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

APPROPRIATION/BUDGET ACTIVITY

0400: Research, Development, Test & Evaluation, Defense-Wide

BA 3: Advanced Technology Development (ATD)

#### R-1 ITEM NOMENCLATURE

PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)

DATE: April 2013

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COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 <sup>#</sup>	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	-	225.441	234.280	170.847	-	170.847	154.659	163.156	190.335	194.897	Continuing	Continuing
CB3: CHEMICAL BIOLOGICAL DEFENSE (ATD)	-	23.838	20.034	18.091	-	18.091	19.224	18.348	20.621	19.960	Continuing	Continuing
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
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
TE3: TEST & EVALUATION (ATD)	-	10.306	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	10.306
TM3: TECHBASE MED DEFENSE (ATD)	-	0.000	182.330	122.717	-	122.717	99.930	107.506	123.790	126.110	Continuing	Continuing
TR3: MEDICAL RADIOLOGICAL DEFENSE (ATD)	-	1.431	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	1.431
TT3: TECHBASE TECHNOLOGY TRANSITION	-	0.000	0.000	6.706	-	6.706	6.257	6.575	8.196	7.852	Continuing	Continuing

<sup>&</sup>lt;sup>#</sup> FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

### A. Mission Description and Budget Item Justification

This program element (PE) demonstrates technologies that enhance the ability of U.S. forces to deter, defend against, and survive Chemical, Biological, and Radiological (CBR) warfare. The PE funds advanced technology development for Joint Service and Service-specific requirements in both medical and physical sciences CBR defense areas. The medical program (was TB3, TC3, TR3, but in FY13 these continue within one project, TM3), aims to produce biological diagnostic assays and reagents, diagnostic device platforms, pretreatments and therapeutics for bacterial, viral, and toxin threats as well as for chemical threats, and medical devices, as countermeasures for CBR threat agents. Specific areas of medical investigation include: prophylaxis, pretreatment, antidotes and therapeutics, personnel and patient decontamination, and medical management of casualties. In the physical sciences area (CB3), the focus is on demonstrations of CB defense technologies, including biological detection, chemical detection, information system technology for hazard prediction and systems performance, and protection, and decontamination. NT3 consolidated all efforts related to non-traditional agents (NTAs), including NTA chemical diagnostics, medical pretreatments, therapeutics, detection, and protection

<sup>##</sup> The FY 2014 OCO Request will be submitted at a later date

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

R-1 ITEM NOMENCLATURE

APPROPRIATION/BUDGET ACTIVITY

0400: Research, Development, Test & Evaluation, Defense-Wide

BA 3: Advanced Technology Development (ATD)

PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)

DATE: April 2013

and hazard mitigation. The PE also provides for the conduct of advanced technology development in the areas of real-time sensing, accelerated biological warfare operational awareness, and the restoration of operations following a biological warfare or chemical warfare attack (project TT3). The PE is dedicated to conducting proof-of-principle field demonstrations, and testing system-specific technologies to meet specific military needs. Work conducted under this PE will transition to and will provide risk reduction for System Integration/Demonstration (PE 0603884BP/PE 0604384BP) activities.

Key efforts within this PE are in support of the FY14 policy priorities for Countering Biological Threats. Approximately \$71.9M 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 \$60.0M 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 \$75.4M 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."

To recap, in FY13, all traditional agent Medical Biological and Medical Chemical Defense efforts (Projects TB3 and TC3) were re-aligned to Project TM3 - Techbase Medical Defense (ATD). CB3 Advanced Technology Development efforts continue to pursue solutions against traditional agents. All non-traditional agent (NTA)-dedicated research (both medical and non-medical) was re-aligned to Project NT3 - Techbase Non-Traditional Agents Defense (ATD). Project TT3, Techbase Technology Transition, pursues efforts to enhance military operational capability, concepts of operation, WMD elimination, and hazard mitigation following a biological warfare or chemical warfare attack.

B. Program Change Summary (\$ in Millions)	FY 2012	FY 2013	FY 2014 Base	FY 2014 OCO	FY 2014 Total
Previous President's Budget	229.200	234.280	220.606	-	220.606
Current President's Budget	225.441	234.280	170.847	-	170.847
Total Adjustments	-3.759	0.000	-49.759	-	-49.759
<ul> <li>Congressional General Reductions</li> </ul>	-	-			
<ul> <li>Congressional Directed Reductions</li> </ul>	-	-			
<ul> <li>Congressional Rescissions</li> </ul>	-	-			
<ul> <li>Congressional Adds</li> </ul>	-	-			
<ul> <li>Congressional Directed Transfers</li> </ul>	-	-			
<ul> <li>Reprogrammings</li> </ul>	-0.608	0.000			
SBIR/STTR Transfer	-3.151	0.000			
Other Adjustments	0.000	0.000	-49.759	-	-49.759

### **Change Summary Explanation**

Funding: FY14

-\$49.759M Other Adjustments (CB3 -\$252K; NT3 -\$7,531K; TM3 -\$48,682K; TT3 +\$6,706K)

Schedule: N/A

PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD) Chemical and Biological Defense Program

**UNCLASSIFIED** 

Page 2 of 43 R-1 Line #39

hibit R-2, RDT&E Budget Item Justification: PB 2014 Chemical and	pit R-2, RDT&E Budget Item Justification: PB 2014 Chemical and Biological Defense Program	
PROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE	,
00: Research, Development, Test & Evaluation, Defense-Wide 3: Advanced Technology Development (ATD)	PE 0603384BP: CHEMICAL/BIOLOGI	CAL DEFENSE (ATD)
Technical: N/A		

Exhibit R-2A, RDT&E Project Ju	ustification	: PB 2014 C	Chemical an	d Biologica	cal Defense Program				DATE: April 2013			
APPROPRIATION/BUDGET ACT 0400: Research, Development, To BA 3: Advanced Technology Devel	est & Evalua	R Evaluation, Defense-Wide PE 0603384BP: CHEMICAL/BIOLOGICAL C				PROJECT CB3: CHEMICAL BIOLOGICAL DEFENSE (ATD)						
COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 <sup>#</sup>	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

<sup>\*</sup>FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

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

This project (CB3) demonstrates technology advancements for Joint Service application in the areas of detection, information systems technology, protection/hazard mitigation, and technology transition efforts. These activities will speed maturing of advanced technologies to reduce risk in system-oriented integration/demonstration efforts. This project also includes efforts dedicated to developing capabilities to protect against Non-Traditional Agents (NTAs). Detection focuses on advanced development of technologies from applied research for standoff and point detection and identification of chemical and biological agents. Information systems advanced technology focuses on areas of advanced warning and reporting, hazard prediction and assessment, simulation analysis and planning, and systems performance modeling. Protection and Hazard Mitigation focuses on advanced development of technologies that protect and reduce the chemical/biological/radiological/nuclear threat or hazard to the Warfighter, weapons platforms, and structures. This project also funds advanced development of chemical and biological defense science and technology initiatives and transitions them to advanced development programs in Budget Activities 4 and 5, through prototypes that are evaluated in Advanced Technology Demonstration (ATDs) and Joint Warfighter Experimentation (JWE). In FY13, all NTA-dedicated research from this Project was re-aligned to Project NT3 - Techbase Non-Traditional Agents Defense (ATD).

B. Acco	mplishments/Planned Programs (\$ in Millions)	FY 2012	FY 2013	FY 2014
<b>Title:</b> 1)	Detection	7.325	5.852	3.514
biologica	otion: Chemical and Biological Stand-off Technology: Focuses on the detection and identification of chemical and all threats in near real-time at a distance from the detector. Future programs focus on the improvement of algorithms, on sources, and detector elements to increase range, reduce false positives, increase sensitivity, and reduce cost.			
Closed	2 Accomplishments: out development of test methodology for next generation chemical standoff technology. Began processes of validating truth systems for point technologies (genomic and proteomic technology) field assessments.			
1	3 Plans: e processes of validating ground truth systems for point technologies (genomic and proteomic technology) field nents.			
FY 2014	4 Plans:			

<sup>##</sup> The FY 2014 OCO Request will be submitted at a later date

Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and B			April 2013				
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)	PE 0603384BP: CHEMICAL/BIOLOGICAL	<b>PROJECT</b> CB3: <i>CHEMICAL I</i> (ATD)	CHEMICAL BIOLOGICAL DEFE				
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013	FY 2014			
Continue processes of validating ground truth systems for point technol assessments.	ogies (genomic and proteomic technology) field						
Title: 2) Detection NTA		7.340	0.000	0.000			
Description: Detection NTA: Focuses on technologies to provide Non-	Traditional Agents (NTA) detection capabilities.						
FY 2012 Accomplishments: Initiated the development of test methodology to validate signatures for in this area was re-aligned to Project NT3 - Techbase Non-Med - Detec		rch					
Title: 3) Information Systems Technology		1.267	0.000	0.000			
<b>Description:</b> Warning and Reporting Information and Analysis: Emphase collaborative information management, fusion of disparate information fundeling, fusion of syndromic/diseases surveillance data, and synthetic acquisition decisions. <b>FY 2012 Accomplishments:</b> Conducted Verification and Validation (V&V) of source term estimation use in complex environments (e.g., variable terrain, urban, water, and be	from multiple sources, environmental databases and c environments for model performance evaluation and (STE) and hazard refinement (HR) algorithms for						
meteorological ensemble predictions in dispersion models to Joint Effect	cts Model (JEM).	0.043	4 747	3.739			
<b>Title:</b> 4) Information Systems Technology <b>Description:</b> Hazard Prediction: Improve battlespace awareness by acatmospheric transport and dispersion, and resulting human effects. Defended of chemical, biological, and industrial materials from weapons and accidental description.	velop predictive capability for the source term of releas	0.913 ses	4.747	3.738			
FY 2012 Accomplishments:  Continued development of the high altitude post-missile intercept effects prediction and counterproliferation model frameworks by drawing upon successfully intercepted weapons as well as intentionally functioning we Continued work on configuration management prototype to implement sidevelopment program requirements. Established field transport and distest archiving.	existing modeling of other agencies and handling both eapons of a chemical, biological or nuclear payload. standard module interfaces to comply with advanced						
FY 2013 Plans:							
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Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and B	iological Defense Program	DATE:	April 2013	
APPROPRIATION/BUDGET ACTIVITY  0400: Research, Development, Test & Evaluation, Defense-Wide  BA 3: Advanced Technology Development (ATD)	R-1 ITEM NOMENCLATURE PE 0603384BP: CHEMICAL/BIOLOGICA DEFENSE (ATD)	PROJECT CB3: CHEMICAL E (ATD)	BIOLOGICAL	DEFENSE
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013	FY 2014
Continue implementation of new numerical schemes for transport and detransport and dispersion models which transitioned from CB2 efforts in prototype to establish upgraded capabilities listed as valid requirements post-missile intercept effects model. Continue with field transport and depermanent test archiving. Continue implementation and testing of new core capable models.	FY12. Continue with work on configuration mana for JEM. Complete development on the high altispersion databases and websites for accessible	gement tude		
FY 2014 Plans:  Continue implementation of new numerical schemes and performance of enhancement of high fidelity urban transport and dispersion. Continue of technology prototype to establish upgraded capabilities listed as valid recapability/JEM (HPAC/JEM). Initiate final development and integration (i.e., hazard predictions given an missile intercepted in flight and hazard payload). Continue providing field transport and dispersion databases a archiving. Continue implementation and testing of new numerical schemodels.	with work on configuration management of science equirements for Hazard Prediction and Assessme of the missile intercept/functioning missile effects dipredictions given a missile that correctly delivers and websites for community accessible permaner	e and nt s model s its nt test		
Title: 5) Information Systems Technology		1.412	0.000	2.000
<b>Description:</b> Operational Effects & Planning: Develop decision support planning and real-time analysis to determine and assess operational eff making. Focus areas include consequence management, population making.	fects, risks, and impacts of CBRN incidents on de			
<b>FY 2012 Accomplishments:</b> Transitioned medical countermeasure models, to include: One Chemica Anthrax, Plague, Lassa Fever, Burkholderia Pseudomallei, and Tularem development will be consolidated under the Operational Effects & Planr	nia models. In FY14, all System Performance Mo			
FY 2014 Plans: Continue system performance model integration with advanced develop generation versions of systems performance models in individual protect				
Title: 6) Information Systems Technology		0.750	1.985	3.144
Description: Data Analysis: Develop Chemical, Biological, Radiologica	I and Nuclear (CBRN) data sharing capabilities.			
FY 2012 Accomplishments:				

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Bio	logical Defense Program		DATE:	April 2013		
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)	R-1 ITEM NOMENCLATURE PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)	PROJECT CB3: CHE (ATD)	B: CHEMICAL BIOLOGICAL DEFE			
B. Accomplishments/Planned Programs (\$ in Millions)			2012	FY 2013	FY 2014	
Performed improvements in CBRN data management capabilities, with e within CBDP systems performance models. Enhanced analysis toolset with decontamination systems.						
FY 2013 Plans: Continue to develop the Chemical and Biological Warfare Agent Effects of Capturing analytical methods for evaluating the effects of CB warfare age initiated in Information Systems Technology, Systems Performance & Info of initial versions of systems performance models in collective protection, decontamination. Initiate system performance model integration with adv. A portion of this effort is funded in Test & Evaluation (TE3). In FY14, all Sconsolidated under the Operational Effects & Planning area.	nts on equipment, personnel, and operations, which ormation Analysis (CB2 - M&S). Conclude developed individual protection, contamination avoidance and vanced development for program-wide exploitation.	ment				
FY 2014 Plans: Integrate additional chapters of the Chemical and Biological Warfare Age source capturing analytical methods for evaluating the effects of CB warfa						
Title: 7) Information Systems Technology			0.867	0.000	0.000	
<b>Description:</b> Medical Surveillance & Information Analysis: Integrate exist warning systems, and leverage and enhance epidemiological models and threat assessment. Contribute to the development of global, near real-tin address secondary infection, fuse medical syndromic, environmental, and modeling, medical resource estimation and decision support tools. Focus estimation, agent-based epidemiological modeling and fusion of disease	d algorithms for disease prediction, impact and biolo ne, disease monitoring and surveillance systems that d clinical data, and feed into agent-based epidemiolo s areas include health/human effects modeling (cas	gical at ogical				
FY 2012 Accomplishments:  Began Validation and Verification (V&V) efforts for existing agent-based educate and disease spread algorithms, with regard to use in robust adaptive re-aligned into Techbase Med Bio-Diagnostics (TM3).						
Title: 8) Biosurveillance (BSV)			0.000	0.000	1.289	
<b>Description:</b> Biosurveillance/Disease Surveillance: Integrate existing diswarning systems, and leverage and enhance epidemiological models and threat assessment. Contribute to the development of global, near real-tinaddress secondary infection, fuse medical syndromic, environmental, and	d algorithms for disease prediction, impact and biolo ne, disease monitoring and surveillance systems that	at				

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Bio	ological Defense Program		DATE:	April 2013			
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)	R-1 ITEM NOMENCLATURE PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)	PROJE CB3: C (ATD)	CHEMICAL BIOLOGICAL DEFEI				
B. Accomplishments/Planned Programs (\$ in Millions)		Г	FY 2012	FY 2013	FY 2014		
modeling, medical resource estimation and decision support tools. Focu disease surveillance data.	us on agent-based epidemiological modeling and fus	ion of					
FY 2014 Plans: Complete effort initiated in Project TM3 (Diagnostics and Disease Surve existing agent-based epidemiological models, to include underlying populiosurveillance data fusion, for use in robust adaptive decision making. diagnostic data) integration for early warning and analytical capabilities of synthesize and interrogate multiple sources of data to provide high confictionary (inclusive of mitigation strategies) of infectious disease outbreaks. Cont to serve as the basis for a biosurveillance cloud for government data. Contegrated set of tools and methods for the collection, storage, recall, and emerging from research, clinical testing, and diagnostics, and other diverging from research.	ulation data and disease spread algorithms, along wind Demonstrate data stream (inclusive of point of need of the BSV Ecosystem. Develop analytic capabilities idence in the prediction, early warning and forecasting inue the development of a scalable, replicable frame continue development of BioID, an infrastructure and discress comparison of a wide array of biologic-related	to g work					
Title: 9) Protection & Hazard Mitigation			0.691	1.637	1.809		
<b>Description:</b> Lightweight Integrated Fabric: Demonstration of lightweigh used as an integrated combat duty uniform.	nt chemical and biological protective textiles that can	be					
FY 2012 Accomplishments: Incorporated next phase of integrated textile systems into a complete se Integrated Protective Ensemble (UIPE) Phase II program. Provided a tracademic candidate materials for use in future UIPE phase initiations. Tadvanced Development - UIPE program so that it can be used in the option.	ade-space analysis of all government, industrial, and ransitioned human performance initial tool set to the						
FY 2013 Plans: Continue to integrate next phase of integrated textile systems into a complete Uniform Integrated Protective Ensemble (UIPE) Phase II program as Demonstrations that may materialize. Continue the trade-space analysis materials for use in future UIPE phase initiations. Continue to transition Development - UIPE program so that it can be used in the optimization of	s well as other applicable Advanced Technology s of all government, industrial, and academic candida the human performance tool set to the Advanced	ate					
FY 2014 Plans: Continue to integrate next phase of integrated textile systems into a community the Uniform Integrated Protective Ensemble (UIPE) Phase II program as Demonstrations that may materialize. Transition new fabric technologies	well as other applicable Advanced Technology	e					

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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 3: Advanced Technology Development (ATD)  R-1 ITEM NOMENCLATURE PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)	PROJECT L CB3: CHEMICAL BIOLOGICAL DEFENSE (ATD)			
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2012	FY 2013	FY 2014	
prototypes and test in a relevant environment. Continue the trade-space analysis of all government, industrial, and acaden candidate materials for use in future UIPE phase initiations. Complete transition the human performance tool set to the Ad-Development - UIPE program so that it can be used in the optimization of protective ensemble design.				
Title: 10) Protection & Hazard Mitigation	0.69	0 1.292	0.937	
<b>Description:</b> Low-Resistance, Low-Profile Filtration: Demonstration of novel filtration media into a lightweight, low-profile, a low-burden individual protective filter, which has enhanced performance against a broader range of challenges that include industrial chemicals.				
FY 2012 Accomplishments: Continued demonstration of novel filtration media into a lightweight, low-profile, and low-burden individual protective filter, very has enhanced performance against a broader range of challenges that includes toxic industrial chemicals. Initiated transition these technologies to the Joint Service General Purpose Mask (JSGPM) and Joint Service Aircrew Mask (JSAM) programs	on of			
FY 2013 Plans: Continue the integration and demonstration of latest generation novel filtration media into a lightweight, low-profile, and low burden individual protective filter, which has enhanced performance against a broader range of challenges that includes to industrial chemicals. Continue transition of these technologies to the JSGPM and JSAM programs.				
FY 2014 Plans: Continue the integration and demonstration of latest generation novel filtration media into a lightweight, low-profile, and low burden individual protective filter, which has enhanced performance against a broader range of challenges that includes to industrial chemicals. Continue transitioning these technologies to the JSGPM and JSAM programs.				
Title: 11) Protection & Hazard Mitigation	0.74	6 0.000	0.467	
<b>Description:</b> Low-Burden Air Purifying Respirator: Demonstration of design alternatives for chemical and biological air-puring respirators to provide enhanced protection with lower physiological burden and improved interface with mission equipment.				
FY 2012 Accomplishments: Advanced concept CBRN technologies were integrated within the confines of the Chem/Bio protection component of the He Electronics and Display System - Upgradable Protection (HEADS-UP) Army Technology Objective (ATO) program, which is multi-service participation for ground applications.				
FY 2014 Plans: Develop prototype respirator and conduct testing in a relevant environment.				
Title: 12) Protection & Hazard Mitigation	0.20	4 0.000	0.000	

PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD) Chemical and Biological Defense Program

**UNCLASSIFIED** 

Page 9 of 43 R-1 Line #39

00: Research, Development, Test & Evaluation, Defense-Wide 3: Advanced Technology Development (ATD)  PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)  (ATD)	-	April 2013				
2012 Accomplishments: monstrated breadboard concepts of a residual life indicator (RLI) for collective filtration systems.  2012 Accomplishments: monstrated breadboard concepts of a residual life indicator (RLI) for collective filtration systems.  2012 Accomplishments: monstrated breadboard concepts of a residual life indicator (RLI) for collective filtration systems.  2012 Accomplishments: monstrated breadboard concepts of a residual life indicator (RLI) for collective filtration systems.  2012 Accomplishments: monstrated breadboard concepts of a residual life indicator (RLI) for collective filtration systems.  2012 Accomplishments: monstrated breadboard concepts of a residual life indicator (RLI) for collective filtration systems.  2012 Accomplishments: monstrated breadboard concepts of a residual life indicator (RLI) for collective filtration systems.  2012 Accomplishments: monstration of non-traditional decontamination technologies and approaches which gain significantly improved effectiveness by complementary application.  2012 Accomplishments: minimued demonstration of non-traditional decontamination technologies and approaches which gain significantly improved ectiveness by complementary application. Integrated robust surface chemistry and decontamination process analysis using a high vacuum system into technology maturation process for hazard mitigation. Demonstrated Integrated Decontamination at Evaluation System (IDTES) live agent testing facility that allows scaled relevant environment evaluations. Pursued the						
scription: Logistically Sustainable Air Purification for Collective Protection: Demonstration of chemical and biological air- ification alternative technologies that minimize or eliminate the need for expendable media within acceptable size, weight, and wer constraints.  2012 Accomplishments: monstrated breadboard concepts of a residual life indicator (RLI) for collective filtration systems.  30 Protection & Hazard Mitigation  30 Scription: Decontamination Family-of-Systems (DFoS): Demonstration of non-traditional decontamination technologies and broaches which gain significantly improved effectiveness by complementary application.  31 2012 Accomplishments: 32 Intinued demonstration of non-traditional decontamination technologies and approaches which gain significantly improved sectiveness by complementary application. Integrated robust surface chemistry and decontamination process analysis using the high vacuum system into technology maturation process for hazard mitigation. Demonstrated Integrated Decontamination at Evaluation System (IDTES) live agent testing facility that allows scaled relevant environment evaluations. Pursued the	lopment, Test & Evaluation, Defense-Wide PE 0603384BP: CHEMICAL/BIOLOGICAL CB3: CHEMICAL BIOLOGICAL DEF					
ification alternative technologies that minimize or eliminate the need for expendable media within acceptable size, weight, and wer constraints.  2012 Accomplishments: monstrated breadboard concepts of a residual life indicator (RLI) for collective filtration systems.  2012 Accomplishments: monstrated breadboard concepts of a residual life indicator (RLI) for collective filtration systems.  2013 Protection & Hazard Mitigation scription: Decontamination Family-of-Systems (DFoS): Demonstration of non-traditional decontamination technologies and proaches which gain significantly improved effectiveness by complementary application.  2012 Accomplishments: ntinued demonstration of non-traditional decontamination technologies and approaches which gain significantly improved ectiveness by complementary application. Integrated robust surface chemistry and decontamination process analysis using ra high vacuum system into technology maturation process for hazard mitigation. Demonstrated Integrated Decontamination at Evaluation System (IDTES) live agent testing facility that allows scaled relevant environment evaluations. Pursued the	2012	FY 2013	FY 2014			
monstrated breadboard concepts of a residual life indicator (RLI) for collective filtration systems.  Ie: 13) Protection & Hazard Mitigation  scription: Decontamination Family-of-Systems (DFoS): Demonstration of non-traditional decontamination technologies and proaches which gain significantly improved effectiveness by complementary application.  Intinued demonstration of non-traditional decontamination technologies and approaches which gain significantly improved ectiveness by complementary application. Integrated robust surface chemistry and decontamination process analysis using a high vacuum system into technology maturation process for hazard mitigation. Demonstrated Integrated Decontamination est Evaluation System (IDTES) live agent testing facility that allows scaled relevant environment evaluations. Pursued the						
scription: Decontamination Family-of-Systems (DFoS): Demonstration of non-traditional decontamination technologies and proaches which gain significantly improved effectiveness by complementary application.  2012 Accomplishments: Intinued demonstration of non-traditional decontamination technologies and approaches which gain significantly improved ectiveness by complementary application. Integrated robust surface chemistry and decontamination process analysis using a high vacuum system into technology maturation process for hazard mitigation. Demonstrated Integrated Decontamination at Evaluation System (IDTES) live agent testing facility that allows scaled relevant environment evaluations. Pursued the						
2012 Accomplishments: Intinued demonstration of non-traditional decontamination technologies and approaches which gain significantly improved ectiveness by complementary application. Integrated robust surface chemistry and decontamination process analysis using ra high vacuum system into technology maturation process for hazard mitigation. Demonstrated Integrated Decontamination set Evaluation System (IDTES) live agent testing facility that allows scaled relevant environment evaluations. Pursued the	1.271	0.397	1.192			
ectiveness by complementary application. Integrated robust surface chemistry and decontamination process analysis using ra high vacuum system into technology maturation process for hazard mitigation. Demonstrated Integrated Decontamination st Evaluation System (IDTES) live agent testing facility that allows scaled relevant environment evaluations. Pursued the						
ent Removal" and "Decontamination Assurance Spray."						
ntinue the development, demonstration, and transition of non-traditional decontamination technologies and approaches ich gain significantly improved effectiveness by complementary application. Continue to integrate and demonstrate robust face chemistry and decontamination process analysis using ultra high vacuum system into technology maturation process for eard mitigation. Continue to develop coatings, innovative chemistries/processes, enzyme approaches to hazard mitigation, man remains decontamination processes, and radiological/nuclear decontamination/hazard mitigation capabilities. Transition antitatively evaluated interim capability for radiological/nuclear decontamination/hazard mitigation.						
ntinue the development, demonstration, and transition of non-traditional decontamination technologies and approaches ich gain significantly improved effectiveness by complementary application. Continue to integrate and demonstrate robust face chemistry and decontamination process analysis using ultra high vacuum system into technology maturation process for zard mitigation. Continue to develop coatings, innovative chemistries/processes, enzyme approaches to hazard mitigation, man remains decontamination processes, and radiological/nuclear decontamination/hazard mitigation capabilities. Transition antitatively evaluated interim capability for radiological/nuclear decontamination/hazard mitigation.						
le: 14) Protection & Hazard Mitigation	0.362	0.000	0.000			

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Exhibit R-2A, RDT&E Project Justi	fication: PB	2014 Chem	ical and Biol	ogical Defen	se Program				DATE: A	pril 2013	
							IOLOGICAL	DEFENSE			
B. Accomplishments/Planned Prog	grams (\$ in N	Millions)							FY 2012	FY 2013	FY 2014
<b>Description:</b> Innovative Systems Cochemical and biological protection of											
FY 2012 Accomplishments: Transitioned research effort "Reactiv	e Airlock for	Armored Ve	hicles, Shipb	oard and Sh	elter Applica	ations."					
Title: 15) Test and Evaluation (T&E)									0.000	4.124	0.00
Continue to develop the Test & Evaluation 1 (CB-1), an authoritative source cappersonnel, and operations. Concludindividual protection, contamination a Med - Modeling and Simulation.	oturing analyt e developme	ical methods nt of initial v	s for evaluati ersions of sy	ng the effect stems perfor	s of CB war	fare agents of lels in collect	on equipment ive protection	i, 1,			
				Accon	nplishment	s/Planned P	rograms Sul	ototals	23.838	20.034	18.09
C. Other Program Funding Summa	ıry (\$ in Milli	ons)									
Line Item  • CB2: CHEMICAL BIOLOGICAL DEFENSE (APPLIED	<b>FY 2012</b> 97.530	<b>FY 2013</b> 44.331	<b>FY 2014 Base</b> 53.901	FY 2014 OCO	FY 2014 Total 53.901	<b>FY 2015</b> 55.042	<b>FY 2016</b> 59.834	<b>FY 201</b> 7 66.483		Cost To Complete Continuing	Total Cos
RESEARCH) • TE3: TEST & EVALUATION (ATD)	10.306	0.000	0.000		0.000	0.000	0.000	0.000	0.000	0.000	10.30
• CA4: CONTAMINATION AVOIDANCE (ACD&P)	13.432	3.038	26.853		26.853	46.788	40.163	34.595		3 Continuing	
• DE4: DECONTAMINATION SYSTEMS (ACD&P)	20.755	12.374	17.870		17.870	10.611	13.174	9.337		) Continuing	
• IS4: INFORMATION SYSTEMS (ACD&P)	5.219	13.831	8.199		8.199	2.845	0.360	0.100		) Continuing	
• TE4: TEST & EVALUATION (ACD&P)	14.458	4.994	15.671		15.671	20.408	15.872	13.044	4 11.04	Continuing	Continuing

PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD) Chemical and Biological Defense Program

UNCLASSIFIED
Page 11 of 43

R-1 Line #39

Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Biological	l Defense Program	DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE	PROJECT
0400: Research, Development, Test & Evaluation, Defense-Wide	PE 0603384BP: CHEMICAL/BIOLOGICAL	CB3: CHEMICAL BIOLOGICAL DEFENSE
BA 3: Advanced Technology Development (ATD)	DEFENSE (ATD)	(ATD)

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

			FY 2014	FY 2014	FY 2014					Cost To	
<u>Line Item</u>	FY 2012	FY 2013	Base	OCO	<u>Total</u>	FY 2015	FY 2016	FY 2017	FY 2018	Complete	<b>Total Cost</b>
• TT4: TECHBASE TECHNOLOGY	2.985	3.377	0.000		0.000	0.000	0.000	0.000	0.000	0.000	6.362

TRANSITION (ACD&P)

Remarks

D. Acquisition Strategy

N/A

**E. Performance Metrics** 

N/A

Exhibit R-2A, RDT&E Project J	ustification	: PB 2014 C	Chemical an	d Biologica	l Defense P	rogram				<b>DATE:</b> Apr	il 2013	
APPROPRIATION/BUDGET AC 0400: Research, Development, T BA 3: Advanced Technology Dev	est & Evalua		se-Wide		R-1 ITEM I PE 060338 DEFENSE	34BP: <i>CHEI</i>	<b>ATURE</b> MICAL/BIOL	OGICAL	PROJECT NT3: TECH AGENTS L		N-TRADITIO ATD)	DNAL
COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 <sup>#</sup>	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

<sup>\*</sup>FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

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

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

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2012	FY 2013	FY 2014
Title: 1) Techbase Medical Defense - NTA Diagnostics	0.000	0.404	0.574
<b>Description:</b> Chem Diagnostics NTA: Focuses on state-of-the-art laboratory/fieldable methods that detect exposure to non-traditional agents in clinical samples. It also targets the identification of biomolecular targets that can be leveraged as analytical methodologies, as well as, laboratory and animal studies characterizing time-course and longevity of a particular analyte/biomarker.			
FY 2013 Plans: Continue development of mature technologies that can quickly diagnose pre-symptomatic NTA exposure. Funding for this research area was re-aligned from Tech Base Med Defense - Diagnostics NTA (TC3).			
FY 2014 Plans: Continue development of mature technologies that can quickly diagnose pre-symptomatic NTA exposure. Transition method development for identification and validation of NTAs in clinical samples to the Laboratory Response Network.			
Title: 2) Techbase Medical Defense - NTA Pretreatments	0.000	0.503	3.960

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<sup>##</sup> The FY 2014 OCO Request will be submitted at a later date

Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and I	Biological Defense Program		DATE: A	April 2013	
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)	R-1 ITEM NOMENCLATURE PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)			ION-TRADIT E (ATD)	IONAL
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2012	FY 2013	FY 2014
<b>Description:</b> Chemical Medical Pretreatments NTA: Develop nerve against non-traditional agents. Enzymes should have the ability to rap binding specificity and high catalytic efficiency for the destruction of ag bioscavenger should be capable of detoxifying numerous molecules of catalytic bioscavenger to protect against a large dose of nerve agent	oidly bind and detoxify nerve agents, and have broad gents. For enzyme approaches, one molecule of cata f nerve agents resulting in the capability for a small qu				
FY 2013 Plans: Continue exploitation of alternative expression systems for production study of use of plasma derived human butylcholinesterase (huBChE) a research area was re-aligned from Tech Base Med Chem - Pretreatment	as prophylactic for all nerve agents. Funding for this	lete			
FY 2014 Plans: Continue exploitation of alternative expression systems for production facilitate high throughput screening and development of medical count		nods to			
Title: 3) Techbase Medical Defense - NTA Therapeutics			0.000	10.055	9.93
<b>Description:</b> Chemical Medical Therapeutics NTA: Determine the toxi refine standard experimental routes. Physiological parameters and parameters and parameters and mechanisms of toxicity.					
FY 2013 Plans: Continue formulation and stability studies. Begin safety studies in smaresearch area was re-aligned from Tech Base Med Chem - Therapeut		for this			
FY 2014 Plans: Continue formulation and stability studies of therapeutic compounds. formulations of centrally active reactivator or anti-cholinergic compoun	•	ed			
Title: 4) Techbase Non-Medical - Detection			0.000	13.373	5.322
<b>Description:</b> Detection NTA: Focuses on technologies to provide NTA	A detection capabilities.				
FY 2013 Plans: Continue the development of test methodology to validate signatures f research area was re-aligned from Tech Base Non-Med Defense -		;			

Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Bi	ological Defense Program		DATE: A	April 2013	
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)	R-1 ITEM NOMENCLATURE PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)		ECT FECHBASE N TS DEFENSI		IONAL
B. Accomplishments/Planned Programs (\$ in Millions)  Continue the development of test methodology to validate signatures for	r chemical aerosol threat materials		FY 2012	FY 2013	FY 2014
Title: 5) Techbase Non-Medical - Modeling & Simulation	Total made materials.		0.000	0.000	0.288
<b>Description:</b> Modeling & Simulation NTA: Provide modeling of NTA macountermeasures. Develop NTA source term algorithms for predicting Counter-proliferation scenarios (bomb on target), and missile intercept. where a missile has released its chemical or biological payload as it was our missile interdiction. Transition NTA agent fate for secondary effects waterborne transport and dispersion, human effects, model Validation a and supporting data management.	CBRN hazards from intentionally functioning weapor "Intentionally Functioning Weapons" refers to the cast s designed, rather than where the release was caust s, environmental/atmospheric chemistry, atmospheric	ns, ase ed by c and			
FY 2014 Plans: Conduct analysis and oversight of the final year of NTA simulant testing terms, for defense against CBRN hazards.	related to creating and verifying NTA modeling sou	rce			
Title: 6) Techbase Non-Medical - Protection & Hazard Mitigation			0.000	0.348	0.000
Description: Protection & Hazard Mitigation - NTA Air Purification: Stud	ly and assessment of filter technologies.				
FY 2013 Plans: Continue development, verification and demonstration of novel materials technologies to the Joint Service General Purpose Mask (JSGPM) and this research area was re-aligned from Tech Base Non-Med Defense - F	Joint Service Aircrew Mask (JSAM) programs. Fund				
Title: 7) Techbase Non-Medical - Protection & Hazard Mitigation			0.000	0.349	1.065
<b>Description:</b> Protection & Hazard Mitigation - NTA Percutaneous Protection	ction: Study and assessment of protective technology	gies.			
FY 2013 Plans: Continue the verification of protective fabrics against non-traditional age technologies (such as reduced thermal-burden fabrics, and lighter weigh performance against NTAs. Funding for this research area was re-align Hazard Mitigation NTA (CB3).  FY 2014 Plans:	nt fabrics) to improve overall protective clothing				

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Exhibit R-2A, RDT&E Project Ju	stification: PB	2014 Chem	ical and Biol	ogical Defen	se Program				DATE: A	pril 2013	
APPROPRIATION/BUDGET ACT 0400: Research, Development, Te BA 3: Advanced Technology Deve	est & Evaluation,	, Defense-W	/ide	PE 06	EM NOMEN 03384BP: C NSE (ATD)		IOLOGICAL			ION-TRADIT E (ATD)	IONAL
B. Accomplishments/Planned P	rograms (\$ in I	Millions)							FY 2012	FY 2013	FY 2014
Continue verification, demonstration against NTAs. Transition technology							thing perforr	mance			
Title: 8) Techbase Non-Medical -	Protection & Ha	azard Mitigat	tion						0.000	0.350	1.238
Description: Protection & Hazard	l Mitigation - NT	A Decontan	nination: Stu	dy and asses	sment of de	contaminati	on technolog	gies.			
FY 2013 Plans: Continue verification and demonstenzyme technology for low-impact decontamination and hazard mitig research area was re-aligned from	t decon of NTAs ation technolog	s. Continue ies and deve	to enhance lelop addition	NTA related al processes	understandi for NTA ha	ng and capa zard mitigati	bilities of cur	rrent			
FY 2014 Plans: Continue verification, demonstration - Decontamination Family of System decontamination of NTAs, and tracurrent decontamination and haza	ems (DFoS) pronsition these tec	gram. Cont chnologies.	inue to deve Continue to	lop and dem enhance NT	onstrate enz A-related ur	yme techno derstanding	logy for low- and capabil	impact			
Title: 9) Techbase Non-Medical -	Test & Evaluation	on							0.000	6.534	0.951
<b>Description:</b> Test and Evaluation activities.	(T&E) NTA: De	evelops test	and evaluati	on technolog	ies and pro	cesses in su	pport of NTA	<b>\</b>			
FY 2013 Plans: Complete initial select agent testir from Tech Base Non-Med Defens				testing. Fu	nding for this	s research a	rea was re-a	ligned			
FY 2014 Plans: Continue further prioritized select	agent testing.										
				Accon	nplishment	s/Planned P	rograms Su	ubtotals	0.000	31.916	23.333
C. Other Program Funding Sum	mary (\$ in Milli	ions)	FY 2014	FY 2014	FY 2014					Cost To	
<u>Line Item</u>	FY 2012	FY 2013	Base	OCO	Total	FY 2015	FY 2016	FY 2017	FY 2018	Complete	
• NT2: TECHBASE NON- TRADITIONAL AGENTS	0.000	60.730	75.053		75.053	71.749	72.932	77.542	77.805	5 Continuing	Continuing

PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD) Chemical and Biological Defense Program

R-1 Line #39

Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Biologica	l Defense Program	DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE	PROJECT
0400: Research, Development, Test & Evaluation, Defense-Wide	PE 0603384BP: CHEMICAL/BIOLOGICAL	NT3: TECHBASE NON-TRADITIONAL
BA 3: Advanced Technology Development (ATD)	DEFENSE (ATD)	AGENTS DEFENSE (ATD)

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

-	2: Other i regram i anamg camma	<u> </u>	<u>0113)</u>	EV 2014	EV 2014	FY 2014					Coat To	
	Line Item	FY 2012	FY 2013	FY 2014 Base	FY 2014 OCO	Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
	DEFENSE (APPLIED											
	RESEARCH)											
	• CA4: CONTAMINATION	13.432	3.038	26.853		26.853	46.788	40.163	34.595	2.873	Continuing	Continuing
,	AVOIDANCE (ACD&P)											
	• DE4: <i>DECONTAMINATION</i>	20.755	12.374	17.870		17.870	10.611	13.174	9.337	5.500	Continuing	Continuing
	SYSTEMS (ACD&P)											
	• IP4: INDIVIDUAL PROTECTION	0.000	1.102	2.708		2.708	6.811	4.680	0.300	0.000	0.000	15.601
	(ACD&P)											_
	• MC4: MEDICAL CHEMICAL	7.697	0.000	2.000		2.000	3.705	5.114	10.920	24.186	Continuing	Continuing
	DEFENSE (ACD&P)											
	• TE4: TEST & EVALUATION	14.458	4.994	15.671		15.671	20.408	15.872	13.044	11.044	Continuing	Continuing
	(ACD&P)											

### **Remarks**

# D. Acquisition Strategy

N/A

### **E. Performance Metrics**

N/A

Exhibit R-2A, RDT&E Project J	ustification	: PB 2014 C	Chemical an	d Biologica	I Defense P	rogram				<b>DATE:</b> Apr	il 2013	
APPROPRIATION/BUDGET AC						NOMENCL			PROJECT			
0400: Research, Development, 7			se-Wide			34BP: <i>CHEI</i>	MICAL/BIOL	.OGICAL	_	ICAL BIOLO	OGICAL DE	FENSE
BA 3: Advanced Technology Dev	eiopment (A	(10)			DEFENSE	(AID)			(ATD)			
COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 <sup>#</sup>	FY 2014 Base	FY 2014 OCO ##	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
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

<sup>\*</sup>FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

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

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

This project includes the Transformational Medical Technologies Initiative (TMTI). The program was launched to respond to the threat of emerging or intentionally engineered biological threats. TMT's mission is to protect the Warfighter from genetically engineered or emerging infectious disease biological threats by providing a rapid response capability from identification of pathogens to the delivery of medical countermeasures. This mission is accomplished through two main efforts:

1) developing broad spectrum (multi-agent) therapeutics against BW or emerging infectious disease agents (e.g. one drug that treats multiple agents); and 2) developing platform technologies to assist in the rapid development of medical countermeasures (MCMs) in response to BW or emerging infectious disease agents (e.g. developing new and innovative ways to mass produce drugs in the event of a biological incident). Effective FY12 this effort was funded as the Transformational Medical Technologies (TMT) Program.

The Medical Countermeasures Initiative (MCMI) was established to coordinate inter-related advanced development and flexible manufacturing capabilities 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 science and technology (S&T) are concentrated in three areas: 1)

<sup>##</sup> The FY 2014 OCO Request will be submitted at a later date

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

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APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)	R-1 ITEM NOMENCLATURE PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)	PROJECT TB3: MEDICAL B (ATD)	IOLOGICAL D	EFENSE
transition of novel platform/expression systems for MCMs, 2) transition addevelopment and manufacturing.	vancement of regulatory science, and 3) integrati	on of novel platform	ns with MCM a	advanced
In FY13, all research in this Project (TB3) was re-aligned to Project TM3 -	Techbase Medical Defense (ATD).			
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013	FY 2014
Title: 1) Medical Countermeasures Initiative (MCMI)		28.87	0.000	0.000
<b>Description:</b> The MCMI will integrate the regulatory science and manufacturadvanced development and flexible manufacturing capability (MCM-Advance)		the		
FY 2012 Accomplishments: Initiated and refined the development of multi-product/multi-use MCM techn MCMs for CBRN threats and emerging infectious diseases. Evaluated and with the intent that FDA regulatory approval of the same platform for one proother products based on the same system. Initiated and refined development and accelerate the development and regulatory review of medicinal product into Techbase Med Defense - Medical Countermeasures Initiative (TM3).	exploited the regulatory advantages of such systoduct will simplify subsequent regulatory approvant of new technologies and approaches that facil	ems, Is of itate		
Title: 2) Diagnostics (Biosurveillance)		12.28	0.000	0.000
<b>Description:</b> Diagnostic Technologies: Development and verification of rap of Biological Warfare Agents (BWAs) and their expressed toxins in biological infection. Discovery of biomarkers of response to exposure. Evaluation of a portable instrument platforms, highly parallel and informative testing formats.	al fluids of Warfighters for the diagnosis of exposunext generation diagnostic technologies including	ıre/		
FY 2012 Accomplishments:  Validated and submitted pre-EUA (Emergency Use Authorization) data to Fito preposition for biopreparedness. Transitioned portable sequence based priority agents. Transitioned technology watch report and mature candidated development as Next Generation Diagnostics System and/or Biosurveillance of antibiotic (Cipro) resistance. Validated and transitioned scale-up protocolantibodies to bacterial and viral BWA targets for use in austere environment genetically representative strain collection and transfer to repository; development agent of high genetic variability. Transitioned atlas/database of phenomena.	genetic analyzer and verified assays for top ten e platform technologies of sufficient utility for adva e platform. Transitioned data packages for detect ls for single domain biosynthetic (recombinant) is. Supplemented/continued accrual of geograph ped quantitative cell culture for an additional eme	inced ition ically/ erging		

PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD) Chemical and Biological Defense Program

DATE: April 2013

Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Bio	ological Defense Program		DATE: A	April 2013	
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)	R-1 ITEM NOMENCLATURE PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)	PROJECT TB3: ME (ATD)	СТ	DLOGICAL D	EFENSE
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2012	FY 2013	FY 2014
bacterial strains to advanced developer. In FY13, all research in this are Diagnostics.	ea was re-aligned into Project TM3 - Techbase Med I	Віо -			
Title: 3) Pretreatments			2.564	0.000	0.000
<b>Description:</b> Bacterial/Toxin Vaccines: Evaluates the best single agent aerosol challenge in large animal models.	bacterial and toxin vaccines for effectiveness against	t			
FY 2012 Accomplishments:  Performed final analysis of data from Phase I Clinical trial. Assembled fithis area was re-aligned into Project TM3 - Techbase Med Bio - Pretreat		ch in			
Title: 4) Pretreatments			19.530	0.000	0.000
<b>Description:</b> Viral Vaccines: Evaluates the best vaccine candidates for duration of protective immune response against aerosol challenge in larg support FDA licensure of mature vaccine candidates. The purpose of destudies under the "Animal Rule".	ge animal models. Animal models will be developed				
FY 2012 Accomplishments:  Completed remaining aerosol efficacy studies for the Ebola Zaire and Et Conducted formulation studies of Ebola and Marburg vaccine componer immunological assays to support advanced development. Coordinated support of the Filovirus vaccine transition. For Alphavirus DNA vaccines for the Venezualan Equine Encephalomyelitis (VEE) component, submit clinical trial. As a part of this trial, assessed alternative methodologies for intra-dermal administration, manufactured clinical grade (sufficient quitrial) lots of the EEE (Eastern) and WEE (Western) DNA components. WEE DNA formulation. For the Alphavirus replicon vaccine, conducted models for Alphaviruses (EEE and WEE), and Filoviruses (Ebola Sudan future FDA 'Animal Rule' requirements necessary for vaccine licensure. FY11, work continued on the selected candidate(s) to fill knowledge gap Project TM3 - Techbase Med Bio - Pretreatments.	nts. Initiated the development of Filovirus and Alphave with the advanced developer to fulfill S&T needs in section, completed an Investigational New Drug (IND) packed the IND package to the FDA and initiated a Phase or vaccine delivery (i.e., electroporation) via intra-musuality to be administered to humans in a Phase I clinic Conducted pre-clinical studies on a trivalent VEE, EE pre-clinical studies. Continued development of anim, Ebola Zaire, Ebola Bundibugyo, and Marburg), to further Although the Filovirus vaccines were transitioned in	virus age e I scular al E, als			
Title: 5) Pretreatments			3.450	0.000	0.000
<b>Description:</b> Vaccine Platforms and Research Tools: Conducts studies vaccine candidates, the effect of alternative vaccine delivery methods are					

PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD) Chemical and Biological Defense Program

Page 20 of 43

R-1 Line #39

xhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Biological Defense Program PPROPRIATION/BUDGET ACTIVITY 400: Research, Development, Test & Evaluation, Defense-Wide R-1 ITEM NOMENCLATURE PE 0603384BP: CHEMICAL/BIOLOGICA			April 2013		
		IFCT			
A 3: Advanced Technology Development (ATD)  DEFENSE (ATD)	PROJECT  AL TB3: MEDICAL BIOLOGICAL DEFEN				
. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013	FY 2014	
accine candidates. Identifies correlates of protection in humans, and predicts the success of lead vaccine candidates in /ork conducted under Vaccine Platforms and Research Tools are distinct from those performed under Viral Vaccines be ne focus is on the use of novel technologies to support vaccine candidates, not on the vaccine candidates themselves. latforms and Research Tools utilize novel technologies to stabilize advanced vaccine candidates as well as alternative condalities.	cause accine				
Y 2012 Accomplishments: ontinued evaluation of the safety and immune stimulating capability of mature Filovirus and Alphavirus vaccine candidate umans by using the Modular Immune In Vitro Construct (MIMIC) technology. Continued formulation studies to produce table, spray-dried formulation of an advanced vaccine candidate. Evaluated additional stabilization technologies that protein a stability to multiple classes of vaccines such as viral vectored vaccines and subunit protein vaccines. Tested alteredle-free) vaccine delivery technologies such as inhalers or skin patches for the delivery of mature vaccine candidates valuated clinical samples from Filovirus and Alphavirus outbreaks in multiple international locations to determine human esponses. In FY13, all research in this area was re-aligned into Project TM3 - Techbase Med Bio - Pretreatments.	a thermo- ovide rnative				
itle: 6) Therapeutics		6.029	0.000	0.000	
<b>escription:</b> Viral Therapeutics: Identify, optimize and evaluate potential therapeutic candidates effective against designate agents.	ated viral				
Y 2012 Accomplishments: valuated polyclonal immunotherapies for Filoviruses in non-human primate models. Initiated projects to develop monocontibody-based therapies for Filovirus infection. Continued evaluation of optimized lead compounds against Alphaviruses nimal models of infection. Continued evaluation of Filovirus vaccines as treatments for post-exposure Filovirus infection lentified and evaluate FDA approved drugs and combinations of drugs for activity against Filoviruses and Alphaviruses i cell culture. Evaluated select FDA-approved drugs for efficacy against Filoviruses in animal models of infection. Initiated expanded screening program to determine efficacy of FDA approved compounds against other viral infectious diseases (lavivirus, Arenavirus, Bunyavirus). Identified and optimized novel host-directed small molecule inhibitors, with activity against Viruses (i.e., Filovirus, Flavivirus, Arenavirus, and Bunyavirus). In FY13, all research in this area was re-aligned roject TM3 - Techbase Med Bio-Therapeutics (ATD).	in n an e. ainst				
itle: 7) Therapeutics		3.753	0.000	0.000	
<b>escription:</b> Bacterial Therapeutics: Identify, optimize, and evaluate potential therapeutic compounds effective against bareat agents.	acterial				
Y 2012 Accomplishments:					

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Bio	logical Defense Program		DATE:	April 2013			
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)	R-1 ITEM NOMENCLATURE PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)	PROJECT TB3: MEDICAL BIOLOGI (ATD)			CAL DEFENSE		
B. Accomplishments/Planned Programs (\$ in Millions)		F	Y 2012	FY 2013	FY 2014		
Evaluated Protein Design Process optimized anthrax capsule depolyment infection. Transitioned data package demonstrating efficacy of FDA appr Y. pestis in nonhuman primate models. Conducted studies to determine Burkholderia, Francisella tularensis in murine animal models. Evaluated enzyme in small animal models. In FY13, all research in this area was retherapeutics (ATD).	roved compounds against lethal challenge of aerosc efficacy against FDA approved compounds against small molecule inhibitors targeting Y. pestis ATPasc						
Title: 8) Transformational Medical Technologies			38.603	0.000	0.000		
<b>Description:</b> Multiagent (Broad Spectrum) Medical Countermeasures: Countermeasures: Countermeasures: Countermeasures: Countermeasures: And Intracellular Bacterial Pathogen (IBP). Focuses on the initiation and countermeasures, to include safety, toxicity, efficacy, and scalability work ability to formulate Good Manufacturing Practices (GMP), pilot lots and for activities in this capability area. The preclinical drug discovery process Drug (IND) application to the Food and Drug Administration (FDA), to detail safety evaluation in humans.	cuntermeasures for Hemorrhagic Fever Virus (HFV) completion of preclinical studies for candidate in accordance with the product's intended use. Thurther mature promising drug candidates will be the sculminates in the submission of an Investigational	focus New					
FY 2012 Accomplishments:  Continued pre-clinical research required to submit IND applications to the indications to refresh the HFV, IBP, and Emerging Infectious Disease (Ell 1 clinical trials and additional studies for INDs as required by the FDA prid development of animal models for future advanced development of MCM incorporating feedback from the FDA and Services into requirements. In TM3 - Techbase Med-Bio Therapeutics.	D product) pipelines. Continued planning for Phase or to safety evaluation in humans. Continued the is currently in the S&T phase of development,						
Title: 9) Transformational Medical Technologies			53.592	0.000	0.000		
<b>Description:</b> Development of Platform Technologies: Continues efforts p Technologies Initiative. Platform Technologies are stand alone enabling strategically aligned, provide a system of systems response capability to an unknown pathogen to the development of an approved countermeasu The enabling technologies are divided into five platform areas: Pathogen Discovery, Countermeasure Evaluation, and Bioinfomatics. Efforts focus for Platform Technologies to include the maturation of components that w response pipeline. Off-the-shelf technologies will be identified, evaluated	technologies that support MCM development and wan adverse biological event - from the identification re ready for delivery to the Warfighter and the nation Characterization, Target Identification, Countermea on advanced technology and development activitie vill begin the process of integrating a countermeasure	hen of n. sure s					

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Biole						
APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE	PROJECT	ROJECT B3: MEDICAL BIOLOGICAL DEFEN			
0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)	PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)	(ATD)	EFENSE			
B. Accomplishments/Planned Programs (\$ in Millions)		FY	2012	FY 2013	FY 2014	

217 to complication of the minimum of	1 1 2012	1 1 2015	1 1 2017
development capabilities. Advanced manufacturing platforms will continue to mature and the technology application will focus on the type of specific therapeutics under development.			
FY 2012 Accomplishments:  Invested to fund Bio-Surveillance efforts and integrated stand-alone platforms into system-wide capabilities. Continued development of rapid drug discovery and development platform technologies, and built upon early success to fully integrate the entire system using robust bioinformatics capabilities, validated the integrated bioinformatics platform. Increased investment to mature and accelerate manufacturing platform technologies for biological drugs to comply with regulatory guidelines. Supported compliance and quality measures that are mandatory for future FDA submissions. Fully integrated pathogen characterization, target identification, countermeasure discovery and countermeasure evaluation platform areas into a rapid response capability supported by a centralized bioinformatics capability that link geographically separated performers from government agencies, industry and academia. In FY13, all research in this area was re-aligned to Project TM3 - Techbase Med-Bio Diagnostics.			
Accomplishments/Planned Programs Subtotals	168.684	0.000	0.000

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

			FY 2014	FY 2014	FY 2014					Cost To	
<u>Line Item</u>	FY 2012	FY 2013	<b>Base</b>	OCO	<u>Total</u>	FY 2015	FY 2016	FY 2017	FY 2018	<b>Complete</b>	<b>Total Cost</b>
• TM3: TECHBASE MED	0.000	182.330	122.717		122.717	99.930	107.506	123.790	126.110	Continuing	Continuing
DEFENSE (ATD)											
<ul> <li>MB4: MEDICAL BIOLOGICAL</li> </ul>	121.170	133.254	122.936		122.936	95.724	78.461	41.661	30.014	Continuing	Continuing
DEFENSE (ACD&P)											
<ul> <li>MB5: MEDICAL BIOLOGICAL</li> </ul>	197.907	212.056	263.443		263.443	228.199	183.390	151.455	184.222	Continuing	Continuing
DEFENSE (EMD)											
<ul> <li>MB7: MEDICAL BIOLOGICAL</li> </ul>	5.371	0.498	0.499		0.499	13.414	14.551	9.816	3.277	Continuing	Continuing
DEFENSE (OP SYS DEV)											

#### Remarks

## D. Acquisition Strategy

N/A

### E. Performance Metrics

N/A

PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD) Chemical and Biological Defense Program

**UNCLASSIFIED** 

Page 23 of 43

R-1 Line #39

Exhibit R-2A, RDT&E Project J	id Biologica	ical Defense Program						DATE: April 2013				
APPROPRIATION/BUDGET AC 0400: Research, Development, 7 BA 3: Advanced Technology Dev	PE 0603384BP: CHEMICAL/BIOLOGICAL				PROJECT TC3: MED (ATD)		ENSE					
COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 <sup>#</sup>	FY 2014 Base	FY 2014 OCO ##	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
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

<sup>\*</sup>FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

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

Accomplishments/Planned Programs (\$ in Millions)

This project (TC3) supports the advanced development of medical countermeasures to include prophylaxes, pretreatments, antidotes, skin decontaminants and therapeutic drugs against identified and emerging chemical warfare threat agents. Analytical stability studies, safety and efficacy screening, and preclinical toxicology studies are performed prior to full-scale development of promising pretreatment or treatment drug compounds. Entry of candidate pretreatment/prophylaxes, therapeutics, and diagnostic technologies into advanced development (i.e., efforts funded in Budget Activities 4 and 5) is facilitated by the development of technical data packages that support the Food and Drug Administration (FDA) Investigational New Drug (IND) application and licensure processes, as well as Department of Defense (DoD) acquisition regulations. Categories for this project include Pretreatments, Diagnostics, and Therapeutics to address Chemical Warfare Agent (CWA) and Non-Traditional Agents (NTAs) exposure. In FY13, all non-NTA research in this Project (TC3) was re-aligned to Project TM3 - Techbase Medical Defense (ATD).

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2012	FY 2013	FY 2014
Title: 1) Diagnostics	0.876	0.000	0.000
<b>Description:</b> Diagnostic Technologies: Focuses on state-of-the-art laboratory/fieldable methods that detect exposure to chemical warfare agents (CWA) (e.g., nerve agents and vesicants) in clinical samples. It also targets the identification of biomolecular targets that can be leveraged as analytical methodologies, as well as laboratory and animal studies characterizing time-course and longevity of a particular analyte/biomarker.			
FY 2012 Accomplishments:  Expanded the current set of analytical methods to more sensitive analytical platforms for the detection of CWAs. In FY13, all research in this area was re-aligned to Project TM3 - Techbase Med Chem - Diagnostics.			
Title: 2) Chem Diagnostics NTA	1.431	0.000	0.000
<b>Description:</b> Chem Diagnostics NTA: Focuses on state-of-the-art laboratory/fieldable methods that detect exposure to non-traditional agents in clinical samples. It also targets the identification of biomolecular targets that can be leveraged as analytical methodologies, as well as, laboratory and animal studies characterizing time-course and longevity of a particular analyte/biomarker.			
FY 2012 Accomplishments:			

<sup>##</sup> The FY 2014 OCO Request will be submitted at a later date

	UNCLASSIFIED				
Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Biolo	ogical Defense Program		DATE: A	April 2013	
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)	R-1 ITEM NOMENCLATURE PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)	PROJEC TC3: ME (ATD)		EMICAL DEF	ENSE
B. Accomplishments/Planned Programs (\$ in Millions)		F	Y 2012	FY 2013	FY 2014
Continued evaluation of mature technologies that can quickly diagnose prothis area was re-aligned to Project NT3 - Techbase Med Defense - NTA D		ch in			
Title: 3) Pretreatments			1.367	0.000	0.000
<b>Description:</b> Nerve Agent, Pretreatments: Develop pretreatments that proagents. The enzymes should have the ability to rapidly bind and detoxify and high enzymatic efficiency for the destruction of agents. For enzyme a should be capable of detoxifying numerous molecules nerve agents result bioscavenger to protect against a large dose of nerve agent.	nerve agents, and have broad binding specificity approaches, one molecule of catalytic bioscavenger				
FY 2012 Accomplishments: Refined methods and expression systems for large-scale production and pretreatment delivery methods and retention approaches in animal models (PBPK). Developed binding proteins in animal models for safety and efficiency of the project TM3 - Techbase Medical Defense - Pretreatments.	s, including physiologically based pharmacokinetics	6			
Title: 4) Chem Pretreatments NTA			0.880	0.000	0.000
<b>Description:</b> Chem Pretreatments NTA: Develop nerve agent enzyme pretraditional agents. Enzymes should have the ability to rapidly bind and deand high catalytic efficiency for the destruction of agents. For enzyme appropriate should be capable of detoxifying numerous molecules nerve agents result bioscavenger to protect against a large dose of nerve agent.	toxify nerve agents, and have broad binding specifionoaches, one molecule of catalytic bioscavenger	city			
FY 2012 Accomplishments: Tested improved nerve agent enzyme pretreatment delivery methods and physiologically based pharmacokinetics. Further developed binding protein research in this area was re-aligned to Project NT3 - Techbase Medical Description.	ins in animal models for safety and efficacy. In FY	13, all			
Title: 5) Therapeutics			3.645	0.000	0.000
<b>Description:</b> Cutaneous and Ocular: Focuses on minimizing injuries to dechemical warfare agents (CWA). This work is designed to support eventual compounds or new indications for licensed products for use in the treatment	al Food and Drug Administration (FDA) licensure o				
FY 2012 Accomplishments:					

PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)

UNCLASSIFIED

Chemical and Biological Defense Program

Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Bi	ological Defense Program	DATE:	April 2013			
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)	R-1 ITEM NOMENCLATURE PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)	PROJECT TC3: MEDICAL CHEMICAL DEFENSE (ATD)				
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013	FY 2014		
Determined the most effective cell-based approaches to facilitate healin Completed evaluation of potential wound healing products for advanced decontaminate penetrating wounds that have been exposed to CWAs. animal models to treat skin and eye injuries as a result of sulfur mustard aligned to Project TM3 - Techbase Med Chem - Therapeutics.	development. Evaluated candidate approaches to Continued to assess molecular biology approaches in	1				
Title: 6) Therapeutics		4.355	0.000	0.00		
<b>Description:</b> Neurologic: Focuses on therapeutic strategies to effective to chemical warfare agents (CWA). This effort involves the development neurotransmitter restorers. Supports eventual Food and Drug Administration indications for licensed products for use in the treatment of chemical war <b>FY 2012 Accomplishments:</b> Continued animal model evaluation of novel and/or FDA approved drugs exposure. Continued development of animal models related to nerve agrandardization of in vitro and in vivo testing of therapeutic candidates. TM3 - Techbase Medical Chemical - Therapeutics	of neuroprotectants, anticonvulsants, and improved ration (FDA) licensure of new compounds or new rfare casualties.  Is not previously tested for treatment of nerve agent gent exposure. Maintained core capabilities for					
Title: 7) Chem Therapeutics NTA		8.628	0.000	0.00		
<b>Description:</b> Non-Traditional Agents (NTA): Determine the toxic effects standard experimental routes. Physiological parameters and pathologic and mechanisms of toxicity.						
FY 2012 Accomplishments:  Completed characterization of a novel therapeutic for manufacturability testing and stability. This work continues efforts initiated in prior years varea. In FY13, all research in this area was re-aligned to Project NT3 -	vithin the Project TC3 - Chemical Therapeutics capab					
	Accomplishments/Planned Programs Sub	totals 21.182	0.000	0.00		

Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Biological		DATE: April 2013	
APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE	<b>PROJECT</b>	
0400: Research, Development, Test & Evaluation, Defense-Wide	PE 0603384BP: CHEMICAL/BIOLOGICAL	TC3: MED	ICAL CHEMICAL DEFENSE
BA 3: Advanced Technology Development (ATD)	DEFENSE (ATD)	(ATD)	

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

	• •	<del></del>	FY 2014	FY 2014	FY 2014					<b>Cost To</b>	
<u>Line Item</u>	FY 2012	FY 2013	Base	OCO	<u>Total</u>	FY 2015	FY 2016	FY 2017	FY 2018	Complete	<b>Total Cost</b>
• TM2: TECHBASE MED	0.000	118.208	98.111		98.111	104.361	102.546	99.523	103.441	Continuing	Continuing
DEFENSE (APPLIED											
RESEARCH)											
• TM3: TECHBASE MED	0.000	182.330	122.717		122.717	99.930	107.506	123.790	126.110	Continuing	Continuing
DEFENSE (ATD)											
• MC4: MEDICAL CHEMICAL	7.697	0.000	2.000		2.000	3.705	5.114	10.920	24.186	Continuing	Continuing
DEFENSE (ACD&P)											
MC5: MEDICAL CHEMICAL	2.336	9.642	55.087		55.087	58.342	57.675	47.340	28.759	0.000	259.181
DEFENSE (EMD)											

### Remarks

# D. Acquisition Strategy

N/A

### **E. Performance Metrics**

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Biological Defense Program										<b>DATE:</b> Apr	il 2013		
APPROPRIATION/BUDGET ACT	TIVITY				R-1 ITEM NOMENCLATURE PROJECT					CT CT			
0400: Research, Development, To		PE 060338	34BP: <i>CHEI</i>	MICAL/BIOL	LOGICAL	TE3: <i>TES1</i>	T & EVALUATION (ATD)						
BA 3: Advanced Technology Deve	elopment (A	TD)			DEFENSE	(ATD)							
COST (\$ in Millions)	All Prior			FY 2014	FY 2014	FY 2014					Cost To	Total	
COST (\$ III WIIIIOIIS)	Years	FY 2012	FY 2013 <sup>#</sup>	Base	OCO ##	Total	FY 2015	FY 2016	FY 2017	FY 2018	Complete	Cost	
TE3: TEST & EVALUATION	-	10.306	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	10.306	
(ATD)				1					1				

<sup>\*</sup>FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

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

This project (TE3) supports the development of test and evaluation methodologies and protocols as new science and technology efforts are discovered and transitioned to advanced development programs. It includes methodology development for chemical and biological defense test and evaluation capabilities, with an emphasis on Non Traditional Agents (NTAs). These methodologies support development testing and operational testing with regard to advanced development programs that have unique chemical and biological defense requirements. These new methodologies and testing capabilities include the development of protocol and standards for use of chemical and biological simulants. In FY13, all NTA-dedicated research was re-aligned to Project NT3 - Techbase Non-Traditional Agents Defense (ATD). All non-NTA related T&E efforts were completed in FY12.

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2012	FY 2013	FY 2014
Title: 1) Test and Evaluation (T&E)	4.649	0.000	0.000
<b>Description:</b> Test and Evaluation, Information System Technology: Develop test and evaluation technologies and processes in support of Information System Technology activities.			
FY 2012 Accomplishments:  Continued the development of CBRN data management capabilities for test and evaluation, with emphasis on enabling access to information for analysis within CBDP systems performance models. Enhanced ability to evaluate decontaminants and decontamination systems by continuing to develop simulation capabilities for decontamination processes.			
Title: 2) Test and Evaluation (T&E) NTA	5.657	0.000	0.000
Description: Develops test and evaluation technologies and processes in support of NTA activities.			
FY 2012 Accomplishments:  Completed facility design efforts by conducting large particle dissemination development and proof of principle tests with several agents. Initiated select agent testing. In FY13, all research in this area was re-aligned to Project NT3 - Techbase Non-Med Test & Evaluation (NTA).			
Accomplishments/Planned Programs Subtotals	10.306	0.000	0.000

<sup>\*\*\*</sup> The FY 2014 OCO Request will be submitted at a later date

Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Biologi	cal Defense Program		DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE	PROJECT	
0400: Research, Development, Test & Evaluation, Defense-Wide	PE 0603384BP: CHEMICAL/BIOLOGICAL	TE3: <i>TES</i> 7	「 & EVALUATION (ATD)
BA 3: Advanced Technology Development (ATD)	DEFENSE (ATD)		

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

		-	FY 2014	FY 2014	FY 2014					<b>Cost To</b>	
Line Iten	<u>FY 201</u>	2 FY 2013	Base	OCO	<u>Total</u>	FY 2015	FY 2016	FY 2017	FY 2018	Complete	<b>Total Cost</b>
• CB3: CHEMICAL B	OLOGICAL 23.83	8 20.034	18.091		18.091	19.224	18.348	20.621	19.960	Continuing	Continuing
DEFENSE (ATD)											
• TE4: TEST & EVAL	UATION 14.45	8 4.994	15.671		15.671	20.408	15.872	13.044	11.044	Continuing	Continuing
(ACD&P)											
• TE5: <i>TEST &amp; EVAL</i>	UATION 16.23	5 6.394	26.202		26.202	20.033	20.200	15.700	14.200	Continuing	Continuing
(EMD)											
• TE7: TEST & EVAL	UATION (OP 3.54	9 4.156	3.690		3.690	3.642	2.846	2.846	2.846	Continuing	Continuing
SYS DEV)											

### **Remarks**

## D. Acquisition Strategy

N/A

## E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Biological Defense Program							DATE: Apr	il 2013				
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)						<b>ATURE</b> MICAL/BIOL		PROJECT TM3: TEC	HBASE ME	D DEFENSI	E (ATD)	
COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 <sup>#</sup>	FY 2014 Base	FY 2014 OCO ##	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
TM3: TECHBASE MED DEFENSE (ATD)	-	0.000	182.330	122.717	-	122.717	99.930	107.506	123.790	126.110	Continuing	Continuing

<sup>\*</sup>FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

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

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

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 research in Project (TB3) was re-aligned into Project TM3 - Techbase Medical Defense (ATD).

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2012	FY 2013	FY 2014
Title: 1) Techbase Med Defense - Medical Countermeasures Initiative	0.000	19.237	16.000
<b>Description:</b> Medical Countermeasures Initiative (MCMI): The MCMI will integrate the regulatory science and manufacturing technologies and processes developed into the Advanced Development and Manufacturing (MCM-ADM) as enablers of the advanced development and flexible manufacturing capability.			
FY 2013 Plans: Further the development of human in vitro immune mimetic assays for FDA acceptance to enable rapid and accurate prediction of the human response to experimental vaccines and other MCMs. Continue to develop and make practical improvements to existing agile, flexible, manufacturing bioprocesses for the purpose of accelerating access to biodefense MCMs. Continue the			

<sup>##</sup> The FY 2014 OCO Request will be submitted at a later date

	UNCLASSIFIED				
Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Bio	ological Defense Program		DATE:	April 2013	
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)	R-1 ITEM NOMENCLATURE PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)	PROJECT TM3: TEC	ECT TECHBASE MED DEFENSE (A		
B. Accomplishments/Planned Programs (\$ in Millions)		FY	2012	FY 2013	FY 2014
development of a plant-based virus-like particle (VLP) vaccine. Identify cut tissue slices to serve as predictive surrogates for accelerated MCM expressions.		ion			
FY 2014 Plans: Continue development of human in vitro immune mimetic assays for FD/of the human response to experimental vaccines and other MCMs. Con existing agile, flexible, manufacturing bioprocesses for the purpose of ac development of a plant-based virus-like particle (VLP) vaccine. Identify cut tissue slices to serve as predictive surrogates for accelerated MCM experiments.	ntinue to develop and make practical improvements to ecclerating access to biodefense MCMs. Continue the additional ex-vivo cell/tissue mimetics such as precis	ie			
Title: 2) Techbase Med Bio - Diagnostics	,		0.000	1.550	0.000
<b>Description:</b> Biosurveillance/Disease Surveillance: Integrate existing diswarning systems, and leverage and enhance epidemiological models and threat assessment. Contribute to the development of global, near real time address secondary infection, fuse medical syndromic, environmental, and modeling, medical resource estimation and decision support tools. Focutive disease surveillance data. This subject area was previously referred to a Modeling".	nd algorithms for disease prediction, impact and biolo me, disease monitoring and surveillance systems tha nd clinical data, and feed into agent-based epidemiolo us on agent-based epidemiological modeling and fus	ogical on of			
FY 2013 Plans: Continue effort of Verification and Validation (V&V) of existing agent-bas population data and disease spread algorithms, along with biosurveilland Funding for this research area was re-aligned from Tech Base Non-Med	ce data fusion, for use in robust adaptive decision ma	aking.			
Title: 3) Techbase Med Bio - Diagnostics			0.000	32.649	10.945
<b>Description:</b> Biological Diagnostic Assays and Reagents: Development for the identification of Biological Warfare Agents (BWAs) and their expression Warfighters for the diagnosis of exposure/infection. Discovery of host bithreat agents. This subject area was previously referred to as "Biological Discovery of Host bithreat agents."	essed pathogens and toxins in clinical specimens fro omarkers generated in response to exposure to biok	m			
FY 2013 Plans: Translate laboratory, data fusion informatic methodologies and specimel required to identify and bio-type emerging, re-emerging, and synthetic thand phenotypes, and therapeutic and vaccine response markers. Devel protocols to advanced development for use in austere biosurveillance er	nreat agent strains, identify antibiotic resistant mutation and transition thermostable reagents/scale-up	ons			

PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD) UNCLASSIFIED

Chemical and Biological Defense Program

	UNCLASSIFIED					
Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Bio	ological Defense Program		DATE:	April 2013		
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)	R-1 ITEM NOMENCLATURE PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)	PROJECTM3: TEC	ECT FECHBASE MED DEFENSE (A			
B. Accomplishments/Planned Programs (\$ in Millions)		F	Y 2012	FY 2013	FY 2014	
to developers of: Medical Counter Measures, microbial forensics capabili biosurveillance infrastructure performing vector surveys, zoonotic epidem diagnostic, disease surveillance and MCM development. Submit pre-Emfor in vitro diagnostics. Funding for this research area was re-aligned fro Med Bio - TMT Platform Technologies (TB3).	niology and provide a direct link between medical nergency Use application data packages to FDA Offic					
FY 2014 Plans: Continue to develop laboratory, data fusion informatics methodologies ar signatures required to identify and bio-type emerging, re-emerging, and i Develop and transition an additional thermostable reagents/scale-up probiosurveillance environments. Collaborate with the Centers for Disease capabilities needed to counter traditional, engineered, emerging and bioletics.	dentify antibiotic resistant mutations and phenotypes tocols to advanced development for use in austere Control (CDC) to improve diagnostic and surveillance	5.				
Title: 4) Techbase Med Bio - Diagnostics			0.000	14.770	0.000	
<b>Description:</b> Next Generation Technologies: Development of next general diagnostic platforms, highly parallel and informative testing formats, and assay formats and hardware solutions to enable point of need diagnostic decisions.	nanotechnology applications. Development of novel					
FY 2013 Plans: Perform pre-clinical validation studies in relevant animal models and humbiomarker panel positive and negative predictive values. Funding for this Med Bio - Diagnostics (TB3) and Techbase Med Bio - TMT Platform Technological Diagnostic Device Platforms.	s research area was re-aligned in FY13 from Tech Ba	ase				
Title: 5) Techbase Med Bio - Diagnostics			0.000	17.880	33.849	
<b>Description:</b> Biological Diagnostic Device Platforms: Diagnostic device of generation technologies to revolutionize clinical diagnostics in care facility incorporate capabilities such as next generation sequencing and advance pathogen biomarkers in a threat agnostic approach that will serve all ech	ies and in hospital laboratories. This investment will ed biomolecular methods to harness both host and					
FY 2013 Plans: Provide documented assessments of candidate devices potential for tran of point of care diagnostic capabilities. Verify clinical utility of host and paper platform prototype(s) that confers the ability to identify and type novel inference.	athogen biomarkers and integrate onto diagnostic	ment				

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Bi	ological Defense Program		DATE:	April 2013	
APPROPRIATION/BUDGET ACTIVITY  0400: Research, Development, Test & Evaluation, Defense-Wide  BA 3: Advanced Technology Development (ATD)  R-1 ITEM NOMENCLATURE  PE 0603384BP: CHEMICAL/BIOLOGICAL  DEFENSE (ATD)		MED DEFENS	SE (ATD)		
B. Accomplishments/Planned Programs (\$ in Millions)			Y 2012	FY 2013	FY 2014
previously characterized pathologies. Funding for this research area waand Techbase Med Bio - TMT Platform Technologies (TB3).	as re-aligned from Tech Base Med Bio - Diagnostics (	TB3)			
FY 2014 Plans: Continue to develop candidate devices for potential transition to advance diagnostic capabilities. Development of hardware solutions and assay for Verify clinical utility of host and pathogen biomarkers and integrate onto identify and type novel infectious agents as a function of their relationsh	formats to enable point of need diagnostic capabilities diagnostic platform prototype(s) that confers the abili	5.			
Title: 6) Techbase Med Bio - Pretreatments			0.000	0.510	0.459
<b>Description:</b> Pretreatments - Bacterial/Toxin Vaccines: Evaluates the b effectiveness against aerosol challenge in large animal models.	est single agent bacterial and toxin vaccines for				
FY 2013 Plans: Deliver final data package for Ricin vaccine. Funding for this research a Pretreatments (TB3).	area was re-aligned from Tech Base Med Bio -				
FY 2014 Plans: Coordinate with the advanced developer to fulfill S&T needs in support of	of the Ricin vaccine transition.				
Title: 7) Techbase Med Bio - Pretreatments			0.000	19.038	17.13
<b>Description:</b> Pretreatments - Viral Vaccines: Evaluates the best vaccine effectiveness and duration of protective immune response against aeros will be developed to support FDA licensure of mature vaccine candidate support pivotal animal studies under the "Animal Rule".	sol challenge in large animal models. Animal models				
FY 2013 Plans: Coordinate with the advanced developer to fulfill S&T needs in support of Filovirus and Alphavirus immunological assays to support product developer Equine Encephalitis (VEE) DNA vaccine delivered by in vivo electroporal Complete pre-clinical studies on a trivalent VEE, Eastern and Western E Continue to conduct pre-clinical studies of the Alphavirus replicon vaccing the development of animals models for Alphaviruses (EEE and WEE), a Bundibugyo, and Marburg), to fulfill future FDA 'Animal Rule' requirement	velopment. Complete Phase I clinical trial of Venezue ation via intra-muscular or intra-dermal administration. Equine Encephalitis (EEE, WEE) DNA formulation. ne in coordination with the advanced developer. Con and Filoviruses (Ebola Sudan, Ebola Zaire, Ebola	elan tinue			

**UNCLASSIFIED** 

Description: Pretreatments - Vaccine Platforms and Research Tools: Conducts studies to determine potential immune interference between lead vaccine candidates, the effect of alternative vaccine delivery methods and thermo-stabilization technologies on the efficacy of lead vaccine candidates. Identifies correlates of protection in humans, and predicts the success of lead vaccine candidates in humans. Work conducted under Vaccine Platforms and Research Tools are distinct from those performed under Viral Vaccines because the focus is on the use of novel technologies to support vaccine candidates, not on the vaccine candidates themselves. Vaccine Platforms and Research Tools utilize novel technologies to stabilize advanced vaccine candidates as well as alternative delivery modalities.  FY 2013 Plans:  Continue formulation studies to produce a thermo-stable, spray-dried formulation of an advanced vaccine candidate. Continue to evaluate stabilization technologies that provide thermal stability to multiple classes of vaccines such as viral vectored vaccines and subunit protein vaccines. Continue to evaluate alternative (needle-free) vaccine delivery technologies such as inhalers or skin patches for the delivery of mature vaccine candidates. Utilize clinical samples from Filovirus or Alphavirus outbreaks in multiple international locations to help define clinically relevant correlates of immunity. Funding for this research area was re-aligned from Tech Base Med Bio - Pretreatments (TB3).  FY 2014 Plans:  Continue formulation studies to produce a thermo-stable, spray-dried formulation of an advanced vaccine candidate. Continue to evaluate stabilization technologies that provide thermal stability to multiple classes of vaccines such as viral vectored vaccines and subunit protein vaccines. Continue to evaluate alternative (needle-free) vaccine delivery technologies such as inhalers or skin patches for the delivery of mature vaccine candidates. Utilize clinical samples from Filovirus or Alphavirus outbreaks in multiple int		UNCLASSIFIED				
0400: Research, Development, Tast & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)  FY 2014 DEFENSE (ATD)  FY 2014 Plans:  Continue development of Alphavirus immunological assays to support product development. Conduct Good Lab Practices (GLP) animal efficacy studies of the VEE DINA vaccine delivered by in vivo electroporation via intra-muscular or intra-demnal administration. Continue to conduct pre-clinical studies of the Alphavirus replicon vaccine in coordination with the advanced development of animals models for Alphavirus replicon vaccine in coordination with the advanced development of animals models for Alphavirus replicon vaccine in coordination with the advanced development of animals models for Alphavirus replicon vaccine in coordination with the advanced development of animals models for Alphavirus replicon vaccine in coordination with the advanced development of animals models for Alphavirus replicon vaccine in coordination with the advanced development of animals models for Alphavirus replicon vaccine in coordination with the advanced development of animals models for Alphavirus replicon vaccine in coordination with the advanced development of animals models for Alphavirus replicon vaccine in coordination with the advanced of the Alphavirus replicon vaccine in coordination with the advanced vaccine requirements necessary for vaccine Platforms and Research Tools: Conducts studies to determine potential immune interference between lead vaccine candidates. Identifies correlates of protection in humans, and predicts the success of lead vaccine candidates. Identifies correlates of protection in humans, and predicts the success of lead vaccine candidates. Identifies correlates of protection in humans, and predicts the success of lead vaccine candidates. Identifies correlates of protection in humans, and predicts the success of lead vaccine candidates. Identifies correlates of protection in humans, and predicts he success of lead vaccine candidates. Identifies not the lead of the p	Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and E	Biological Defense Program	DA.	<b>TE:</b> April 2013		
vaccines transitioned in FY11, work will continue on the selected candidate(s) to fill knowledge gaps. Funding for this research area was re-aligned from Tech Base Med Bio - Pretreatments (TB3).  FY 2014 Plans:  Continue development of Alphavirus immunological assays to support product development. Conduct Good Lab Practices (GLP) animal efficacy studies of the VEE DINA vaccine delivered by in vivo electroporation via inter-muscular or intra-dermal administration. Continue to conduct pre-clinical studies of the Alphavirus replicon vaccine in coordination with the advanced development. Continue the development of animals models for Alphaviruses (EEE and WEE), to fulfill future FDA 'Animal Rule' requirements necessary for vaccine licensure.  Tittle: 8) Techbase Med Bio - Pretreatments  Description: Pretreatments - Vaccine Platforms and Research Tools: Conducts studies to determine potential immune interference between lead vaccine candidates, the effect of alternative vaccine delivery methods and thermo-stabilization technologies on the efficacy of lead vaccine candidates. Identifies correlates of protection in humans, and predicts the success of lead vaccine candidates in humans. Work conducted under Vaccine Platforms and Research Tools are distinct from those performed under Viral Vaccines because the focus is on the use of novel technologies to suspoit studies, not on the vaccine candidates as well as alternative delivery modalities.  FY 2013 Plans:  Continue formulation studies to produce a thermo-stable, spray-dried formulation of an advanced vaccine candidate. Continue to evaluate stabilization technologies that provide thermal stability to multiple classes of vaccines such as viral vectored vaccines and subunit protein vaccines. Continue to evaluate alternative (needle-free) vaccine delivery technologies such as inhalers or skin patches for the delivery of mature vaccine candidates. Utilize clinical samples from Filovirus or Alphavirus outbreaks in multiple international locations to help define clinically	0400: Research, Development, Test & Evaluation, Defense-Wide	PE 0603384BP: CHEMICAL/BIOLOGICAL				
vaccines transitioned in FY11, work will continue on the selected candidate(s) to fill knowledge gaps. Funding for this research area was re-aligned from Tech Base Med Bio - Pretreatments (TB3).  FY 2014 Plans:  Continue development of Alphavirus immunological assays to support product development. Conduct Good Lab Practices (GLP) animal efficacy studies of the VEE DINA vaccine delivered by in vivo electroporation via inter-muscular or intra-dermal administration. Continue to conduct pre-clinical studies of the Alphavirus replicon vaccine in coordination with the advanced development. Continue the development of animals models for Alphaviruses (EEE and WEE), to fulfill future FDA 'Animal Rule' requirements necessary for vaccine licensure.  Tittle: 8) Techbase Med Bio - Pretreatments  Description: Pretreatments - Vaccine Platforms and Research Tools: Conducts studies to determine potential immune interference between lead vaccine candidates, the effect of alternative vaccine delivery methods and thermo-stabilization technologies on the efficacy of lead vaccine candidates. Identifies correlates of protection in humans, and predicts the success of lead vaccine candidates in humans. Work conducted under Vaccine Platforms and Research Tools are distinct from those performed under Viral Vaccines because the focus is on the use of novel technologies to suspoit studies, not on the vaccine candidates as well as alternative delivery modalities.  FY 2013 Plans:  Continue formulation studies to produce a thermo-stable, spray-dried formulation of an advanced vaccine candidate. Continue to evaluate stabilization technologies that provide thermal stability to multiple classes of vaccines such as viral vectored vaccines and subunit protein vaccines. Continue to evaluate alternative (needle-free) vaccine delivery technologies such as inhalers or skin patches for the delivery of mature vaccine candidates. Utilize clinical samples from Filovirus or Alphavirus outbreaks in multiple international locations to help define clinically	B. Accomplishments/Planned Programs (\$ in Millions)		FY 201	2 FY 2013	B FY 2014	
Continue development of Alphavirus immunological assays to support product development. Conduct Good Lab Practices (GLP) animal efficacy studies of the VEE DNA vaccine delivered by in vivo electroporation via intra-muscular or intra-dermal administration. Continue to conduct pre-clinical studies of the Alphavirus replicon vaccine in coordination with the advanced developer. Continue the development of animals models for Alphavirus replicon vaccine in the throughout the development of animals models for Alphaviruses (EEE and WEE), to fulfill future FDA 'Animal Rule' requirements necessary for vaccine licensure.  7title: 8) Techbase Med Bio - Pretreatments  Description: Pretreatments - Vaccine Platforms and Research Tools: Conducts studies to determine potential immune interference between lead vaccine candidates, the effect of alternative vaccine delivery methods and thermo-stabilization technologies on the efficacy of lead vaccine candidates. Identifies correlates of protection in humans, and predicts the success of lead vaccine candidates in humans. Work conducted under Vaccine Platforms and Research Tools are distinct from those performed under Viral Vaccines because the focus is on the use of novel technologies to support vaccine candidates, not on the vaccine candidates as well as alternative delivery modalities.  FY 2013 Plans:  Continue formulation studies to produce a thermo-stable, spray-dried formulation of an advanced vaccine candidate. Continue to evaluate stabilization technologies that provide thermal stability to multiple classes of vaccines such as viral vectored vaccines and subunit protein vaccines. Continue to evaluate alternative (needle-free) vaccine delivery technologies such as inhalers or skin patches for the delivery of mature vaccine candidates. Utilize clinical samples from Filovirus or Alphavirus outbreaks in multiple international locations to help define clinically relevant correlates of immunity.  Continue formulation studies to produce a thermo-stable, spray-dried formulation of a		idate(s) to fill knowledge gaps. Funding for this resear	rch			
Title: 8) Techbase Med Bio - Pretreatments  Description: Pretreatments - Vaccine Platforms and Research Tools: Conducts studies to determine potential immune interference between lead vaccine candidates, the effect of alternative vaccine delivery methods and thermo-stabilization technologies on the efficacy of lead vaccine candidates. Identifies correlates of protection in humans, and predicts the success of lead vaccine candidates in humans. Work conducted under Vaccine Platforms and Research Tools are distinct from those performed under Viral Vaccines because the focus is on the use of novel technologies to support vaccine candidates, not on the vaccine candidates as well as alternative delivery modalities.  FY 2013 Plans:  Continue formulation studies to produce a thermo-stable, spray-dried formulation of an advanced vaccine candidate. Continue to evaluate stabilization technologies that provide thermal stability to multiple classes of vaccines such as viral vectored vaccines and subunit protein vaccines. Continue to evaluate alternative (needle-free) vaccine delivery technologies such as inhalers or skin patches for the delivery of mature vaccine candidates. Utilize clinical samples from Filovirus or Alphavirus outbreaks in multiple international locations to help define clinically relevant correlates of immunity. Funding for this research area was re-aligned from Tech Base Med Bio - Pretreatments (TB3).  FY 2014 Plans:  Continue formulation studies to produce a thermo-stable, spray-dried formulation of an advanced vaccine candidate. Continue to evaluate stabilization technologies that provide thermal stability to multiple classes of vaccines such as viral vectored vaccines and subunit protein vaccines. Continue to evaluate talternative (needle-free) vaccine delivery technologies such as inhalers or skin patches for the delivery of mature vaccine candidates. Utilize clinical samples from Filovirus or Alphavirus outbreaks in multiple international locations to help define clinically relevant correlates of im	Continue development of Alphavirus immunological assays to support (GLP) animal efficacy studies of the VEE DNA vaccine delivered by in administration. Continue to conduct pre-clinical studies of the Alphavir developer. Continue the development of animals models for Alphaviru	vivo electroporation via intra-muscular or intra-dermal rus replicon vaccine in coordination with the advanced				
interference between lead vaccine candidates, the effect of alternative vaccine delivery methods and thermo-stabilization technologies on the efficacy of lead vaccine candidates. Identifies correlates of protection in humans, and predicts the success of lead vaccine candidates in humans. Work conducted under Vaccine Platforms and Research Tools are distinct from those performed under Viral Vaccines because the focus is on the use of novel technologies to support vaccine candidates, not on the vaccine candidates themselves. Vaccine Platforms and Research Tools utilize novel technologies to stabilize advanced vaccine candidates as well as alternative delivery modalities.  FY 2013 Plans:  Continue formulation studies to produce a thermo-stable, spray-dried formulation of an advanced vaccine candidate. Continue to evaluate stabilization technologies that provide thermal stability to multiple classes of vaccines such as viral vectored vaccines and subunit protein vaccines. Continue to evaluate alternative (needle-free) vaccine delivery technologies such as inhalers or skin patches for the delivery of mature vaccine candidates. Utilize clinical samples from Filovirus or Alphavirus outbreaks in multiple international locations to help define clinically relevant correlates of immunity. Funding for this research area was re-aligned from Tech Base Med Bio - Pretreatments (TB3).  FY 2014 Plans:  Continue formulation studies to produce a thermo-stable, spray-dried formulation of an advanced vaccine candidate. Continue to evaluate stabilization technologies that provide thermal stability to multiple classes of vaccines such as viral vectored vaccines and subunit protein vaccines. Continue to evaluate alternative (needle-free) vaccine delivery technologies such as inhalers or skin patches for the delivery of mature vaccine candidates. Utilize clinical samples from Filovirus or Alphavirus outbreaks in multiple international locations to help define clinically relevant correlates of immunity.	Title: 8) Techbase Med Bio - Pretreatments		0.0	000 3.2	00 2.880	
Continue formulation studies to produce a thermo-stable, spray-dried formulation of an advanced vaccine candidate. Continue to evaluate stabilization technologies that provide thermal stability to multiple classes of vaccines such as viral vectored vaccines and subunit protein vaccines. Continue to evaluate alternative (needle-free) vaccine delivery technologies such as inhalers or skin patches for the delivery of mature vaccine candidates. Utilize clinical samples from Filovirus or Alphavirus outbreaks in multiple international locations to help define clinically relevant correlates of immunity. Funding for this research area was re-aligned from Tech Base Med Bio - Pretreatments (TB3).  FY 2014 Plans:  Continue formulation studies to produce a thermo-stable, spray-dried formulation of an advanced vaccine candidate. Continue to evaluate stabilization technologies that provide thermal stability to multiple classes of vaccines such as viral vectored vaccines and subunit protein vaccines. Continue to evaluate alternative (needle-free) vaccine delivery technologies such as inhalers or skin patches for the delivery of mature vaccine candidates. Utilize clinical samples from Filovirus or Alphavirus outbreaks in multiple international locations to help define clinically relevant correlates of immunity.	interference between lead vaccine candidates, the effect of alternative technologies on the efficacy of lead vaccine candidates. Identifies corr of lead vaccine candidates in humans. Work conducted under Vaccine performed under Viral Vaccines because the focus is on the use of nov vaccine candidates themselves. Vaccine Platforms and Research Too	vaccine delivery methods and thermo-stabilization relates of protection in humans, and predicts the succe Platforms and Research Tools are distinct from those vel technologies to support vaccine candidates, not on	e the			
Continue formulation studies to produce a thermo-stable, spray-dried formulation of an advanced vaccine candidate. Continue to evaluate stabilization technologies that provide thermal stability to multiple classes of vaccines such as viral vectored vaccines and subunit protein vaccines. Continue to evaluate alternative (needle-free) vaccine delivery technologies such as inhalers or skin patches for the delivery of mature vaccine candidates. Utilize clinical samples from Filovirus or Alphavirus outbreaks in multiple international locations to help define clinically relevant correlates of immunity.	Continue formulation studies to produce a thermo-stable, spray-dried for to evaluate stabilization technologies that provide thermal stability to mand subunit protein vaccines. Continue to evaluate alternative (needle patches for the delivery of mature vaccine candidates. Utilize clinical sinternational locations to help define clinically relevant correlates of immoderations.	nultiple classes of vaccines such as viral vectored vacce-free) vaccine delivery technologies such as inhalers of samples from Filovirus or Alphavirus outbreaks in mult	cines or skin iple			
Title: 9) Techbase Med Bio - Therapeutics 0 000 6 100 17 773	Continue formulation studies to produce a thermo-stable, spray-dried for to evaluate stabilization technologies that provide thermal stability to mean and subunit protein vaccines. Continue to evaluate alternative (needle patches for the delivery of mature vaccine candidates. Utilize clinical stabilizations.)	nultiple classes of vaccines such as viral vectored vacce-free) vaccine delivery technologies such as inhalers of samples from Filovirus or Alphavirus outbreaks in mult	cines or skin			
1.1.1.1.07   1.1.1.1.00   1.1.1.00   1	Title: 9) Techbase Med Bio - Therapeutics		0.0	000 6.1	00 17.773	

PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD) UNCLASSIFIED

Chemical and Biological Defense Program

	UNCLASSIFIED					
Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and B	iological Defense Program	DA	<b>TE:</b> April 2013			
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)	R-1 ITEM NOMENCLATURE PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)	PROJECT TM3: TECHBA	PROJECT TM3: TECHBASE MED DEFENSE			
B. Accomplishments/Planned Programs (\$ in Millions)		FY 20	12 FY 2013	FY 2014		
<b>Description:</b> Viral Therapeutics: Identify, optimize and evaluate potenti threat agents.	al therapeutic candidates effective against designate	d viral				
FY 2013 Plans: Continue evaluation of immunotherapies for Filoviruses in non-human preatment of Filovirus infection. Continue screening program to determine infectious diseases (i.e. Alphavirus, Filovirus, Flavivirus, Arenavirus, Busubmit Investigational New Drug (IND) applications to the FDA for addit the viral therapeutics product pipeline. Funding for this research area was (TB3).	ne efficacy of FDA approved compounds against em- nyavirus). Continue pre-clinical research required to ional products or additional product indications to refr	esh				
FY 2014 Plans: Evaluate immunotherapies for Filoviruses in non-human primate models for Filovirus infections. Continue screening program to determine effica infectious diseases. Evaluate FDA-approved host-directed tyrosine kina Flavivirus, Arenavirus, Bunyavirus, and Orthopoxvirus. Continue pre-clithe FDA for additional products or additional product indications to refre research previously conducted under the Multiagent Broad Spectrum C Therapeutics program under BA3 Techbase Med Defense - Bio CM (TM)	icy of FDA approved compounds against emerging ase inhibitors for efficacy against Alphavirus, Filovirus inical research required to submit IND applications to sh the viral therapeutics product pipeline. In FY14, ountermeasure thrust area will be transitioned into the	5,				
Title: 10) Techbase Med Bio - Therapeutics		0	.000 5.100	17.170		
<b>Description:</b> Bacterial Therapeutics: Identify, optimize and evaluate pothreat agents.	tential therapeutic compounds effective against bacte	erial				
FY 2013 Plans: Evaluate FDA approved compounds for efficacy in non-human primate tularensis. Develop small molecule inhibitors of the electron transport of Perform pharmacokinetic studies of humanized CapD in mouse models applications to the FDA for additional products or additional product indipipeline. Funding for this research area was re-aligned from Tech Base	hain and the ATP synthase bacterial biothreat agents.  Continue pre-clinical research required to submit IN ications to refresh the bacterial therapeutics product	S				
FY 2014 Plans: Evaluate FDA approved compounds for efficacy in non-human primate F. tularensis. Continue development of small molecule inhibitors of the biothreat agents. Perform pharmacokinetic studies of human CapD in r	electron transport chain and the ATP synthase bacte	rial				

Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Bi	ological Defense Program		DATE: A	April 2013	
APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE	PROJ	ECT		
0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)	PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)	TM3: 7	TECHBASE I	MED DEFEN	SE (ATD)
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2012	FY 2013	FY 2014
submit IND applications to the FDA for additional products or additional product pipeline. In FY14, research previously conducted under the Mu be transitioned into the Bacterial Therapeutics program under BA3 Tech	Itiagent Broad Spectrum Countermeasure thrust are				
Title: 11) Techbase Med Bio - Therapeutics			0.000	1.645	0.52
<b>Description:</b> Toxin Therapeutics: Identify, optimize and evaluate potent threat agents.	ial therapeutic candidates effective against biologic	al toxin			
FY 2013 Plans: Evaluate small molecule non-peptidic inhibitors for pharmacokinetic and in mouse model of BoNT A intoxication for efficacy. Funding for this restriction (TB3).					
FY 2014 Plans: Continue evaluation of small molecule non-peptidic inhibitors for pharma molecule inhibitors in mouse model of BoNT A intoxication for efficacy.	acokinetic and toxicology profiles. Test novel small				
Title: 12) Techbase Med Bio - Therapeutics			0.000	48.225	0.000
<b>Description:</b> Multiagent (Broad Spectrum) Medical Countermeasures: Countermeasures: Countermeasures: Countermeasures: Countermeasures: Countermeasures: Countermeasures: Countermeasures, to include safety, toxicity, efficacy, and scalability work ability to formulate Good Manufacturing Practices (GMP), pilot lots and confactivities in this capability area. The preclinical drug discovery process Drug (IND) application to the Food and Drug Administration (FDA), to desafety evaluation in humans. In FY14, research under this thrust area we program under BA3 Techbase Med Defense - Bio CM (TM3).	countermeasures for Hemorrhagic Fever Virus (HFV d completion of preclinical studies for candidate is in accordance with the product's intended use. The further mature promising drug candidates will be the seculminates in the submission of an Investigation are termine if candidate countermeasures are suitable	he focus Il New for			
FY 2013 Plans: Continue pre-clinical research required to submit IND applications to the indications to refresh the Hemorrhagic Fever Virus (HFV), Intracellular E (EID) product pipelines. Continue planning for Phase 1 clinical trials and to safety evaluation in humans. Continue the development of animal metals.	Bacterial Pathogen (IBP) and Emerging Infectious D	A prior			

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Biol	logical Defense Program	DATE	:: April 2013	
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)	R-1 ITEM NOMENCLATURE PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)	PROJECT TM3: TECHBAS	E MED DEFEN	SE (ATD)
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2012	FY 2013	FY 2014
in the S&T phase of development, incorporating feedback from the FDA a area was re-aligned from Tech Base Med Bio - Transformational Medical		earch		
Title: 13) Techbase Med Chem - Diagnostics		0.00	0.469	0.460
<b>Description:</b> Chemical Diagnostics: Focuses on state-of-the-art laborator warfare agents (CWA) (e.g., nerve agents and vesicants) in clinical sampl targets that can be leveraged as analytical methodologies, as well as laborated longevity of a particular analyte/biomarker.	les. It also targets the identification of biomolecular			
FY 2013 Plans: Expand the current set of analytical methods to more sensitive analytical presearch area was re-aligned from Tech Base Med Chem - Diagnostics (1)		is		
FY 2014 Plans: Continue to expand the current set of analytical methods to more sensitive clinical samples.	e analytical platforms for the detection of CWAs in			
Title: 14) Techbase Med Chem - Pretreatments		0.00	0 4.122	0.000
<b>Description:</b> Chemical Medical Pretreatments - Nerve Agent, Pretreatments against all organophosphorous nerve agents. The enzymes should have have broad binding specificity and high enzymatic efficiency for the destruor of catalytic bioscavenger should be capable of detoxifying numerous mole quantity of catalytic bioscavenger to protect against a large dose of nerve	the ability to rapidly bind and detoxify nerve agents action of agents. For enzyme approaches, one molecules nerve agents resulting in the capability for a	ecule		
FY 2013 Plans: Continue characterization of recombinant human butyrylcholinesterase (recombination of systems). Funding for this research area was re-aligned from		ve		
Title: 15) Techbase Med Chem - Therapeutics		0.00	0 7.633	5.525
<b>Description:</b> Chemical Medical Therapeutics - Neurologic: Focuses on the injuries resulting from exposure to chemical warfare agents (CWA). This anticonvulsants, and improved neurotransmitter restorers. Supports even new compounds or new indications for licensed products for use in the tree	effort involves the development of neuroprotectants atual Food and Drug Administration (FDA) licensure	,		
FY 2013 Plans:				

Exhibit R-2A, RDT&E Project Jus	tification: PB	2014 Chemi	ical and Biol	ogical Defen	se Program				DATE: A	April 2013	
APPROPRIATION/BUDGET ACTIV 0400: Research, Development, Tes BA 3: Advanced Technology Develo	t & Evaluation,	, Defense-W	/ide	PE 06	EM NOMEN 03384BP: C NSE (ATD)	CLATURE HEMICAL/B	IOLOGICAL	PROJE TM3: T		MED DEFEN	SE (ATD)
B. Accomplishments/Planned Pro	ograms (\$ in N	<u>Millions)</u>							FY 2012	FY 2013	FY 2014
Complete studies developing approcapability for product testing, using Practice or GLP), is needed to ensuregulatory actions. Funding for this	standardized ı ıre quality and	methodologi consistency	es under we	ll-controlled st data subm	laboratory co	onditions (e.c	g., Good Labo OA in support				
FY 2014 Plans:											
Continue efforts supporting regulate Title: 16) Techbase Med Defense -		tacilitate FD	A licensure i	ncluding in v	itro and in vi	vo testing.			0.000	0.202	0.00
<b>Description:</b> Radiological Medical radiological/nuclear exposure. The	Department o	of Defense is	the only gov	vernmental a	agency curre						
prophylaxis to protect Warfighters of FY 2013 Plans: Further explore the development of throughput and suitable for medical	a biodosimetr	y hand-held	diagnostic d	levice that is	minimally in						
prophylaxis to protect Warfighters of <b>FY 2013 Plans:</b> Further explore the development of	a biodosimetr	y hand-held	diagnostic d	levice that is was re-aligr	minimally in ned from Tec	ch Base Med		tion	0.000	182.330	122.71
prophylaxis to protect Warfighters of FY 2013 Plans: Further explore the development of throughput and suitable for medical Countermeasures (TR3).  C. Other Program Funding Summ	a biodosimetr triage. Fundii ary (\$ in Milli	ry hand-held ng for this re ons) FY 2013	diagnostic d	levice that is was re-aligr	minimally in ned from Tec	s/Planned P	Rad - Radia rograms Sul FY 2016	btotals  FY 2017	Y FY 2018	182.330  Cost To Complete	<u>.</u>
prophylaxis to protect Warfighters of FY 2013 Plans: Further explore the development of throughput and suitable for medical Countermeasures (TR3).  C. Other Program Funding Summ	a biodosimetr triage. Fundi	ry hand-held ng for this re ons)	diagnostic desearch area  FY 2014  Base 98.111	levice that is was re-aligr  Accon	minimally in ned from Tec nplishments FY 2014	ch Base Med	Rad - Radia	btotals	Y FY 2018	Cost To	Total Cos
prophylaxis to protect Warfighters of FY 2013 Plans: Further explore the development of throughput and suitable for medical Countermeasures (TR3).  C. Other Program Funding Summ  Line Item  TM2: TECHBASE MED  DEFENSE (APPLIED  RESEARCH)  MB4: MEDICAL BIOLOGICAL	a biodosimetr triage. Fundii ary (\$ in Milli	ry hand-held ng for this re ons) FY 2013	diagnostic desearch area	levice that is was re-aligr  Accon	minimally in ned from Tec nplishments FY 2014 Total	s/Planned P	Rad - Radia rograms Sul FY 2016	btotals  FY 2017	FY 2018	Cost To 3 Complete	Total Cos Continuin
prophylaxis to protect Warfighters of FY 2013 Plans: Further explore the development of throughput and suitable for medical Countermeasures (TR3).  C. Other Program Funding Summ  Line Item  TM2: TECHBASE MED DEFENSE (APPLIED RESEARCH)  MB4: MEDICAL BIOLOGICAL DEFENSE (ACD&P)  MC4: MEDICAL CHEMICAL	a biodosimetr triage. Fundii nary (\$ in Milli FY 2012 0.000	ons)  FY 2013 118.208	diagnostic desearch area  FY 2014  Base 98.111	levice that is was re-aligr  Accon	minimally in ned from Tec nplishments FY 2014 Total 98.111	<b>EXECUTE</b> SAME AND SERVICE AND ADMINISTRATION OF THE PROPERTY	Rad - Radia rograms Sul FY 2016 102.546	<b>FY 2017</b> 99.523	FY 2018 30.014	Cost To Complete Continuing	Total Cos Continuin
prophylaxis to protect Warfighters of FY 2013 Plans: Further explore the development of throughput and suitable for medical Countermeasures (TR3).  C. Other Program Funding Summ  Line Item  TM2: TECHBASE MED  DEFENSE (APPLIED	a biodosimetr triage. Fundii eary (\$ in Milli FY 2012 0.000	ons)  FY 2013 118.208	FY 2014 Base 98.111	levice that is was re-aligr  Accon	minimally in ned from Tec nplishments FY 2014 Total 98.111	FY 2015 104.361	Rad - Radia rograms Sul  FY 2016 102.546 78.461	FY 2017 99.523 41.66	FY 2018 103.44 30.014 24.186	Cost To Complete Continuing Continuing	Total Cos Continuin Continuin

PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD) Chemical and Biological Defense Program

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Page 38 of 43

R-1 Line #39

Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Biological	I Defense Program		DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE	<b>PROJECT</b>	

0400: Research, Development, Test & Evaluation, Defense-Wide

BA 3: Advanced Technology Development (ATD)

PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)

TM3: TECHBASE MED DEFENSE (ATD)

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

			FY 2014	FY 2014	FY 2014					Cost To	
<u>Line Item</u>	FY 2012	FY 2013	<b>Base</b>	OCO	<u>Total</u>	FY 2015	FY 2016	FY 2017	FY 2018	<b>Complete</b>	<b>Total Cost</b>
MB7: MEDICAL BIOLOGICAL	5.371	0.498	0.499		0.499	13.414	14.551	9.816	3.277	Continuing	Continuing
DEFENSE (OP SYS DEV)											

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Ju	d Biologica	cal Defense Program				DATE: April 2013						
APPROPRIATION/BUDGET ACTIVITY					R-1 ITEM NOMENCLATURE				PROJECT			
0400: Research, Development, Te		PE 0603384BP: CHEMICAL/BIOLOGICAL				TR3: MEDICAL RADIOLOGICAL DEFENSE						
BA 3: Advanced Technology Deve	elopment (A	TD)			DEFENSE (ATD)				(ATD)			
COST (\$ in Millions)	All Prior			FY 2014	FY 2014	FY 2014					Cost To	Total
COST (\$ III WIIIIONS)	Years	FY 2012	FY 2013 <sup>#</sup>	Base	oco ##	Total	FY 2015	FY 2016	FY 2017	FY 2018	Complete	Cost
TR3: MEDICAL RADIOLOGICAL	-	1.431	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	1.431
DEFENSE (ATD)												

<sup>\*</sup>FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

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

This project (TR3) funds advanced technology development of medical countermeasures against radiological exposure. Specifically, innovative technical approaches will be used to develop, refine, and transition promising products to advanced development efforts to mitigate health consequences resulting from Acute Radiation Exposure (ARS) and Delayed Effects of Acute Radiation Exposure (DEARE). Promising products and pertinent science and technology data will be used to support Investigational New Drug (IND) applications and Food and Drug Administration (FDA) licensure processes, with an emphasis on the development of pretreatments to protect military responders in the event of a radiological incident. Research efforts and data are collaboratively shared with other government agencies so that more mature and promising product candidates will be quickly transitioned to advanced development efforts. In FY13, all research in this Project (TR3) was re-aligned to Project TM3 - Techbase Medical Defense (ATD).

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2012	FY 2013	FY 2014
Title: 1) Radiological Medical Countermeasures	1.431	0.000	0.000
<b>Description:</b> Radiation Medical Countermeasures: Develops medical countermeasures to protect the Warfighter against radiological/nuclear exposure. The Department of Defense is the only governmental agency currently developing medical prophylaxis to protect Warfighters or other responders in the event of a radiological incident.			
FY 2012 Accomplishments: Completed mechanism of action studies for potential therapeutics for radiological exposure. In FY13, all Project TR3 research was re-aligned into Techbase Medical Defense - RAD CM (TM3).			
Accomplishments/Planned Programs Subtotals	1.431	0.000	0.000

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

			FY 2014	FY 2014	FY 2014					Cost To	
<u>Line Item</u>	FY 2012	FY 2013	<b>Base</b>	OCO	<u>Total</u>	FY 2015	FY 2016	FY 2017	FY 2018	<b>Complete</b>	<b>Total Cost</b>
• TM2: TECHBASE MED	0.000	118.208	98.111		98.111	104.361	102.546	99.523	103.441	Continuing	Continuing
DEFENSE (APPLIED											

RESEARCH)

PE 0603384BP: CHEMICAL/BIOLOGICAL DEFENSE (ATD)
Chemical and Biological Defense Program

UNCLASSIFIED
Page 40 of 43

R-1 Line #39

<sup>##</sup> The FY 2014 OCO Request will be submitted at a later date

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	PE 0603384BP: CHEMICAL/BIOLOGICAL	TR3: MED	ICAL RADIOLOGICAL DEFENSE				
BA 3: Advanced Technology Development (ATD)	DEFENSE (ATD)	(ATD)					

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

		<del></del>	FY 2014	FY 2014	FY 2014					Cost To	
<u>Line Item</u>	FY 2012	FY 2013	<b>Base</b>	OCO	<u>Total</u>	FY 2015	FY 2016	FY 2017	FY 2018	Complete	<b>Total Cost</b>
• TR2: MEDICAL RADIOLOGICAL	0.935	0.000	0.000		0.000	0.000	0.000	0.000	0.000	0.000	0.935
DEFENSE (APPLIED											
RESEARCH)											
• TM3: TECHBASE MED	0.000	182.330	122.717		122.717	99.930	107.506	123.790	126.110	Continuing	Continuing
DEFENSE (ATD)											
• MR4: MEDICAL RADIOLOGICAL	0.000	4.050	0.000		0.000	0.000	0.000	0.000	8.610	Continuing	Continuing
DEFENSE (ACD&P)											
• MR5: MEDICAL RADIOLOGICAL	0.000	2.027	0.000		0.000	0.000	0.000	0.000	0.000	0.000	2.027
DEFENSE (EMD)											

### **Remarks**

## D. Acquisition Strategy

N/A

### **E. Performance Metrics**

N/A

Exhibit R-2A, RDT&E Project Ju	d Biologica	ical Defense Program					DATE: April 2013					
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 3: Advanced Technology Development (ATD)									PROJECT TT3: TECHBASE TECHNOLOGY TRANSITION			
COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 <sup>#</sup>	FY 2014 Base	FY 2014 OCO ##	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
TT3: TECHBASE TECHNOLOGY TRANSITION	-	0.000	0.000	6.706	-	6.706	6.257	6.575	8.196	7.852	Continuing	Continuing

<sup>\*</sup>FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

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

This project (TT3) validates high-risk/high-payoff technologies, concepts-of-operations, and a new Joint Combat Development concept development and experimentation process that could significantly improve Warfighter capabilities in preparation for transition of mature technologies to advanced development programs requiring chemical and biological (CB) defense technologies. These programs offer an opportunity to identify and efficiently mature emerging technologies including limited objective experiments, laboratory experiments, risk reduction efforts, engineering and integration. These demonstrations and programs seek to demonstrate the potential for enhanced military operational capability and/or cost effectiveness. This project addresses four family of products areas: Biological Resiliency, Weapons of Mass Destruction (WMD) Elimination, Hazard Mitigation and Facilities Protection. Biological resiliency efforts are targeted to reduce biological threats by: (1) improving Department of Defense (DoD) access to the life sciences to combat infectious disease regardless of its cause; (2) establishing and reinforcing DoD concept of operations (CONOPS) against the misuse of the life sciences; and (3) instituting a suite of coordinated DoD and interagency activities that collectively will help influence, identify, inhibit, and/or interdict those who seek to misuse the life sciences. WMD Elimination addresses detection, identification, verification and baseline assessments in support of expeditionary forces deployed in non-permissive environments. Hazard Mitigation addresses Chemical, Biological, and Radiological (CBR) remediation and decontamination processes and demonstrates technologies and methods to restore assets such as mobile equipment, fixed sites, critical infrastructures, personal, and equipment to operational status as a result of having reduced or eliminated CBR contamination. Facilities protection transitions mature technologies to improve individual and critical infrastructure protection capabilities for

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2012	FY 2013	FY 2014
Title: 1) Experiment & Technology Demonstrations	0.000	0.000	6.706
FY 2014 Plans: Conduct technical and operational demonstrations for persistent and contagious bio agent scenarios in the US European Command Area of Responsibility (EUCOM AOR). Initiate bio-resiliency planning efforts in a second AOR. Conduct and complete a series of vignettes addressing sampling and analysis (to include forensics preparation), wide area decontamination and medical/epidemiological management. Complete Coalition Warfare Program science and technology (S&T) efforts with international partner in EUCOM AOR. Conduct a field experiment process to assess early technology capability contributions towards the WMD Elimination mission area, in collaboration with the CBDP Joint Combat Developer and with outcomes to support the creation of an initial capabilities document (ICD). Demonstrate decontamination technologies for the interior of airframes against bio			

<sup>##</sup> The FY 2014 OCO Request will be submitted at a later date

Exhibit R-2A, RDT&E Project Justification: PB 2014 Chemical and Biological Defense Program  DATE: April 2013							
APPROPRIATION/BUDGET ACTIVITY	PROJECT						
0400: Research, Development, Test & Evaluation, Defense-Wide	PE 0603384BP: CHEMICAL/BIOLOGICAL	TT3: TECHBASE TECHNOLOGY					
BA 3: Advanced Technology Development (ATD)	DEFENSE (ATD)	TRANSITION					

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2012	FY 2013	FY 2014
agents as part of a JCTD initiative with US TRANSCOM. Initiate analysis and market research for a complete facilities protection system that is rapidly deployable, to include threat detection, building hardening, and personal protection.			
system that is rapidly deployable, to include threat detection, building hardening, and personal protection.			
Accomplishments/Planned Programs Subtotals	0.000	0.000	6.706

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

			FY 2014	FY 2014	FY 2014					<b>Cost To</b>	
Line Item	FY 2012	FY 2013	<u>Base</u>	<u>oco</u>	<u>Total</u>	FY 2015	FY 2016	FY 2017	FY 2018	<b>Complete</b>	<b>Total Cost</b>
CB2: CHEMICAL BIOLOGICAL	97.530	44.331	53.901		53.901	55.042	59.834	66.483	66.214	Continuing	Continuing
DEFENSE (APPLIED											
RESEARCH)											
CB3: CHEMICAL BIOLOGICAL	23.838	20.034	18.091		18.091	19.224	18.348	20.621	19.960	Continuing	Continuing
DEFENSE (ATD)											
• TT4: TECHBASE TECHNOLOGY	2.985	3.377	0.000		0.000	0.000	0.000	0.000	0.000	0.000	6.362
TRANSITION (ACD&P)											

### Remarks

## D. Acquisition Strategy

N/A

### **E. Performance Metrics**

N/A