decontamination Family-of-Systems" in Techbase Non-Med Defense - Physical Science Applied Research (PSAR) (CB2).					
Title: 18) Protection and Hazard Mitigation NTA Description: NTA Air Purification: Study and assessment of filter technologies. FY 2012 Accomplishments: Continued development and testing of novel materials to improve performance against NTAs. Materials explored included crystalline nano-porous framework materials, catalytic, nano-fibrous, and composite materials. In FY13, all research in this area was re-aligned into Techbase Non-Traditional Agents Defense Non-Medical (Applied Research) (NT2).			1.158	0.000	0.000
Title: 19) Protection & Hazard Mitigation NTA Description: NTA Percutaneous Protection: Study and assessment of protective technologies. FY 2012 Accomplishments: Continued development of technologies to improve overall protective clothing performance against NTAs. Performed component and system modeling, in order to: (1) evaluate and utilize aerosol-based closure testing; and (2) model aerosol transport within individual protective equipment ensembles. Designed and tested novel closures in accordance with modeling results/predictions. Fabricated prototype systems and then tested/measured their aerosol performance. In FY13, all research in this area was re-aligned into Techbase Non-Traditional Agents Defense Non-Medical (Applied Research) (NT2).			2.501	0.000	0.000
Title: 20) Protection & Hazard Mitigation NTA Description: NTA Decontamination: Study and assessment of decontamination technologies. FY 2012 Accomplishments: Continued development of decontamination technologies against NTAs. Continued to develop decontamination technologies and formulations that are optimized against NTAs. Continued development and test decontamination formulations and system-of-systems approaches that improve performance against NTAs and manage process residuals, including effluent control. Continued development of durable and temporary, reactive and barrier coatings to mitigate NTA contamination. In FY13, all research in this area is re-aligned into Techbase Non-Traditional Agents Defense Non-Medical (Applied Research) (NT2).			2.302	0.000	0.000
Title: 21) Physical Science Applied Research (PSAR)			0.000	10.796	10.508

PE 0602384BP: *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)*

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Biological Defense Program			DATE: April 2013		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>		R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>		PROJECT CB2: <i>CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2012	FY 2013	FY 2014
Description: Chemical and Biological Point Detection Technology: Emphasis on the detection and identification of chemical and biological threats. Objectives include the development of nanoscale detector for sensing of chemical and biological agents, design for prototype whole pathogen genome sequencing system, and development of a portable point detector for chemical warfare (CW) detection in potable water. FY 2013 Plans: Complete concept development of nano-scale biological agent identification and sensing technologies. Complete feasibility studies of nanoscale detection systems. Continue integration studies for Next Generation Chemical Detection (NGCD) based on Microelectromechanical System (MEMS) components for gas chromatography (GC) and mass spectrometry (MS). Complete development of breadboard prototype for complete sequencing entire pathogen genomes with automated sample preparation which also applies to biosurveillance. Continue algorithm development to increase range capabilities, reduce false positives, and provide decision capabilities for large data sets. Funding for this research area was re-aligned from Tech Base Non-Med - Detection (CB2). FY 2014 Plans: Continue integration studies for NGCD based on MEMS components for GC and MS. Continue algorithm development to increase range capabilities, reduce false positives, and provide decision capabilities for large data sets.					
Title: 22) Physical Science Applied Research (PSAR) Description: Threat Agent Science: Supports defensive countermeasure development against current and new threats by delivering the scientific understanding and relevant estimates of the hazards posed to humans by exposure to chemical or biological agents. Toxicological and/or infectious-dose information and environmental response supports development and/or enhancing both operational risk and exposure guidelines; limits for detection and protection; goals for decontamination; and medical countermeasures. Funding for this research was re-aligned from Tech Base Non-Med - Threat Agent Science (CB2). FY 2013 Plans: Develop a systems approach to toxicological understanding of physiological injury by threat agents. Determine infectious dose of biological agents of interest and potential emergent threats from reservoir hosts or other technological breakthroughs such as Do-it-Yourself (DIY) biology. DIY biology is a growing movement in which individuals or sometimes small informal organizations, change the genetics of life forms using small resources and often with little or no formal training, oversight by professionals, or regulation by governments. Continue investigations that describe fundamental mechanisms that contribute to BWA persistence and transport. Define particle properties and predict aerosolization behavior to inform hazard assessment. Study emerging technological breakthroughs such as DIY biology that may impact novel threat emergence. Study agent modulation in natural or			0.000	2.469	1.196

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013	FY 2014
laboratory environments to inform forensic examination of threats. Funding for this research area was re-aligned from Tech Base Non-Med - Threat Agent Science (CB2).				
FY 2014 Plans: Continue investigations that describe fundamental mechanisms that contribute to BWA persistence and transport in the environment. Define particle properties and predict aerosolization behavior to inform hazard assessment. Study biological modulation in natural or laboratory environments through genetic drift to inform forensic examination of threats.				
Title: 23) Physical Science Applied Research (PSAR) Description: Hazard Prediction: 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 CB agents or industrial materials from CB or accidents.		0.000	1.983	2.974
FY 2013 Plans: Complete development of a waterborne transport tool investigation of transport methods for biological agents and other materials. Initiate development of waterborne inverse species transport module based on feasibility study results. Funding for this research area was re-aligned from Tech Base Non-Med - Modeling & Simulation (CB2). In FY14, the Virtual Testing and Evaluation testbed being developed in the Warning & Reporting area will now be consolidated under this Hazard Prediction.				
FY 2014 Plans: Continue development of waterborne inverse species transport modeling capability in conjunction with completion of the validation and verification effort for waterborne transport models. Initiate final work on advancing the urban modeling capability and optimizing the urban sub-system for interfacing transport models of varying fidelity and speed. Continue development of a generalized Virtual Testing and Evaluation testbed for evaluating/stressing source characterization and hazard refinement techniques, under a wide range of operational conditions.				
Title: 24) Physical Science Applied Research (PSAR) Description: Operational Effects & Planning: 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.		0.000	2.371	2.863
FY 2013 Plans: Continue studies on social/cultural norms for application in agent based models. Continue study of social reaction to disease and disease mitigation strategies to support biosurveillance. Continue development of human cognitive models that incorporate the effects of chemical biological agent interaction with other battle stressors to facilitate operational decision making. Initiate special population analysis to model emerging disease and the effects of targeted countermeasures. Continue operational				

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APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 2: Applied Research	R-1 ITEM NOMENCLATURE PE 0602384BP: CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	PROJECT CB2: CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013	FY 2014
effects research and analysis efforts. Funding for this research area was re-aligned from Tech Base Non-Med - Modeling & Simulation (CB2). In FY14 all biosurveillance work in TBNM PSAR/CB2 will be consolidated under the Biosurveillance (BSV)/ Disease Surveillance area. In addition, in FY14 System Performance Models being developed in the Data Analysis area will be consolidated into this Operational Effects & Planning area. FY 2014 Plans: Continue operational effects research and analysis efforts to provide the CBDP with objective, quantitative analysis in support of science and technology initiatives, material developments, operational guidance, and requirements setting. Continue system performance model integration and advanced development for program-wide exploitation.				
Title: 25) Physical Science Applied Research (PSAR) Description: Data Analysis: Develop CBRN data sharing capabilities and simulation tools. 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. Conclude development of initial versions of systems performance models in collective protection, individual protection, contamination avoidance and decontamination. Initiate system performance model integration and advanced development for program-wide exploitation. Funding for this research area was re-aligned from Tech Base Non-Med - Modeling & Simulation (CB2). In FY14 all Systems Performance Model development will be consolidated under the Operational Effects & Planning area. In addition, in FY14 the time-varying toxic industrial studies will be consolidated under this Data Analysis area. FY 2014 Plans: Develop additional chapters 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. Complete study on animal and human effects from time-varying toxic industrial chemical concentration exposures		0.000	1.490	1.451
Title: 26) Physical Science Applied Research (PSAR) Description: Warning and Reporting Information & 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 2013 Plans: Initiate study on animal and human effects from time-varying toxic industrial chemical concentration exposures. Initiate development of a generalized Virtual Testing and Evaluation testbed for evaluating/stressing source characterization and hazard refinement techniques, under a wide range of operational conditions. Initiate interior building transport and dispersion		0.000	2.333	0.000

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013	FY 2014
modeling effort to improve modeling of indoor-to-outdoor dispersion and to enhance the indoor modeling capabilities of advanced development programs. Continue study on integration of biosurveillance data with disease spread models to enable early warning and reporting capabilities, performing R&D to improve performance of novel data assimilation algorithm used to integrate global biosurveillance data. Funding for this research area was re-aligned from Tech Base Non-Med - Modeling & Simulation (CB2). In FY14, development previously supported by this area will be moved into the Operational Effects & Planning and Hazard Prediction areas.				
Title: 27) Physical Science Applied Research (PSAR) Description: Protection & Hazard Mitigation - Lightweight Integrated Fabric: Development of lightweight chemical and biological protective textiles that can be used as an integrated combat duty uniform. FY 2013 Plans: Complete initial development work, fabrication, and testing of prototype integrated fabrics to determine protection, mechanical properties, and comfort characteristics (such as heat and water vapor transfer properties). Continue use of computational methods to assess and refine future prototypes. Continue improved thermal modeling simulations. Continue to develop new low burden fabrics and ensemble designs to support the Uniform Integrated Protection Ensemble/Joint Service Lightweight Integrated Suit Technology (UIPE/JSLIST) programs. Continue with development areas that include: evaluation of superoleophobic materials, refinement of "man in simulant test" sensors, continuation of aerosol system testing, advanced adsorbent nanofiber/textile production technology, and smart materials. FY13 funding for this research area was re-aligned from Tech Base Non-Med protection and Hazard Mitigation (CB2). FY 2014 Plans: Continue to develop new low burden fabrics and ensemble designs to support the UIPE/JSLIST programs with a focus on whole system assessments. Continue with development areas that include: evaluation of superoleophobic materials, refinement of "man in simulant test" sensors, continuation of aerosol system testing, advanced adsorbent nanofiber/textile production technology, and smart materials. Continue exploring multifunctional material design and synthesis to identify dynamic materials that integrate functionality and durability to improve CB protection by increasing protection factors and reducing physical burden. Continue exploring integration of functionality that may provide adaptive materials and capabilities for CB defense countermeasures that sense, transduce, respond and mitigate threats.		0.000	5.225	6.319
Title: 28) Physical Science Applied Research (PSAR) Description: Protection & Hazard Mitigation - Low-Resistance, Low-Profile Filtration: Development and integration 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 (TICs).		0.000	5.211	3.594

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2012	FY 2013	FY 2014
FY 2013 Plans: Continue development of next generation filtration technology. Continue focus on low resistance/low profile novel filter media with augmented performance against TICs and chemical agents. Continue to replace legacy filter media with novel media that offers broad spectrum protection. Continue with technology areas to include: metal organic frameworks, novel adsorbents and reactive hybrids. Funding for this research area was re-aligned from Tech Base Non-Med - Protection and Hazard Mitigation (CB2).					
FY 2014 Plans: Continue development of next generation filtration technology. Continue focus on low resistance/low profile novel filter media with augmented performance against TICs and chemical agents. Continue to replace legacy filter media with novel media that offers broad spectrum protection. Continue with technology areas to include: metal organic frameworks, novel adsorbents and reactive hybrids and transition these technologies to the Joint Service General Purpose Mask (JSGPM) and Joint Service Aircrew Mask (JSAM) programs.					
Title: 29) Physical Science Applied Research (PSAR) Description: Protection & Hazard Mitigation - Low-Burden Air Purifying Respirator: Development and analysis of design alternatives for chemical and biological air-purifying respirators to provide enhanced protection with lower physiological burden and improved interface with mission equipment.			0.000	3.237	2.111
FY 2013 Plans: Continue development of next generation low burden respirator technology. Develop and integrate novel seal, anti-fogging, and dual cavity technologies. Develop and verify methods for a Respiratory Battlefield Evaluation System (RBEs). Funding for this research area was re-aligned from Tech Base Non-Med - Protection and Hazard Mitigation (CB2).					
FY 2014 Plans: Continue development of next generation low burden respirator technology. Develop and integrate novel seal, anti-fogging, and dual cavity technologies. Develop and verify methods for RBEs. Develop a scalable respirator technology to quickly configure to different protective capabilities from air purifying respirator (APR) to self-contained breathing apparatus (SCBA).					
Title: 30) Physical Science Applied Research (PSAR) Description: Protection & Hazard Mitigation - Decontamination Family-of-Systems (DFoS): Development and analysis of non-traditional decontamination technologies and approaches which gain significantly improved effectiveness by complementary application.			0.000	9.216	11.676
FY 2013 Plans:					

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2012	FY 2013	FY 2014
Continue the development of new formulations adjusted for agent, material substrate, and environment; combine with optimized application systems and initiate additional efforts based on the results of the dial-a-decon analysis of alternatives. Continue coatings efforts to examine durable and temporary coatings that pursue reactive and barrier options and initiate efforts based on the results of the coatings analysis of alternatives. Continue development of delivery and application methods on decontamination efficacy on complex surfaces. Continue to develop decontamination assurance sprays for biological agents and other agents of interest. Continue development of enzymes for sensitive equipment/platform decon (previously under General Purpose Formulations in FY12). Initiate radiological/nuclear decontamination/hazard mitigation effort. Funding for this research area was re-aligned from Tech Base Non-Med - Protection and Hazard Mitigation(CB2).					
FY 2014 Plans: Continue the development of new formulations adjusted for agent, material substrate, and environment; combine with optimized application systems and initiate additional efforts based on the results of the dial-a-decon analysis of alternatives. Continue coatings efforts to examine durable and temporary coatings that pursue reactive and barrier options and initiate efforts based on the results of the coatings analysis of alternatives. Continue development of delivery and application methods on decontamination efficacy on complex surfaces. Continue to develop decontamination assurance sprays for biological agents and other agents of interest. Continue development of enzymes for sensitive equipment/platform decon (previously under General Purpose Formulations in FY12). Initiate radiological/nuclear decontamination/hazard mitigation effort. Investigate technologies to decontaminate spores over a wide area, approaches include looking at germinants paired lytic enzymes, directed energy, and predatory nematodes. Demonstrate the ability of technologies to decontaminate spores in complex, dirty environments.					
Title: 31) Physical Science Applied Research			0.000	0.000	11.209
Description: Biosurveillance (BSV)/Disease Surveillance: Integrate existing disparate military and civilian datasets, investigate methodologies to appropriately integrate open source data into advanced warning systems, and leverage and enhance advanced 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 2014 Plans: Continue efforts in FY13 from Diagnostics and Disease Surveillance (TM2 Bio). Complete effort on biosurveillance data stream evaluation and analysis to identify most useful biosurveillance data streams for prediction and early warning and leverage this research for BSV Ecosystem effort. Complete effort to devise structured outside continental U.S. (OCONUS) expansion roadmap for agent-based epidemiological models and continue to increase OCONUS analytic capability through targeted areas. Leverage this research for BSV Ecosystem effort. Advance research into data integration platforms through the BSV Ecosystem effort. Develop approaches for unique and emerging data collection, aggregation and provision of human, vector and animal/zoonotic					

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013
health surveillance data. Develop algorithms, verification, and validation for these data feeds to synthesize and interrogate multiple sources of data to provide high confidence in the prediction, early warning and forecasting (inclusive of mitigation strategies) of infectious disease outbreaks. Leverage biosurveillance and point of need diagnostic efforts to support in-context, rapid detection, identification and response capabilities on the global scale through integrated access via the BSV Ecosystem. Funding for this research area was re-aligned from Tech Base Med Bio - Diagnostics (TM2).			
Title: 32) Threat Agent Science Description: Physiological Response: Delivers the scientific understanding and relevant estimates of the hazards posed to humans by exposure to chemical or biological agents. Toxicological and/or infectious-dose information supports developing and/or enhancing both operational risk and exposure guidelines; limits for detection and protection; goals for decontamination; and medical countermeasures. FY 2012 Accomplishments: Improved understanding of bioavailability following dermal exposures for chemical agents, as well as studied in vitro and in vivo binding of agents and analogues.		1.497	0.000
Title: 33) Threat Agent Science Description: Agent Characterization: Examines critical characteristics of chemical and biological warfare agents (CWAs and BWAs), beginning with physiochemical properties and subsequently determining the challenge levels to military personnel in operationally relevant environments that provides key information to development or improvement of both physical and medical countermeasures and decision support tools. Research focuses on: characterizing the realistic threat posed by CWA and BWA aerosol and particulate agent dissemination; examining the fundamental mechanisms that contribute to BWAs persistence and transport; understanding the fundamental interactions between CWA and BWA agents and substrates; investigating aqueous transport of CWA and BWA agents and the underlying mechanisms of binding CB agents onto hydrated surfaces; and identifying agent decomposition products harmful to military personnel. In FY12, this area included research formerly performed under Agent Fate. FY 2012 Accomplishments: Expanded investigations of fundamental mechanisms that contribute to BWA persistence and transport; transfer information from previous studies to operational models. Identified markers of cultured versus naturally occurring agents, as well as markers of persistence of biological agents. Continued to support test and evaluation needs for both CWA and BWA simulants. Characterized environmental factors affecting persistence and binding to environmental elements such as soil. Advanced the understanding of fundamental interactions between agents and substrates in order to improve predictive modeling supporting		2.672	0.000

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B. Accomplishments/Planned Programs (\$ in Millions)									FY 2012	FY 2013	FY 2014
other capability areas, such as detection and hazard mitigation. In FY13, all research in this area was re-aligned to CB2 Physical Sciences Applied Research (PSAR).											
Title: 34) Threat Agent Science NTA									21.704	0.000	0.000
Description: Threat Agent Science NTA: Provides enabling science and technology which informs development and testing of NTA defense technology such as detection, decontamination, protection, hazard assessment, and more. This preliminary assessment provides the basis for all countermeasure development and assessment.											
FY 2012 Accomplishments: Continued efforts from FY11, working through the list of priority agents. Provided necessary operational and residual contact hazards as well as aerosol and percutaneous toxicity standards for NTAs. Delivered prioritized fundamental analysis, including physicochemical properties such as volatility, solubility, mass transport, reactivity, stability and other factors. Examined physical parameters governing NTA stability on operational materials. In FY13, all NTA-dedicated Research was re-aligned to Non-Medical Techbase Non-Traditional Agents Defense Non-Medical(Applied Research) (NT2).											
Accomplishments/Planned Programs Subtotals									97.530	44.331	53.901
C. Other Program Funding Summary (\$ in Millions)											
Line Item	FY 2012	FY 2013	FY 2014 Base	FY 2014 OCO	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
• CB3: CHEMICAL BIOLOGICAL DEFENSE (ATD)	23.838	20.034	18.091		18.091	19.224	18.348	20.621	19.960	Continuing	Continuing
Remarks											
D. Acquisition Strategy											
N/A											
E. Performance Metrics											
N/A											

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COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 [#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
NT2: TECHBASE NON-TRADITIONAL AGENTS DEFENSE (APPLIED RESEARCH)	-	0.000	60.730	75.053	-	75.053	71.749	72.932	77.542	77.805	Continuing	Continuing
# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012												
## The FY 2014 OCO Request will be submitted at a later date												
A. Mission Description and Budget Item Justification												
This project (NT2) provides early applied research to enhance and develop defensive capabilities against Non-Traditional Agents (NTAs). This project focuses on expanding scientific knowledge required to develop defensive capabilities and to demonstrate fast and agile scientific responses to enhance or develop capabilities that address emerging threats. Efforts in this project support an integrated approach to counter emerging threats through innovative science and technology (S&T) solutions for detection, protection, decontamination, and medical countermeasures. 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.												
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2012	FY 2013	FY 2014	
Title: 1) Techbase Medical Defense - NTA									0.000	3.371	6.992	
Description: Chemical Medical Pretreatments NTA: Develops 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.												
FY 2013 Plans:												
Chemical Medical Pretreatments NTA: Develops pretreatments that provide protection against non-traditional agents. Products should have the ability to rapidly bind and detoxify nerve agents, and have broad binding specificity and high catalytic efficiency.												
FY 2014 Plans:												
Continue studies to determine efficacy of catalytic bioscavenger for NTA exposure. Pursue development of small molecule pretreatments against NTA exposure.												
Title: 2) Techbase Medical Defense - NTA									0.000	13.050	18.618	
Description: Chemical Medical Therapeutics NTA: Investigates common mechanisms of agent injury. Determines the toxic effects of agents by probable routes of field exposure, as well as standard experimental routes. Physiological parameters												

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2012	FY 2013	FY 2014
and pathological assessment will be used to establish the general mode and mechanism(s) of toxicity. Develops, assesses, evaluates, and validates therapeutics for treatment resulting from exposure to Non-Traditional Agents (NTA).					
FY 2013 Plans: Continue efforts originating in FY12 in Chemical Therapeutics NTA (TC2 NTA). Initiate investigation of other compounds of interest including mechanism of action and toxicity, and initiate search for effective countermeasures. Funding for this research area was re-aligned from Tech Base Med Defense - Med Chem Therapeutics NTA (TC2).					
FY 2014 Plans: Continue investigation of advanced and emerging threats including mechanism of action and toxicity, and continue search for effective countermeasures. Develop centrally active novel therapeutic compounds that cross the blood brain barrier. Screen currently licensed Food and Drug Administration (FDA) approved countermeasures to determine potential efficacy against other classes of NTAs. Pursue absorption, distribution, metabolism and excretion studies to further elucidate agent effects.					
Title: 3) Techbase Medical Defense - NTA			0.000	0.386	2.344
Description: Chemical Medical Diagnostics NTA: Focuses on developing state-of-the-art laboratory/fieldable methods to detect exposure to non-traditional agents in clinical samples. Identifies 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. Non-NTA Chem Diagnostics support the analytics for traditional agent diagnostics and hand-held diagnostic technologies that might be applied to NTA diagnostics.					
FY 2013 Plans: Continue to identify biomarkers to create an enhanced capability to pre-symptomatically diagnose NTA exposure. Continue method development for identification and validation of NTAs in clinical samples for additional compounds of interest. Funding for this research area was re-aligned from Tech Base Med Defense - Med Chem Diagnostics NTA (TC2).					
FY 2014 Plans: Continue to identify biomarkers to create an enhanced capability to pre-symptomatically diagnose NTA exposure. Continue method development for identification and validation of NTAs in clinical samples for additional compounds of interest.					
Title: 4) Techbase Non-Med NTA			0.000	11.580	15.686
Description: Detection NTA: Primary focus is to assess the potential of optical technologies to meet the needs to detect the presence of NTAs.					
FY 2013 Plans:					

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APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 2: Applied Research	R-1 ITEM NOMENCLATURE PE 0602384BP: CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	PROJECT NT2: TECHBASE NON-TRADITIONAL AGENTS DEFENSE (APPLIED RESEARCH)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013	FY 2014
Complete and demonstrate feasibility development of plant sentinel concept. Continue development from technology concepts and models to meet the needs to detect contamination on surfaces in pre- and post-decontamination application. Continue integration studies for chemical aerosol detection into the Next Generation Chemical Detection (NGCD). Funding for this research area was re-aligned from Tech Base Non-Med Defense - Detection NTA (CB2). FY 2014 Plans: Continue development from technology concepts and models to meet the needs to detect contamination on surfaces in pre and post decontamination application. Continue integration studies for chemical aerosol detection into the NGCD.				
Title: 5) Techbase Non-Med NTA Description: Threat Agent Science NTA: Provide enabling science and technology on threat agents to prepare for surprise which informs development and testing of NTA defense technology such as detection, decontamination, protection, hazard assessment, and more. This preliminary assessment of new threats provides the basis for all countermeasure development and assessment. FY 2013 Plans: Expand assessment of novel threats into new classes of agents providing operationally relevant exposure limits using an integrated systems toxicology approach. Define critical physical/chemical properties and characterize/predict agent reactivity and interaction with environmental substrates. Provide supportable data to enable countermeasure development and testing as well as inform concept of operations policy, doctrine and procedure. Funding for this research area was re-aligned from Tech Base Non-Med Defense - Threat Agent Science NTA (CB2). FY 2014 Plans: Continue assessment of priority classes of novel threat agents providing operationally relevant exposure limits using an integrated systems toxicology approach. Define critical physical/chemical properties and characterize/predict agent reactivity and interaction with environmental substrates. Provide supportable knowledge, enabling countermeasure development and testing and informing concept of operations policy, doctrine and procedure. Move towards in-silico efforts to characterize threat agents.		0.000	26.261	25.297
Title: 6) Techbase Non-Med NTA Description: Modeling & Simulation NTA: Provide modeling of NTA materials for hazard prediction. Develop NTA source term algorithms for predicting CBRN hazards from intentionally functioning weapons, counter-proliferation scenarios (bomb on target), and missile intercept. "Intentionally Functioning Weapons" refers to the case where a missile has released its chemical or biological payload as it was designed, rather than where the release was caused by our missile interdiction. Investigate NTA agent fate for secondary effects, environmental/atmospheric chemistry, atmospheric and waterborne transport and dispersion, human effects, model Validation and Verification (V&V), scaled testing, casualty estimation, and supporting data management.		0.000	1.464	1.369

PE 0602384BP: *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)*

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Biological Defense Program		DATE: April 2013		
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 2: Applied Research		R-1 ITEM NOMENCLATURE PE 0602384BP: CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)		PROJECT NT2: TECHBASE NON-TRADITIONAL AGENTS DEFENSE (APPLIED RESEARCH)
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013	FY 2014
FY 2013 Plans: Continue with actual experimentation involving small scale testing for NTA simulants for use in creating and verifying NTA modeling source terms, for defense against CBRN hazards. Continue to develop NTA source term models. Funding for this research area was re-aligned from Tech Base Non-Med Defense - Modeling & Simulation NTA (CB2).				
FY 2014 Plans: Complete experimentation phase of small scale testing for NTA simulants for use in creating and verifying NTA modeling source terms, for defense against CBRN hazards. Continue to develop new NTA source term scenario models and flexible scenario NTA source models.				
Title: 7) Techbase Non-Med NTA Description: Protection and Hazard Mitigation NTA - Air Purification: Study and assessment of filter technologies.		0.000	1.262	1.290
FY 2013 Plans: Continue development and testing of novel materials to improve performance against NTAs. Replace legacy filter media with novel media that offers broad spectrum NTA protection. Continue with technology areas that include: crystalline nano-porous framework materials, novel adsorbents, catalytic, nano-fibrous, composite materials and reactive hybrids. Transition these technologies to the Joint Service General Purpose Mask (JSGPM) and Joint Service Aircrew Mask (JSAM) programs. Funding for this research area was re-aligned from Tech Base Non-Med Defense - Protection & Hazard Mitigation NTA (CB2).				
FY 2014 Plans: Continue development and testing of novel materials to improve performance against NTAs. Replace legacy filter media with novel media that offers broad spectrum NTA protection. Continue with technology areas that include: crystalline nano-porous framework materials, novel adsorbents, catalytic, nano-fibrous, composite materials and reactive hybrids. Transition these technologies to the Joint Service General Purpose Mask (JSGPM) and Joint Service Aircrew Mask (JSAM) programs.				
Title: 8) Techbase Non-Med NTA Description: Protection & Hazard Mitigation NTA - Percutaneous Protection: Study and assessment of protective technologies.		0.000	2.084	2.000
FY 2013 Plans: Continue development of low burden technologies to improve overall protective clothing performance against NTAs leading toward verification, demonstration and transition. Funding for this research area was re-aligned from Tech Base Non-Med Defense - Protection & Hazard Mitigation NTA (CB2).				
FY 2014 Plans:				

PE 0602384BP: *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)*

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Biological Defense Program									DATE: April 2013		
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 2: Applied Research				R-1 ITEM NOMENCLATURE PE 0602384BP: CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)				PROJECT NT2: TECHBASE NON-TRADITIONAL AGENTS DEFENSE (APPLIED RESEARCH)			
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2012	FY 2013	FY 2014
Continue development of low burden technologies to improve overall protective clothing performance against NTAs leading toward verification, demonstration and transition.											
Title: 9) Techbase Non-Med NTA Description: Protection & Hazard Mitigation NTA - Decontamination: Study and assessment of decontamination technologies. FY 2013 Plans: Continue development of decontamination technologies against NTAs. Continue to develop decontamination technologies and formulations that are optimized against NTAs. Continue to develop, demonstrate, and transition enzyme technology for low-impact decon of NTAs. Continue to integrate with the Decontamination Family-of-Systems effort. Funding for this research area was re-aligned from Tech Base Non-Med Defense - Protection & Hazard Mitigation NTA (CB2). FY 2014 Plans: Continue development of decontamination technologies against NTAs. Continue to develop decontamination technologies and formulations that are optimized against NTAs. Continue to develop, demonstrate, and transition enzyme technology for low-impact decon of NTAs. Continue to integrate with the Decontamination Family-of-Systems effort.									0.000	1.272	1.081
Title: 10) Techbase Non-Med NTA Description: Protection & Hazard Mitigation NTA - Low-Burden Air Purifying Respirator: Development and analysis of design alternatives for chemical and biological air purifying respirators to provide enhanced protection against NTAs with lower physical burden and improved interface with mission equipment. FY 2014 Plans: Develop and integrate novel seal, anti-fogging, and dual cavity technologies to protect against NTAs.									0.000	0.000	0.375
Accomplishments/Planned Programs Subtotals									0.000	60.730	75.053
C. Other Program Funding Summary (\$ in Millions)											
Line Item	FY 2012	FY 2013	FY 2014 Base	FY 2014 OCO	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
• NT3: TECHBASE NON-TRADITIONAL AGENTS DEFENSE (ATD)	0.000	31.916	23.333		23.333	29.248	30.727	37.728	40.975	Continuing	Continuing
Remarks											

PE 0602384BP: *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)*

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Biological Defense Program		DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>	R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	PROJECT NT2: <i>TECHBASE NON-TRADITIONAL AGENTS DEFENSE (APPLIED RESEARCH)</i>
<u>D. Acquisition Strategy</u> N/A		
<u>E. Performance Metrics</u> N/A		

PE 0602384BP: *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)*

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Biological Defense Program										DATE: April 2013		
APPROPRIATION/BUDGET ACTIVITY					R-1 ITEM NOMENCLATURE				PROJECT			
0400: Research, Development, Test & Evaluation, Defense-Wide BA 2: Applied Research					PE 0602384BP: CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)				TB2: MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)			
COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 [#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
TB2: MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)	-	87.849	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	87.849

[#] FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

^{##} The FY 2014 OCO Request will be submitted at a later date

A. Mission Description and Budget Item Justification

This project (TB2) funds applied research on vaccines, therapeutic drugs, and diagnostic capabilities to provide effective medical defense against validated biological threat agents or emerging infectious disease threats including bacteria, toxins, and viruses. Innovative biotechnology approaches will be incorporated to advance medical systems designed to rapidly identify, diagnose, prevent, and treat disease due to exposure to biological threat agents. Categories for this project include core science efforts in biological defense capability areas, such as Pretreatments, Diagnostics, and Therapeutics. Medical Science and Technology (S&T) efforts in this Budget Activity refine promising medical initiatives identified in Budget Activity 1, resulting in the development of countermeasures to protect against and treat the effects of exposure to biological agents.

This project includes the Transformational Medical Technologies Initiative (TMTI), (funded as the Transformational Medical Technologies (TMT) program in FY12). 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 biological threats by providing a rapid response capability from identification of pathogens to the delivery of medical countermeasures. This mission is accomplished through two main efforts: 1) developing broad spectrum (multi-agent) therapeutics against biological 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 biological agents (e.g. developing new and innovative ways to mass produce drugs in the event of a biological incident).

The Medical Countermeasures Initiative (MCMI) was established to coordinate inter-related advanced development and flexible manufacturing capabilities, based on partnerships 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 two areas: 1) advancement of regulatory science, and 2) advancements in flexible manufacturing technologies for MCMs.

In FY13, all Project TB2 research is re-aligned into Project TM2 - Techbase Medical Defense.

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

	FY 2012	FY 2013	FY 2014
Title: 1) Medical Countermeasures Initiative (MCMI)	11.985	0.000	0.000

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Biological Defense Program			DATE: April 2013		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>		R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>		PROJECT TB2: <i>MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2012	FY 2013	FY 2014
Description: Medical Countermeasures Initiative (MCMI): Coordinate inter-related advanced development and flexible manufacturing capabilities, based on partnerships between the government and industry, providing a dedicated, cost-effective, reliable, and sustainable MCM process that meets the needs of the Warfighter and national security. Specifically, the MCMI provides a capability for the advanced development and flexible manufacturing of biological MCM (including TMT developed MCMs) to address CBRN threats, including novel and previously unrecognized, naturally-occurring emergent infectious diseases. MCMI efforts within S&T are concentrated in advancing two areas: 1) regulatory science and 2) flexible manufacturing technologies for MCMs. FY 2012 Accomplishments: Conducted studies to explore increasing the efficiency, responsiveness, and speed of biopharmaceutical manufacturing through use of more flexible, non-traditional host-vector systems. Initiated and refined development of multi-product/multi-use platform technologies for flexible manufacturing processes for MCMs. Evaluated and exploited the regulatory advantages of such systems, with the intent that regulatory approval of the platform for one product will simplify subsequent approvals of other products based on the same system. In FY13, all research in this area was re-aligned into Techbase Med Defense - Medical Countermeasures Initiative (TM2).					
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 pathogens or toxins in clinical specimens from 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 2012 Accomplishments: Verified performance of informative genetic and affinity probes and optimized number of probes required to capture predictive signature coverage. Verified performance of pre-symptomatic diagnostic biomarker panels in blinded BWA and emerging threat pathogen-exposed animal samples. Developed pan-emerging threat agent genotyping assay for fieldable sequence-based genetic analyzer to supplement/replace strain-specific assays. In FY13, all research in this area was re-aligned into Techbase Med Defense - Diagnostics (TM2).			15.846	0.000	0.000
Title: 3) Pretreatments Description: Bacterial/Toxins Vaccines: Generate novel or improved vaccines against bacterial and toxin biothreat agents, and demonstrate preliminary efficacy in small animal models. Identify correlates of protective immunity in animal models.			5.505	0.000	0.000

PE 0602384BP: *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)*

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Biological Defense Program		DATE: April 2013	
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>	R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	PROJECT TB2: <i>MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013
<i>FY 2012 Accomplishments:</i> Identified correlates of immunity, elicited by Burkholderia species vaccine candidates, which predict vaccine efficacy. In a concurrent effort, opened investigative avenues in search of vaccine candidates directed against Burkholderia species. Continued efforts designed to examine the efficacy of adjuvants co-administered with existing vaccine candidates against Burkholderia species. Continued efforts to boost immune response to the currently licensed anthrax vaccine using novel adjuvants which might have applicability to other vaccine candidates in the future. Additionally, research continued to produce vaccine candidates designed to protect against emerging or genetically engineered anthrax strains. Examined the efficacy of rationally designed, next-generation Type A Francisella tularensis vaccine against aerosol challenge in rat and non-human primate models. Continued research designed to evaluate outer membrane proteins isolated from Type A Francisella tularensis as vaccine candidates against aerosol challenge with the pathogen in small and large animal models. In FY13, all research in this area was re-aligned to Techbase Med Defense - Bio CM (TM2).			
<i>Title:</i> 4) Pretreatments <i>Description:</i> Vaccine Platforms and Research Tools: Design novel multi-agent vaccine platforms capable of expressing multiple antigens, investigate the ability of non-specific stimulators of immunity to enhance the effectiveness of newly generated vaccines, characterize alternative vaccine delivery (needle-free) methods and novel vaccine stabilization methodologies, and conduct studies to further advance a laboratory-based, human artificial immune system to render it capable of predicting the human immune response to biodefense vaccines under development. <i>FY 2012 Accomplishments:</i> Continued development of new platform technologies that support the presentation of multiple antigens to the immune system. Developed relevant animal models for the evaluation of the immune response to multi-antigen platforms. Continued development of alternative methodologies for vaccine delivery (i.e., electroporation) via intra-muscular or intra-dermal administration. Continued to advance the surrogate human immune system, Modular Immune In Vitro Construct (MIMIC), which provides an in vitro assessment of the human immune response. Completed studies to assess the cross-reactivity of antigens present in different Filoviruses and Alphaviruses. Used MIMIC to define human correlates of immunity in responses to various bio-threat agents. Continued to develop methodologies which remove the need for cold storage and transport for vaccines and renders them stable in variable and extreme temperatures. In FY13, all research in this area was re-aligned to Techbase Med Defense - Bio CM (TM2).		5.667	0.000
<i>Title:</i> 5) Therapeutics <i>Description:</i> Viral Therapeutics: Identify, optimize and evaluate lead candidate therapeutics for efficacy against viral pathogens. <i>FY 2012 Accomplishments:</i>		2.040	0.000

PE 0602384BP: *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)*

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APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>	R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	PROJECT TB2: <i>MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013
Initiated efforts to evaluate and develop antibody-based therapeutics to treat Filovirus infections. Began and continued efforts to identify and evaluate novel broad-spectrum host and pathogen-directed small molecule therapeutics for Biothreat Viruses (i.e. Filovirus, Flavivirus, Arenavirus, Bunyavirus). Optimized therapeutic inhibitors of host and viral tyrosine phosphatases for Orthopoxvirus infection. In FY13 all research in this area was re-aligned to Techbase Med Defense-Bio CM (TM2).			
Title: 6) Therapeutics Description: Bacterial Therapeutics: Identify, optimize and evaluate lead therapeutic candidates effective against designated bacterial threat agents. FY 2012 Accomplishments: Expanded FDA approved drug screening program for Burkholderia, Francisella tularensis and determined in vitro susceptibilities. Continued evaluation of novel compounds against bacterial biological warfare agents. Optimized lead series of MurB compounds targeting cell wall biosynthesis. Determined synergy between MurB antibacterial agents and conventional antibiotics against B. anthracis and Y. pestis. Identified and validated compounds that inhibit bacterial SOS induction thereby potentiating the effects of FDA approved drugs. Selected a second FDA approved drug to focus on for Burkholderia and F. Tularensis. In FY13, all research in this area was re-aligned to Techbase Med Defense-Bio CM (TM2).		6.789	0.000
Title: 7) Therapeutics Description: Toxin Therapeutics: Identify, optimize and evaluate therapeutic candidates that are effective against biological toxin agents. FY 2012 Accomplishments: Validated host proteins responsible for BoNT light-chain stabilization. Continued co-crystallization studies of BoNT-inhibitor complexes. Characterized host proteins that interact with BoNT and identified small molecule inhibitors preventing host-toxin interactions. Validated differential expression of host genes involved in neuron response to BoNT intoxication. Identified and developed therapies that target host proteins involved in BoNT persistence in the neuron. Validated host proteins involved in ricin dislocation as potential drug targets. Continued development of small molecule inhibitors to toxin threat agents (BoNT, ricin, and staphylococcal enterotoxin B). In FY13, all research in this area was re-aligned to Techbase Med Defense-Bio CM (TM2).		8.465	0.000
Title: 8) Transformational Medical Technologies Description: Development of Platform Technologies: Continues efforts previously funded under the Transformational Medical Technologies Initiative. 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		14.761	0.000

PE 0602384BP: *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)*

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Biological Defense Program			DATE: April 2013		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>		R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>		PROJECT TB2: <i>MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2012	FY 2013	FY 2014
Discovery, Countermeasure Evaluation, and Bioinformatics. Applied research efforts include the maturation of the components necessary to develop an integrated capability from pathogen identification and characterization to countermeasure delivery. Off-the-shelf technologies will be identified, evaluated, and where applicable, refined to demonstrate the ability to provide drug development capabilities.					
FY 2012 Accomplishments: Invested to further develop host and pathogen based platforms to higher levels of maturity and funded Biosurveillance indications and warnings of a fused nature in accordance with the Platform Technologies objectives of pathogen characterization, target identification, and bioinformatics. Continued to mature pathogen identification and characterization capabilities, including genetic sequencing, integrate existing capabilities. Continued to develop genetic sequencing and analysis technologies to characterize advanced threats. Continued integration of leading edge technologies with existing technologies to enhance pathogen characterization, target identification, countermeasure discovery and countermeasure evaluation platform areas. In FY13 all research in this area was re-aligned to Techbase Med Defense - Diagnostics (TM2).					
Title: 9) Transformational Medical Technologies Description: Multiagent (Broad Spectrum) Medical Countermeasures (MCM): Continues efforts previously funded under the Transformational Medical Technologies Initiative. It supports existing and new efforts in the drug discovery phase of drug development. Applied research efforts also include the investigation of existing drugs to explore their efficacy against BW agents. This involves the initiation of experiments to identify markers, correlates of protection, assays, and endpoints for further non-clinical and clinical studies and development of a scalable and reproducible manufacturing process amenable to Food and Drug Administration (FDA) Good Manufacturing Practices (GMP). FY 2012 Accomplishments: Supported new MCM discovery efforts to refresh the Hemorrhagic Fever Virus (HFV) and Intracellular Bacterial Pathogen (IBP) product pipelines. Continued to identify and initiate the development of intervention strategies targeting host response to biological pathogens, inclusive of enhancing the immune system and treating symptoms to reduce the severity of disease. In FY13 all research in this area was re-aligned to Project TM2 - Techbase Med Defense-Bio CM.			16.791	0.000	0.000
Accomplishments/Planned Programs Subtotals			87.849	0.000	0.000

PE 0602384BP: *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)*

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Biological Defense Program									DATE: April 2013		
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 2: Applied Research				R-1 ITEM NOMENCLATURE PE 0602384BP: CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)				PROJECT TB2: MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)			
C. Other Program Funding Summary (\$ in Millions)											
Line Item	FY 2012	FY 2013	FY 2014 Base	FY 2014 OCO	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
• TM2: TECHBASE MED DEFENSE (APPLIED RESEARCH)	0.000	118.208	98.111		98.111	104.361	102.546	99.523	103.441	Continuing	Continuing
• TM3: TECHBASE MED DEFENSE (ATD)	0.000	182.330	122.717		122.717	99.930	107.506	123.790	126.110	Continuing	Continuing
• MB4: MEDICAL BIOLOGICAL DEFENSE (ACD&P)	121.170	133.254	122.936		122.936	95.724	78.461	41.661	30.014	Continuing	Continuing
• MB5: MEDICAL BIOLOGICAL DEFENSE (EMD)	197.907	212.056	263.443		263.443	228.199	183.390	151.455	184.222	Continuing	Continuing
• MB7: MEDICAL BIOLOGICAL DEFENSE (OP SYS DEV)	5.371	0.498	0.499		0.499	13.414	14.551	9.816	3.277	Continuing	Continuing
Remarks											
D. Acquisition Strategy N/A											
E. Performance Metrics N/A											

PE 0602384BP: *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)*

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Biological Defense Program **DATE:** April 2013

APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>					R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>				PROJECT TC2: <i>MEDICAL CHEMICAL DEFENSE (APPLIED RESEARCH)</i>			
COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013[#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
TC2: <i>MEDICAL CHEMICAL DEFENSE (APPLIED RESEARCH)</i>	-	36.695	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	36.695

[#] FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

^{##} The FY 2014 OCO Request will be submitted at a later date

A. Mission Description and Budget Item Justification

This project (TC2) funds applied research for the investigation of new medical countermeasures to include prophylaxes, pretreatments, antidotes, diagnostics, skin decontaminants and therapeutic drugs against identified and emerging chemical warfare threat agents to include a class of agents called Non Traditional Agents (NTAs). Capability areas include: Pretreatments; pretreatments for NTAs; diagnostics; diagnostics for NTAs; therapeutics; and therapeutics for NTAs. Pretreatments includes researching prophylaxes to protect against chemical agents and NTAs. Diagnostics focuses on researching diagnostic tools that help identify exposure to chemical agents and NTAs. Therapeutics focuses on researching post-exposure countermeasures to protect against chemical agents and NTAs. Research and development efforts in this project focus on formulation and scale-up of candidate compounds. In FY13, all research in this area is re-aligned into Techbase Medical Defense (TM2).

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

	FY 2012	FY 2013	FY 2014
Title: 1) Diagnostics Description: Diagnostic Technologies: Focuses on developing state-of-the-art laboratory/fieldable methods that detect exposure to chemical warfare agents (CWA) (e.g., nerve agents and vesicants) in clinical samples. Identifies 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 2012 Accomplishments: Completed studies of existing CWA biomarkers to determine effectiveness for early detection. Completed sulfur mustard biomarker studies for identifying pre-symptomatic treatment options. Continued investigation of a novel sensor using a phage library display. In FY13, all research in this area was re-aligned into Techbase Med Defense - Diagnostics (TM2).	0.777	0.000	0.000
Title: 2) Chem Diagnostics NTA Description: Focuses on developing state-of-the-art laboratory/fieldable methods to detect exposure to non-traditional agents in clinical samples. Identifies 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. Non-NTA Chem Diagnostics support the analytics for traditional agent diagnostics and hand-held diagnostic technologies that might be applied to NTA diagnostics.	1.900	0.000	0.000

PE 0602384BP: *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)*

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013
<i>FY 2012 Accomplishments:</i> Further identified biomarkers to create an enhanced capability to pre-symptomatically diagnose NTA exposure. Continued method development for identification and validation of NTAs in clinical samples. Initiated method development for identification and validation of NTAs in clinical samples for additional compounds of interest. In FY13, all research in this area was re-aligned into Project NT2 - Techbase Med Defense - NTA Diagnostics.			
<i>Title:</i> 3) Pretreatments <i>Description:</i> Nerve Agent, Pretreatments: Develops pretreatments that provide protection against all organophosphorous nerve agents. 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. <i>FY 2012 Accomplishments:</i> Utilized novel methods to develop candidate proteins capable of neutralizing chemical warfare agents (CWAs) in vivo. Assessed processes to produce, screen, and purify newly designed enzymes. Evaluated efficacy of small molecule approaches toward acetylcholinesterase (AChE) protection. In FY13, all research within this area was re-aligned into Project TM2 - Techbase Medical Defense - Chemical CM.		6.692	0.000
<i>Title:</i> 4) Chem Pretreatments NTA <i>Description:</i> Develops 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. <i>FY 2012 Accomplishments:</i> Determined efficacy of enzyme candidates for all NTA exposure. In FY13, all research in this area was re-aligned to Project NT2 - Techbase Medical Defense - NTA.		2.754	0.000
<i>Title:</i> 5) Therapeutics <i>Description:</i> Cutaneous and Ocular: Focuses on therapeutic strategies to effectively minimize injuries to dermal (i.e., skin) and ocular tissues resulting from exposure to chemical warfare agents (CWAs). Involves the development of effective practical field and clinic management strategies and physical and pharmacological interventions to treat the injury processes. This work is designed to develop potential candidates that will ultimately be submitted for FDA licensure or new indications for previously licensed products for use in the treatment of chemical warfare casualties. <i>FY 2012 Accomplishments:</i>		2.810	0.000

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APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>	R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	PROJECT TC2: <i>MEDICAL CHEMICAL DEFENSE (APPLIED RESEARCH)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013
Evaluated the effectiveness of multiple anti-inflammatory approaches in vitro and in vivo against sulfur mustard exposure. Continued to develop molecular biology approaches to assess candidate countermeasures against skin and eye injury caused by sulfur mustard. Evaluated therapeutic approaches to mitigate the chronic effects of sulfur mustard exposure. In FY13, all research within this project was re-aligned to Project TM2 - Techbase Medical Defense - Chemical CM.			
Title: 6) Therapeutics Description: Neurologic: Focuses on therapeutic strategies to effectively minimize neurologic injuries resulting from exposure to CWAs. This effort involves the development of neuroprotectants, anticonvulsants, and improved neurotransmitter restorers. This work is designed to develop potential candidates that will ultimately be submitted for FDA licensure or new indications for previously licensed products for use in the treatment of chemical warfare casualties. FY 2012 Accomplishments: Utilized mechanistic understanding of reactivation to identify compounds capable of reactivating nerve-agent inhibited acetylcholinesterase (AChE) at delayed times after exposure. Identified approaches for neuroprotection, as defined by the minimization of chronic functional decrement due to nerve agent exposure. Conducted in silico and in vitro evaluation of novel and/or Food and Drug Administration licensed products for treatment of acute nerve agent exposure. In FY13, all research within this area was re-aligned to Project TM2 - Techbase Medical Defense - Chemical CM.		9.778	0.000
Title: 7) Chem Therapeutics NTA Description: Investigates common mechanisms of agent injury. Determines the toxic effects of agents by probable routes of field exposure, as well as standard experimental routes. Physiological parameters and pathological assessment will be used to establish the general mode and mechanism(s) of toxicity. Develops, assesses, evaluates, and validates therapeutics for treatment resulting from exposure to Non-Traditional Agents (NTA). FY 2012 Accomplishments: Continued binding studies to support the design and synthesis of an improved reactivator. Continued evaluation of improved products to treat NTA exposure. Continued development of animal models for various routes of exposure to NTA. Conducted in silico and in vitro evaluation of novel and/or Food and Drug Administration licensed products for treatment of NTA exposure. Studied mechanisms of NTA injury for therapeutic intervention. In FY13, all research in this area was re-aligned into Techbase Medical Defense - NTA (NT2).		11.984	0.000
Accomplishments/Planned Programs Subtotals		36.695	0.000

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C. Other Program Funding Summary (\$ in Millions)											
Line Item	FY 2012	FY 2013	FY 2014 Base	FY 2014 OCO	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
• TM2: TECHBASE MED DEFENSE (APPLIED RESEARCH)	0.000	118.208	98.111		98.111	104.361	102.546	99.523	103.441	Continuing	Continuing
• TM3: TECHBASE MED DEFENSE (ATD)	0.000	182.330	122.717		122.717	99.930	107.506	123.790	126.110	Continuing	Continuing
• MC4: MEDICAL CHEMICAL DEFENSE (ACD&P)	7.697	0.000	2.000		2.000	3.705	5.114	10.920	24.186	Continuing	Continuing
• MC5: MEDICAL CHEMICAL DEFENSE (EMD)	2.336	9.642	55.087		55.087	58.342	57.675	47.340	28.759	0.000	259.181
Remarks											
D. Acquisition Strategy N/A											
E. Performance Metrics N/A											

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COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013[#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
TM2: <i>TECHBASE MED DEFENSE (APPLIED RESEARCH)</i>	-	0.000	118.208	98.111	-	98.111	104.361	102.546	99.523	103.441	Continuing	Continuing

[#] FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

^{##} The FY 2014 OCO Request will be submitted at a later date

A. Mission Description and Budget Item Justification

This project (TM2) funds applied research for innovative technology approaches to advance medical systems designed to rapidly identify, diagnose, prevent, and treat disease due to exposure to all three of radiological, chemical and biological threat agents. Categories for this project include core science efforts in Medical Chemical, Medical Biological, Diagnostics, and the Medical Countermeasures Initiative (MCMI). Against radiological threats, this project provides investment for the development of pretreatments (prophylaxis) and post-irradiation therapeutics against radiological/nuclear exposure. Against chemical and biological agents, this project funds applied research for the investigation of new medical countermeasures to include prophylaxes, pretreatments, antidotes, skin decontaminants, and therapeutic drugs against identified and emerging biological and chemical warfare agents. Medical Science and Technology (S&T) efforts in this Budget Activity refine promising medical initiatives identified in Budget Activity 1, resulting in the development of countermeasures to protect against and treat the effects of exposure to chemical and biological (CB) agents. Diagnostic research focuses on providing high quality data closer to the point-of-need comprising device innovation, panels of biomarkers driven by bioinformatics, and epidemiological modeling tools.

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 science and technology (S&T) are concentrated in advancing two areas: 1) regulatory science and 2) flexible manufacturing technologies and processes for MCMs. Efforts conducted in these areas are enablers supporting the DoD Medical Countermeasures Advanced Development and Manufacturing (MCM-ADM) capability.

In FY13, all Project TB2 research was re-aligned into Project TM2 - Techbase Medical Defense.

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

	FY 2012	FY 2013	FY 2014
Title: 1) Techbase Med Defense - Diagnostics	0.000	5.600	0.000
Description: Biosurveillance/Disease Surveillance: Integrate existing disparate military and civilian datasets, investigate methodologies to appropriately integrate open source data into advanced warning systems, and leverage and enhance advanced 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			

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2012	FY 2013	FY 2014
estimation and decision support tools. Focus on agent-based epidemiological modeling and fusion of disease surveillance data. This subject area was previously referred to as "Disease Surveillance/Epidemiological and Predictive Modeling".					
FY 2013 Plans: Continue FY12 efforts from Information Systems Technology, Medical & Surveillance Information and Analysis (CB2 - M&S). Continue effort on biosurveillance data stream evaluation and analysis to identify most useful biosurveillance data streams for prediction and early warning. Continue effort to devise structured outside contiguous U.S. (OCONUS) expansion roadmap for agent-based epidemiological models and increase OCONUS analytic capability through targeted areas. Continue research into data integration platforms and expand biosurveillance portfolio to support in-context, rapid detection, identification and response capabilities on the global scale. Funding for this research area was re-aligned from Tech Base Med Bio - Diagnostics (TB2).					
Title: 2) Techbase Med Defense - Diagnostics Description: Chemical Diagnostics: Focuses on developing state-of-the-art laboratory/fieldable methods that detect exposure to chemical warfare agents (CWA) (e.g., nerve agents and vesicants) or radiological agents in clinical samples. Identifies 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: Develop assays for enhancing the ability to identify exposure (sublethal) to emerging chemical agent threats using newly-identified biomolecular targets. Funding for this research area was re-aligned from Tech Base Med Chem - Diagnostics (TC2). FY 2014 Plans: Continue to develop assays for enhancing the ability to identify sublethal exposure to emerging chemical agent threats using newly-identified biomolecular targets.			0.000	1.175	0.600
Title: 3) Techbase Med Defense - Diagnostics Description: Biological Diagnostic Assays and Reagents: 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. This subject area was previously referred to as "Biological Diagnostic Technologies". FY 2013 Plans: Optimize processes and platform technologies employed in laboratory characterization of host and pathogen biomarker signatures of exposure and disease processes. Mature pipeline of genomics, proteomics, systems biology, and bioinformatics tools and methods to simultaneously support companion diagnostic tests, the development of MCMs and the analytic processes required to			0.000	16.652	14.967

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2012	FY 2013	FY 2014
identify known, emerging, and re-emerging pathogens. Funding for this research area was re-aligned from Tech Base Med Bio - Diagnostics (TB2) and Techbase Med Bio - TMT Platform Technologies (TB2). FY 2014 Plans: Continue to optimize processes and platform technologies employed in laboratory characterization of host and pathogen biomarker signatures of exposure and disease processes. Continue to mature pipeline of genomics, proteomics, systems biology, and bioinformatics tools and methods to simultaneously support diagnostic tests, the development of MCMs and the analytic processes required to identify known, emerging, and re-emerging pathogens. Develop nanomaterial structure designs to enable companion diagnostics.					
Title: 4) Techbase Med Defense - Diagnostics 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: Discover and verify panel of pre-symptomatic differential diagnostic biomarkers of exposure to virulent bacterial and viral bio- and emerging threat class and agents. Development of portable diagnostic devices capable of use by minimally trained personnel, aiding in rapid diagnostics at the point of need. Funding for this research area in FY13 was re-aligned from Tech Base Med Bio - Diagnostics (TB2) and Techbase Med Bio - TMT Platform Technologies (TB2). In FY14 the funding for this research is consolidated into Biological Diagnostic Device Platforms.			0.000	7.561	0.000
Title: 5) Techbase Med Defense - Diagnostics Description: Biological Diagnostic Device Platforms: 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: Develop and mature point of need diagnostic platform technologies with orthogonal capabilities. Implement design control phased development and acceptance criteria to identify a minimum of two Next Generation Diagnostic Systems, Increment 2, candidate device platforms. Funding for this research area was re-aligned from Tech Base Med Bio - Diagnostics (TB2) and Techbase Med Bio - TMT Platform Technologies (TB2). FY 2014 Plans:			0.000	9.047	12.833

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013
Continue to develop and mature point of need diagnostic platform technologies with orthogonal capabilities. Develop a multiplexed point of care diagnostic platform for detection of biothreat agent exposure.			
Title: 6) Techbase Med Defense - Medical Countermeasures Initiative Description: Medical Countermeasures Initiative (MCMi): Integrate the regulatory science and manufacturing technologies and processes developed into the DoD Medical Countermeasures Advanced Development and Manufacturing (MCM-ADM) organization as enablers of the advanced development and flexible manufacturing capability. FY 2013 Plans: Investigate organotypic platforms for MCM evaluation: ex-vivo liver, kidney, alveolar lung sacs with the goal of enhancing the product development process. Construct next generation high yield protein expression platforms for biotechnology-based MCMs. Develop high capacity downstream technologies and process analytic technologies to enhance rapid manufacturing process development and control with the goal of accelerating the manufacturing of biotechnology-based MCMs. Funding for this research area was re-aligned from MCMi - Medical Countermeasures Initiative (TB2). FY 2014 Plans: Continue to investigate organotypic platforms for MCM evaluation: (ex-vivo heart, liver, kidney, alveolar lung sacs, and blood-brain barrier) with the goal of accelerating and enhancing the FDA-regulated medicinal product development process. Construct next generation high yield protein expression platforms for biotechnology-based MCMs. Develop high capacity downstream technologies and process analytic technologies to enhance rapid manufacturing process development and control with the goal of accelerating the manufacturing of biotechnology-based MCMs.		0.000	12.972
Title: 7) Techbase Med Defense - Bio CM Description: Pretreatments - Bacterial/Toxins Vaccines: Generate novel or improved vaccines against bacterial and toxin biothreat agents, and demonstrate preliminary efficacy in small animal models. Identify correlates of protective immunity in animal models. FY 2013 Plans: Refine appropriate animal models for aerosolized Burkholderia mallei and pseudomallei as well as Type A Francisella tularensis with regulatory guidance. Evaluate multiple novel subunit Burkholderia vaccine candidates in small or large animal models with and without adjuvants. Define predictive value of correlates of immunity, elicited by Burkholderia species vaccine candidates. Evaluate the tolerability of novel adjuvants using the Anthrax vaccine for proof of concept, but which may potentially have applicability to other vaccine candidates. Additionally, research will continue to produce vaccine candidates designed to protect against emerging or genetically engineered Anthrax strains. Test multiple novel subunit vaccine candidates for protection against		0.000	7.063
			6.875

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013	FY 2014
aerosolized Type A Francisella tularensis infection in appropriate small and large animal models. Funding for this research area was re-aligned from Tech Base Med Bio - Pretreatments (TB2).				
FY 2014 Plans: Continue refining appropriate animal models for aerosolized Burkholderia mallei and pseudomallei as well as Type A Francisella tularensis with regulatory guidance. Continue evaluating multiple novel subunit Burkholderia vaccine candidates in small or large animal models with and without adjuvants. Continue defining predictive value of correlates of immunity, elicited by Burkholderia species vaccine candidates. Continue evaluating the tolerability of novel adjuvants using the Anthrax vaccine for proof of concept, but which may potentially have applicability to other vaccine candidates. Additionally, research will continue to produce vaccine candidates designed to protect against emerging or genetically engineered Anthrax strains. Test multiple novel subunit vaccine candidates for protection against aerosolized Type A Francisella tularensis infection in appropriate small and large animal models.				
Title: 8) Techbase Med Defense - Bio CM		0.000	3.098	3.040
Description: Pretreatments - Vaccine Platforms and Research Tools: Design novel multi-agent vaccine platforms capable of expressing multiple antigens, investigate the ability of non-specific stimulators of immunity to enhance the effectiveness of newly generated vaccines, characterize alternative vaccine delivery (needle-free) methods and novel vaccine stabilization methodologies, and conduct studies to further advance a laboratory based, human artificial immune system to render it capable of predicting the human immune response to biodefense vaccines under development.				
FY 2013 Plans: Utilize relevant animal models for the evaluation of the immune response to novel multi-antigen platforms. Further refine the capabilities of the surrogate human immune system, MIMIC (i.e., Modular Immune In vitro Construct), which provides an in vitro assessment of the human immune response. Initiate studies designed to lend regulatory credence to functional assays on the MIMIC to evaluate cross-reactivity of different Filovirus and Alphavirus strains. Increase efforts to develop methodologies which remove the need for cold storage and transport for vaccines and render them stable in variable and extreme temperatures. Funding for this research area was re-aligned from Tech Base Med Bio - Pretreatments (TB2).				
FY 2014 Plans: Utilize relevant animal models for the evaluation of the immune response to novel multi-antigen platforms. Further refine the capabilities of the surrogate human immune system, MIMIC (i.e., Modular Immune In vitro Construct), which provides an in vitro assessment of the human immune response. Continue studies designed to lend regulatory credence to functional assays on the MIMIC to evaluate cross-reactivity of different Filovirus and Alphavirus strains. Increase efforts to develop methodologies which remove the need for cold storage and transport for vaccines and render them stable in variable and extreme temperatures.				
Title: 9) Techbase Med Defense - Bio CM		0.000	8.150	16.541

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013
Description: Therapeutics - Viral Therapeutics: Identify, optimize and evaluate lead candidate therapeutics for efficacy against viral pathogens. FY 2013 Plans: Evaluate FDA approved drug combinations against Arenavirus, Bunyavirus, and Flavivirus infection. Conduct structure-based drug discovery for Alphaviruses. Identify and evaluate novel broad-spectrum host and pathogen directed small molecule therapeutics for emerging infectious diseases (i.e. Alphavirus, Filovirus, Flavivirus, Arenavirus, Bunyavirus). A portion of TB2/ TBMDB TMT Multiagent (Broad Spectrum) Medical Countermeasures will be continued in viral therapeutics (TB2/TBMDB THER). Funding for this research area was re-aligned from Tech Base Med Bio - Therapeutics (TB2). FY 2014 Plans: Conduct structure-based drug discovery for Alphaviruses. Develop antibody-based therapeutics for Filovirus infections. Identify and evaluate novel broad-spectrum host and pathogen directed small molecule therapeutics for emerging infectious diseases (i.e. Alphavirus, Filovirus, Flavivirus, Arenavirus, Bunyavirus). In FY14, research previously conducted under the Multiagent Broad Spectrum Countermeasure thrust area will be transitioned into the Viral Therapeutics program under BA2 Techbase Med Defense - Bio CM (TM2).			
Title: 10) Techbase Med Defense - Bio CM Description: Therapeutics - Bacterial Therapeutics: Identify, optimize and evaluate lead therapeutic candidates effective against designated bacterial threat agents. FY 2013 Plans: Expand FDA approved drug screening program for Burkholderia, Francisella tularensis and determine in vitro susceptibilities. Continue evaluation of novel compounds against bacterial biological warfare agents. Develop lead series of MurB compounds targeting cell wall biosynthesis. Determine synergy between MurB antibacterial agents and conventional antibiotics against B. anthracis and Y. pestis. Evaluate the electron transport chain, multi drug efflux systems, and purine pathways as a target for broad-spectrum antibacterial development. Funding for this research area was re-aligned from Tech Base Med Bio - Therapeutics (TB2). FY 2014 Plans: Continue expansion of FDA approved drug screening program for Burkholderia, Francisella tularensis and determine in vitro susceptibilities. Continue evaluation of novel compounds against bacterial biological warfare agents. Evaluate bioactive peptides for the ability to stimulate host protective pathways. Determine synergy between lead series MurB antibacterial cell wall inhibitors and conventional antibiotics against B. anthracis and Y. pestis. Evaluate the electron transport chain, multidrug efflux systems, and purine pathways as a target for broad-spectrum antibacterial development. In FY14, research previously conducted under the		0.000	7.150
			15.624

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013
Multiagent Broad Spectrum Countermeasure thrust area will be transitioned into the Bacterial Therapeutics program under BA2 Techbase Med Defense - Bio CM (TM2).			FY 2014
Title: 11) Techbase Med Defense - Bio CM Description: Therapeutics - Toxin Therapeutics: Identify, optimize and evaluate therapeutic candidates that are effective against biological toxin agents. FY 2013 Plans: Characterize host proteins that interact with BoNT and identify small molecule inhibitors preventing host-toxin interactions. Validate differential expression of host genes involved in neuron response to BoNT intoxication. Identify and develop therapies that target host proteins involved in BoNT persistence in the neuron. Continue co-crystallization studies of BoNT-inhibitor complexes. Funding for this research area was re-aligned from Tech Base Med Bio - Therapeutics (TB2). FY 2014 Plans: Continue to characterize host proteins that interact with BoNT and identify small molecule inhibitors preventing host-toxin interactions. Continue to validate differential expression of host genes involved in neuron response to BoNT intoxication. Continue to identify and develop therapies that target host proteins involved in BoNT persistence in the neuron. Continue co-crystallization studies of BoNT-inhibitor complexes.		0.000	2.395
Title: 12) Techbase Med Defense - Bio CM Description: Multiagent (Broad Spectrum) Medical Countermeasures (MCM): Continues efforts previously funded under the Transformational Medical Technologies Initiative. It supports existing and new efforts in the discovery phase of drug development. Applied research efforts also include the investigation of existing drugs to explore their efficacy against BW agents. This involves the initiation of experiments to identify markers, correlates of protection, assays, and endpoints for further non-clinical and clinical studies and development of a scalable and reproducible manufacturing process amenable to Food and Drug Administration (FDA) Good Manufacturing Practices (GMP). In FY14, research under this thrust area will be transitioned into the Bacterial and Viral Therapeutics program under BA2 Techbase Med Defense - Bio CM (TM2). FY 2013 Plans: Continue to support new MCM discovery efforts to refresh the Hemorrhagic Fever Virus (HFV) and Intracellular Bacterial Pathogen (IBP) product pipelines. Continue to identify and initiate the development of intervention strategies targeting host response to biological pathogens, inclusive of enhancing the immune system and treating symptoms to reduce the severity of disease. Funding for this research area was re-aligned from Tech Base Med Bio - TMT Broad Spectrum MCM (TB2).		0.000	18.235
Title: 13) Techbase Med Defense - Chem CM		0.000	4.400

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2012	FY 2013	FY 2014
Description: Chemical Medical Pretreatments - Nerve Agent, Pretreatments: Develops pretreatments that provide protection against all organophosphorous nerve agents. 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. FY 2013 Plans: Initiate search for Catalytic Bioscavenger of V agents. Assess feasibility and begin initial studies to develop a broad spectrum cocktail of V and G agent catalytic bioscavengers. Funding for this research area was re-aligned from Tech Base Med Chem - Pretreatments (TC2). FY 2014 Plans: Continue search for catalytic bioscavenger of V agents. Continue studies to develop a broad spectrum cocktail of V and G agent catalytic bioscavengers. Pursue development of small molecule pretreatment against G and V agents.					
Title: 14) Techbase Med Defense - Chem CM Description: Chemical Medical Therapeutics - Cutaneous and Ocular: Focuses on therapeutic strategies to effectively minimize injuries to dermal (i.e., skin) and ocular tissues resulting from exposure to chemical warfare agents (CWAs). Involves the development of effective practical field and clinic management strategies and physical and pharmacological interventions to treat the injury processes. This work is designed to develop potential candidates that will ultimately be submitted for FDA licensure or new indications for previously licensed products for use in the treatment of chemical warfare casualties. FY 2013 Plans: Continue to utilize molecular biology approaches to elucidate drug targets and gain further mechanistic understanding of delayed ocular injury due to sulfur mustard exposure. Funding for this research area was re-aligned from Tech Base Med Chem - Therapeutics (TC2).			0.000	1.270	0.000
Title: 15) Techbase Med Defense - Chem CM Description: Chemical Medical Therapeutics - Neurologic: Focuses on therapeutic strategies to effectively minimize neurologic injuries resulting from exposure to CWAs. This effort involves the development of neuroprotectants, anticonvulsants, and improved neurotransmitter restorers. This work is designed to develop potential candidates that will ultimately be submitted for FDA licensure or new indications for previously licensed products for use in the treatment of chemical warfare casualties. FY 2013 Plans:			0.000	9.775	5.938

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Biological Defense Program										DATE: April 2013		
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 2: Applied Research				R-1 ITEM NOMENCLATURE PE 0602384BP: CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)				PROJECT TM2: TECHBASE MED DEFENSE (APPLIED RESEARCH)				
B. Accomplishments/Planned Programs (\$ in Millions)										FY 2012	FY 2013	FY 2014
Continue investigating potential for broad spectrum/centrally active reactivator. Continue search for Neuroprotectant effective up to 4 hours after seizure initiation. Funding for this research area is re-aligned from Tech Base Med Chem - Therapeutics (TC2). FY 2014 Plans: Continue investigating potential for broad spectrum/centrally active cholinesterase reactivator. Continue studies to facilitate therapeutics crossing the blood brain barrier. Explore molecular, nanomaterial based drug delivery platforms.												
Title: 16) Techbase Med Defense - Rad CM Description: Radiation Medical Countermeasures: Develop medical countermeasures to protect the Warfighter against acute radiological/nuclear exposure, to include developing both pretreatments (prophylaxis) and post-irradiation therapeutics against radiological/nuclear exposure. DoD is the only governmental agency currently developing medical prophylaxis to protect Warfighters and/or other responders in the event of a radiological incident. FY 2013 Plans: Continue evaluation of novel biomarkers useful for biodosimetry and identification of potential therapeutic approaches. Funding for this research area was re-aligned from Tech Base Med Rad - Radiation Countermeasures (TR2).										0.000	0.613	0.000
Accomplishments/Planned Programs Subtotals										0.000	118.208	98.111
C. Other Program Funding Summary (\$ in Millions)												
Line Item	FY 2012	FY 2013	FY 2014 Base	FY 2014 OCO	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost	
• TB2: MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)	87.849	0.000	0.000		0.000	0.000	0.000	0.000	0.000	0.000	87.849	
• TC2: MEDICAL CHEMICAL DEFENSE (APPLIED RESEARCH)	36.695	0.000	0.000		0.000	0.000	0.000	0.000	0.000	0.000	36.695	
• TR2: MEDICAL RADIOLOGICAL DEFENSE (APPLIED RESEARCH)	0.935	0.000	0.000		0.000	0.000	0.000	0.000	0.000	0.000	0.935	
• TB3: MEDICAL BIOLOGICAL DEFENSE (ATD)	168.684	0.000	0.000		0.000	0.000	0.000	0.000	0.000	0.000	168.684	
• TC3: MEDICAL CHEMICAL DEFENSE (ATD)	21.182	0.000	0.000		0.000	0.000	0.000	0.000	0.000	0.000	21.182	

PE 0602384BP: *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)*

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APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>	R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	PROJECT TM2: <i>TECHBASE MED DEFENSE (APPLIED RESEARCH)</i>
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C. Other Program Funding Summary (\$ in Millions)

Line Item	FY 2012	FY 2013	FY 2014 Base	FY 2014 OCO	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
• TM3: <i>TECHBASE MED DEFENSE (ATD)</i>	0.000	182.330	122.717		122.717	99.930	107.506	123.790	126.110	Continuing	Continuing
• TR3: <i>MEDICAL RADIOLOGICAL DEFENSE (ATD)</i>	1.431	0.000	0.000		0.000	0.000	0.000	0.000	0.000	0.000	1.431
• MB4: <i>MEDICAL BIOLOGICAL DEFENSE (ACD&P)</i>	121.170	133.254	122.936		122.936	95.724	78.461	41.661	30.014	Continuing	Continuing
• MC4: <i>MEDICAL CHEMICAL DEFENSE (ACD&P)</i>	7.697	0.000	2.000		2.000	3.705	5.114	10.920	24.186	Continuing	Continuing
• MB5: <i>MEDICAL BIOLOGICAL DEFENSE (EMD)</i>	197.907	212.056	263.443		263.443	228.199	183.390	151.455	184.222	Continuing	Continuing
• MC5: <i>MEDICAL CHEMICAL DEFENSE (EMD)</i>	2.336	9.642	55.087		55.087	58.342	57.675	47.340	28.759	0.000	259.181
• MB7: <i>MEDICAL BIOLOGICAL DEFENSE (OP SYS DEV)</i>	5.371	0.498	0.499		0.499	13.414	14.551	9.816	3.277	Continuing	Continuing

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Biological Defense Program **DATE:** April 2013

APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>	R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	PROJECT TR2: <i>MEDICAL RADIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>
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COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 [#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
TR2: <i>MEDICAL RADIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	-	0.935	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	0.935

[#] FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

^{##} The FY 2014 OCO Request will be submitted at a later date

A. Mission Description and Budget Item Justification

This project (TR2) funds applied research to develop medical countermeasures to protect the Warfighter against acute radiological exposure. Specifically, innovative technical approaches will be used to develop products to mitigate health consequences resulting from Acute Radiation Exposure (ARS) and Delayed Effects of Acute Radiation Exposure (DEARE). The research and development of medical countermeasures for radiation exposure will ultimately enhance the survivability of Warfighters and will serve to significantly minimize the development of acute radiation syndromes and subsequent health problems. Results of efforts funded under this project are collaboratively shared with other government agencies, while the Department of Defense maintains an emphasis on the development of pretreatments to protect military personnel who could be involved in responding to a radiological incident. In FY13, all research in this area is re-aligned into Techbase Medical Defense (TM2).

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

	FY 2012	FY 2013	FY 2014
Title: 1) Radiological Medical Countermeasures Description: Radiation Medical Countermeasures: Develop medical countermeasures to protect the Warfighter against acute radiological/nuclear exposure, to include developing both pretreatments (prophylaxis) and post-irradiation therapeutics against radiological/nuclear exposure. DoD is the only governmental agency currently developing medical prophylaxis to protect Warfighters and/or other responders in the event of a radiological incident. FY 2012 Accomplishments: Evaluated novel biomarkers for biodosimetry and identification of potential therapeutic approaches. In FY13, all Project TR2 research was re-aligned into Techbase Medical Defense - RAD CM (TM2).	0.935	0.000	0.000
Accomplishments/Planned Programs Subtotals	0.935	0.000	0.000

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C. Other Program Funding Summary (\$ in Millions)											
Line Item	FY 2012	FY 2013	FY 2014 Base	FY 2014 OCO	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
• TM2: <i>TECHBASE MED DEFENSE (APPLIED RESEARCH)</i>	0.000	118.208	98.111		98.111	104.361	102.546	99.523	103.441	Continuing	Continuing
• TM3: <i>TECHBASE MED DEFENSE (ATD)</i>	0.000	182.330	122.717		122.717	99.930	107.506	123.790	126.110	Continuing	Continuing
Remarks											
D. Acquisition Strategy N/A											
E. Performance Metrics N/A											

PE 0602384BP: *CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)*

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