

**UNCLASSIFIED**

<b>CBDP BUDGET ITEM JUSTIFICATION SHEET (R-2 Exhibit)</b>	DATE <b>February 2004</b>
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BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA3 - Advanced Technology Development (ATD)</b>	PE NUMBER AND TITLE <b>0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ATD)</b>
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COST (In Thousands)	FY 2003 Actual	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	Cost to Complete	Total Cost
Total Program Element (PE) Cost	105700	156496	117343	84778	89432	89810	86916	Continuing	Continuing
CB3 CHEMICAL BIOLOGICAL DEFENSE (ATD)	46712	93505	40527	25836	30838	31309	31957	Continuing	Continuing
CM3 HOMELAND DEFENSE (ATD)	2299	1794	2449	2429	2425	0	0	0	11396
CP3 COUNTERPROLIFERATION SUPPORT (ATD)	10815	4208	5257	4563	4114	3194	3259	Continuing	Continuing
TB3 MEDICAL BIOLOGICAL DEFENSE (ATD)	34677	45944	55621	39416	39440	42499	38625	Continuing	Continuing
TC3 MEDICAL CHEMICAL DEFENSE (ATD)	11197	11045	13489	12534	12615	12808	13075	Continuing	Continuing

<p>Line No: 033</p> <p align="center">Page 1 of 51 Pages</p> <p align="right">Exhibit R-2 (PE 0603384BP)</p>
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BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/                  BA3 - Advanced Technology Development (ATD)</b>	PE NUMBER AND TITLE <b>0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ATD)</b>
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**A. Mission Description and Budget Item Justification:** This program element demonstrates technologies that enhance the ability of U.S. forces to defend against, and survive chemical and biological (CB) warfare. This program element (PE) funds advanced technology development for Joint Service and Service-specific requirements in both medical and non-medical CB defense areas. The medical program aims to produce drugs, vaccines, and medical devices as countermeasures for CB threat agents. Specific areas of medical investigation include: prophylaxis, pretreatment, antidotes and therapeutics, personnel and patient decontamination, and medical management of casualties. In the non-medical area, the focus is on demonstrations of CB defense technologies, including biological detection, chemical detection, and decontamination. These demonstrations, conducted in an operational environment with active user and developer participation, integrate diverse technologies to improve DoD Chemical/Biological Warfare (CBW) defense and deterrence. These demonstrations are leveraged by the Counterproliferation Support Program and include remote Biological Detection. Also research efforts are planned to evaluate technologies for Weapons of Mass Destruction Civil Support Teams (WMD-CSTs). Work conducted under this PE transitions to and provides risk reduction for System Integration/Demonstration (PE 0603884BP/PE 0604384BP) activities. The work in this PE is consistent with the Joint Service NBC Defense Research, Development, and Acquisition (RDA) Plan. This PE also provides for the conduct of advanced technology development in the areas of real-time sensing, accelerated BW operational awareness, and the restoration of operations following a BW/CW attack. This program is dedicated to conducting proof-of-principle field demonstrations, and tests of system-specific technologies to meet specific military needs.

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BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA3 - Advanced Technology Development (ATD)</b>	PE NUMBER AND TITLE <b>0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ATD)</b>
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<b>B. <u>Program Change Summary:</u></b>		<b><u>FY 2003</u></b>	<b><u>FY 2004</u></b>	<b><u>FY 2005</u></b>
Previous President's Budget (FY 2004 PB)		107763	103725	98843
Current Biennial Budget Estimates (FY 2005)		105700	156496	117343
Total Adjustments		-2063	52771	18500
a. Congressional General Reductions		0	-1679	0
b. Congressional Increases		0	70450	0
c. Reprogrammings		-280	0	0
d. SBIR/STTR Transfer		-1596	0	0
e. Other Adjustments		-187	0	18500

**Change Summary Explanation:**

**Funding:** FY04 - Congressional adjustment for CBD (+\$61,096K CB3; -\$3,505K TB3; -\$2,036K TC3).

FY05 - Realignment of funds due to reprioritization of programs within the Chemical Biological Defense Program to provide full funding of high priority developmental items (+\$7,500K CB3; +\$11,000K TB3).

**Schedule:**

**Technical:**

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COST (In Thousands)	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	Cost to	Total Cost
	Actual	Estimate	Estimate	Estimate	Estimate	Estimate	Estimate	Complete	
CB3 CHEMICAL BIOLOGICAL DEFENSE (ATD)	46712	93505	40527	25836	30838	31309	31957	Continuing	Continuing

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

**Project CB3 CHEMICAL BIOLOGICAL DEFENSE (ATD):** This project demonstrates technology advancements for Joint Service application in the areas of chemical and biological agent detection and identification, decontamination, and individual/collective protection which will speed maturing of advanced technologies to reduce risk in system-oriented integration/demonstration efforts. This project funds the Joint Service Family of Decontamination Systems (JSFDS) program, the Joint Service Active Stand-off CW Detection System (ARTEMIS) program, the Joint Service Sensitive Equipment Decontamination (JSSED) Program, the Joint Biological Stand-off Detection System (JBSDS), the Joint Service Wide Area Detector (JSWAD), and Joint Operational Effects Federation (JOEF). Additionally, this program funds the Small Unit Biological Detector (SUBD), Consequence Management Interoperability Service (CMIS), and the Chemical Biological Individual Sampler (CBIS).

**B. Accomplishments/Planned Program**

	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Testing and Trials	0	0	4500

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**FY 2005 Planned Program:**

- 3500 Support Additional TREs - Conduct technology readiness assessments on technologies transitioning from the applied research program to include consequence management technologies. Examples are decontamination solution formulations, stand-off chemical detection, chem-bio agent water monitor, chemical point detectors with TIC/TIM/NTA capabilities, and biological agent identifiers and triggers.
- 1000 Hot Lightweight Chemical Detector (LCD) - Characterize and assess the performance of a breadboard (heated inlet version of the UK fielded LCD) against NTAs and traditional agents. The breadboard assessment will be the basis for the design and build of a prototype. The performance of the prototype will be assessed for transition suitability to the acquisition program Joint Chemical Agent Detector (JCAD).

**Total** 4500

	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Detection	2922	8835	18900

**FY 2003 Accomplishments:**

- 1312 Lightweight Integrated CB Detection - Continued evaluation and development of DOE's micro chem lab to meet Joint Modular CB detector requirements.

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**FY 2003 Accomplishments (Cont):**

- 1610 Point Detection, Detector Modifications - Completed and demonstrated standard operating procedures for enhanced wet chemistry test kits and aerosol collectors/samplers as a "quick fix" for new chemical targets. Complete laboratory modification of point detection systems to enhance performance against new chemical targets and transitioned data package to the Automated Chemical Agent Detector Alarm acquisition program.

**Total** 2922

**FY 2004 Planned Program:**

- 400 Stand-off, Sensor Assessment Non-Traditional Agents (NTA) - Continue development of spectral database. Initiate enhancements of physics based performance models to include NTAs for the assessment of fielded and developmental systems to detect and identify NTAs.
- 3420 Chemical/Biological Agent Water Monitor (DTO CB37) - Detection of Agent in Water - Initiate limited utility assessment to demonstrate technology. Develop assessment criteria and initiate a prototype design and build for the assessment.
- 5015 Lightweight Integrated CB Detection (DTO CB50) - Complete evaluation and continued development of DOE's micro chem lab to include bio threats. Initiate the evaluation of the pyrolysis-GC-IMS system and a trade off study to downselect the appropriate system concept to meet the Joint Modular CB Detection requirements.

**Total** 8835

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**FY 2005 Planned Program:**

- 5900 Lightweight Integrated CB Detection (DTO CB50) - Downselect technologies to the best two or three approaches. Prepare design concepts based on these approaches.
- 3000 Stand-off Biological Aerosol Detection (DTO CB35) - Establish a series of field test to evaluate and demonstrate the capability to detect and discriminate biological vs non- biological agents.
- 6250 Chemical/Biological Agent Water Monitor (DTO CB37) - Detection of Agent in Water - Complete prototype build and assessment methodology.
- 1750 Point Detection, Biological Identification - Complete prototype build and assessment methodology.
- 2000 LISA Prototype - Assess the performance of the first generation detection algorithm under operational environments. Develop the second generation detection algorithm based on the assessed shortfalls of the first generation algorithm. Support additional work to transition technology into Chemical Unmanned Ground Reconnaissance (CUGR) ACTD.

**Total** 18900

	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Protection	0	270	500

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**FY 2004 Planned Program:**

- 270 Individual Protection, Clothing Non Traditional Agent (NTA) - Identify appropriate simulant chemicals for NTA aerosols when testing protective clothing layers and systems. Determine the effects of water phase in protective clothing layers on protection against NTA simulants.

**Total** 270

**FY 2005 Planned Program:**

- 500 Individual Protection, Clothing Non-Traditional Agent (NTA) - Continue to identify appropriate simulant chemicals for NTAs aerosols when testing protective clothing layers and systems. Determine the effects of water phase in protective clothing layers on protection against NTA simulants.

**Total** 500

	<u><b>FY 2003</b></u>	<u><b>FY 2004</b></u>	<u><b>FY 2005</b></u>
Decontamination	2992	900	2000

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**FY 2003 Accomplishments:**

- 598 Evaluation of Fielded Decontaminants Against NTAs - Completed stirred reactor studies on standard and emerging decontaminants against three NTAs. Conducted post decontamination contact hazard assessments for two NTAs. Conducted assessment studies on XE-555 resin and A-200 sorbent powder, used respectively in the M291 and M295 immediate decontamination kits, for two NTAs.
- 2394 Decontamination, Sensitive Equipment - Completed the JSSED interior decontamination analysis of alternatives (AoA), which has been staffed to and accepted by the Program Manager. Conducted field demonstration trials on thermal decontamination approaches in actual cargo aircraft. Conducted chamber trials using vapor phase hydrogen peroxide system for decontamination of interiors.

**Total** 2992

**FY 2004 Planned Program:**

- 900 Decontamination, Oxidative Formulation (DTO CB44) - Demonstrate products with existing applicator systems. Modify or develop alternative applicators. Conduct basic integration of products into a "simulated environment". Extend test bed to include multiple agents and NTAs. Conduct robust chamber studies using full-scale conceptual system testing with live agents.

**Total** 900

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**FY 2005 Planned Program:**

- 2000 Decontamination, Oxidative Formulation (DTO CB44) - Conduct safety, health and environmental studies. Complete live agent and applicator breadboard testing. Complete TRL 5/6 requirements.

**Total** 2000

	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Information Technology Systems	3066	4280	1400

**FY 2003 Accomplishments:**

- 2064 Chemical and Biological Warfare Effects on Operations (DTO CB43) - Prepared for transition of the fighterbase and casualty modules to Joint Operational Effects Federation (JOEF) program to support Block I Demonstration. Completed the first phase of independent verification of software. Baselined RESTOP ACTD results as model validation. Delivered airbase representation module and generic airbase module to the Defense Threat Reduction Agency.
- 1002 Chemical and Biological Hazard Environment Prediction (DTO CB55) - Transitioned Vapor Liquid Solid Tracking (VLSTRACK) Version 3.1 capabilities to the JEM Block I and JOEF programs. Continued development of advanced predictive capabilities (MESO). Enhanced the ability to analyze transport and flows over complex terrain and around structures such as ships (enhancements included addressing biological agent slurry transport, dusty agent behavior, and complex agent sources and sinks).

**Total** 3066

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**FY 2004 Planned Program:**

- 1711 Chemical and Biological Warfare Effects on Operations (DTO CB43) - Preparation for transition of the fighterbase and casualty modules to Joint Operational Effects Federation (JOEF) program to support Block I Demonstration. Complete the first phase of independent verification of software. Baseline RESTOP ACTD results as model validation. Deliver airbase representation module and generic airbase module to the Defense Threat Reduction Agency.
- 900 Planning, Training, and Analysis - Transition of STAFFS model to JOEF. Integration support putting NBC CREST and impact models into JOEF.
- 260 Chemical and Biological Hazard Environment Prediction (DTO CB55) - Transition advanced predictive capabilities (MESO) to JEM Block II program. Further enhance the complex terrain and flow around structures modeling capability to address effects of vegetation and surface scavenging.
- 910 Simulation Based Acquisition - Initiate investigation of prototype software development requirements to meet performance specifications for a Virtual Prototyping System (VPS) that would support acquisition of CB defense end items to protect a variety of installations/facility types. If resources allow, and an affirmative decision is made, prototyping efforts would begin in this fiscal year.
- 499 Point Detection, Biological Identification - Initiate development of an automated system to populate a biomarkers database system based on Mass Spec analysis.

**Total** 4280

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**FY 2005 Planned Program:**

- 200 Chemical and Biological Hazard Environment Prediction (DTO CB55) - Transition advanced predictive capabilities (MESO) to JEM Block II program. Further enhance the complex terrain and flow around structures modeling capability to address effects of vegetation and surface scavenging.
- 500 Chemical and Biological Warfare Effects on Operations (DTO CB43) - Test and finalize toward JOEF transition Block 2. Develop Marine Expeditionary Force HQ, depot, and railhead modules. Perform internal V&V.
- 700 Simulation Based Acquisition - Complete prototype VPS and conduct a technology demonstration. Conduct analyses and studies to support a Milestone A determination for VPS.

**Total** 1400

	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Advanced Tech Development	37732	77640	13227

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<p><b>FY 2003 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>• 465 Fielded Decontamination Assessment, Non-Traditional Agent (NTA) - Completed assessment of fielded decon system for NTAs.</li> <li>• 900 Technical Readiness Evaluation - Conducted Technical Readiness Evaluations (TRE) of point and stand-off CB detection systems. Conducted contact hazard evaluations using NATO protocols. Conducted off-gas hazard evaluations using NATO/TTCP protocols.</li> <li>• 14412 Technical Transition - Developed an improved sample processing interface for UV Matrix Assisted Laser Desorption Ionization (MALDI) -Time Of Flight (TOF) mass spectrometer and incorporate into DARPA BioTOF device. Completed evaluation of upconverting phosphors for bio identification. Completed evaluation of anthrax-specific antibodies. Evaluated and refined catalytic oxidation filtration device. Initiated development of pathogen agents database with UV/IR MALDI and construct automated sample processing interface. Completed evaluation of Sandia foam for military decon. Completed development of sample handling interface for HANAA. Extended MAGIChip capability to address additional pathogen agents. Initiated assessment of additional technologies in detection, decontamination, and filtration from other government agencies.</li> <li>• 2119 Miniature Chemical and Biological Detectors - Developed a prototype with a miniaturized reader and self-contained disposable credit card sized cartridges containing a detection array, all necessary reagents and buffers, and the microfluidics to conduct specific assays. The technology is based on individually addressable polymer microspheres.</li> </ul>		
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<p><b>FY 2003 Accomplishments (Cont):</b></p> <ul style="list-style-type: none"> <li>• 7406 Rapid Response Countermeasures to Biological and Chemical Threats - Continued studies to enhance public health and safety in the event of an animal or human based bioterrorism event; developed and demonstrated a wide area, real time human health monitoring and reporting database; continued to develop very rapid methods to detect biological threat agents on surfaces, in food and in water; continued studies into factors affecting biological toxicity of selected agents; initiated design study for antibody libraries; initiated photocatalytic air disinfection methods study; continued to investigate taggants using non standard DNA; began development of a small, high performance cooler for first responders.</li> <li>• 2887 CBRN Threat Test Using Public/Private Assets (Sensor Net) - Designed an Information Technology Infrastructure for Comprehensive Incident Management. This will provide a common data pathway for homeland security sensors such as CBRNE, meteorology, and visual sensors.</li> <li>• 1926 Bioterrorism/Agroterrorism Prediction and Risk Assessment - Initiated a predictive model to study of effects of a virus introduced to US native species (i.e., cattle).</li> <li>• 3464 Advanced Chemical Detector - Explored and validated an advanced chemical threat agent detector.</li> <li>• 1345 High Intensity Pulsed Radiation Facility for Chem-Bio Defense - Developed studies to understand the effects of radiation on biological materials as a method to neutralize the pathogenic effects without disrupting the cellular characteristics of the biological materials.</li> <li>• 785 Stand-off Sensor Assessment, Non-Traditional Agents (NTA) - Established infrastructure to develop spectral signature. Developed spectral signature database. Assessed optical techniques to the detection of NTAs.</li> </ul>		
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**FY 2003 Accomplishments (Cont):**

- 2023 Bioterrorism Defense and Advanced Sensors - Explored and validated the utility of advanced sensor technologies in combating bioterrorism.

**Total** 37732

**FY 2004 Planned Program:**

- 2524 Chemical and Biological Detectors - Develop technologies for chemical and biological detectors.
- 7272 Countermeasures to Biological and Chemical Threats Response - Explore and evaluate technologies for countermeasures to biological and chemical threats response.
- 1979 Handheld Biological Agent Detection System - Evaluate technologies for handheld biological agent detection system.
- 1188 Innovative Materials for MEMS Fabrication - Explore technologies for innovative materials for MEMS fabrication.
- 2969 Immunochemical Bio/Chem Agent Detector - Develop and validate immunochemical biological and chemical agent detector technologies.
- 6427 Bio-MEMS - Develop and validate bio-MEMS technologies.
- 1979 Vaporized Hydrogen Peroxide Tech for Decontamination - Develop and validate vaporized hydrogen peroxide technologies for decontamination.
- 2250 Technical Readiness Evaluation (TRE) - Conduct TREs of point and stand-off CB detection systems. Conduct stirred reactor, contact hazard, and off gas testing on emerging decontaminants not tested previously.

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**FY 2004 Planned Program (Cont):**

- 9845 Technical Transition - Complete development of integrated UV MALDI-TOF and IR MALDI-TOF mass spectrometers. Complete catalytic oxidation filtration device. Complete evaluation of MAGIChip. Continue assessment of technologies in detection, decontamination, and filtration from other government agency programs.
- 1979 Rapid Response Database Center - Develop and validate rapid response database.
- 4848 Reactive Air Purification - Explore reactive air purification technologies.
- 1979 High Intensity Pulsed Radiation Facility for CB Agent Defeat - Explore technologies for a high intensity pulsed radiation facility for CB agent defeat.
- 6677 Sensor Net/CBRN Threat using Public and Private Assets - Develop and validate technologies for sensor net/CBRN threat using public and private assets.
- 990 Rapid Response Sensor Networking - Evaluate technologies for rapid response sensor networking.
- 24734 Chem-Bio Defense Initiative - Develop multiple technologies and methodologies for the rapid detection of, and protection from biological agents utilizing both point and stand-off platforms.

**Total** 77640

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**FY 2005 Planned Program:**

- 9847 Technical Transition - Conduct competitive assessment of all mature mass spectrometric biodetection approaches. Complete assessment of selected technologies in detection, decontamination, and protection from other government agency programs identified for evaluation in previous FY.
- 2380 Technical Readiness Evaluation - Conduct Technology Readiness Evaluations (TRE) of point and stand-off CB detection systems. Conduct stirred reactor, contact hazard and off gas testing on emerging decontaminants not tested previously.
- 1000 Stand-off, Sensor Assessment Non-Traditional Agent (NTA) - Complete spectral database of NTAs. Complete enhancements of physics based performance models to include NTAs for the assessment of fielded and developmental systems to detect and identify NTAs. The assessment will be used to develop a cost-benefit analysis on the value and potential to upgrade either fielded or developmental systems to detect and identify NTAs.

**Total** 13227

	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
SBIR/STTR	0	1580	0

**FY 2004 Planned Program:**

- 1580 SBIR - Small Business Innovative Research

**Total** 1580

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<b>C. <u>Other Program Funding Summary:</u></b>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>To Compl</u>	<u>Total Cost</u>
BJ4 BIOLOGICAL DEFENSE (ACD&P)	3408	0	0	0	0	0	0	0	3408
CA4 CONTAMINATION AVOIDANCE (ACD&P)	22084	22642	14938	2494	2495	12493	2503	Cont	Cont
CO4 COLLECTIVE PROTECTION (ACD&P)	1781	0	0	0	0	0	0	0	1781
CP3 COUNTERPROLIFERATION SUPPORT (ATD)	10815	4208	5257	4563	4114	3194	3259	Cont	Cont
CP4 COUNTERPROLIFERATION SUPPORT (ACD&P)	12463	14836	17075	24313	25462	26059	26633	Cont	Cont
DE4 DECONTAMINATION SYSTEMS (ACD&P)	6480	24462	17886	6798	3872	0	6696	Cont	Cont
IP4 INDIVIDUAL PROTECTION (ACD&P)	3300	0	0	0	0	0	0	0	3300

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COST (In Thousands)	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	Cost to	Total Cost
	Actual	Estimate	Estimate	Estimate	Estimate	Estimate	Estimate	Complete	
CM3 HOMELAND DEFENSE (ATD)	2299	1794	2449	2429	2425	0	0	0	11396

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

**Project CM3 HOMELAND DEFENSE (ATD):** This project funds Pre-Systems Acquisition in support of Consequence Management teams around the Nation. National Guard Weapons of Mass Destruction Civil Support Teams (WMD CSTs) are being established in every state. These teams were created based upon the Defense Reform Initiative Directive #25 (DRID #25), Integrating National Guard and Reserve Component Support for Response to Attacks Using Weapons of Mass Destruction (WMD). The role of the Civil Support Teams (CSTs) were further codified in the National Security Strategy of October 1998, which builds upon the National Guard's ties to the communities throughout the nation, and its long-standing tradition of responding to national emergencies. The strategy allows the National Guard to provide forces and resources that the emergency manager requires to manage the potentially catastrophic effects of a WMD situation. The National Guard, as the lead organization for military support to local and state authorities, leverages its geographic dispersion across the nation to reduce response times, and allow for the majority of the country to be protected. As a result of Presidential and Secretary of Defense directives, the Department of Defense established the WMD CSTs to rapidly respond in support of a local incident commander to assess a suspected WMD incident scene, advise them of appropriate courses of action that will protect local populations from loss of life, injury, and significant property damage, and facilitate the development of their requests for assistance (RFAs) based on CSTs knowledge of available local, state and federal resources that can assist in the mitigation of a WMD emergency.

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This program funds the acquisition, validation and testing of commercial off-the-shelf (COTS)/government off-the-shelf (GOTS) components on the existing Table of Distribution and Allowances (TDA) for WMD CSTs as well as those systems or components that are responsive to validated WMD CST requirements. This program also funds the evaluation of new commercial products and capabilities that may meet requirements and may be considered for the WMD CST TDA.

**B. Accomplishments/Planned Program**

	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
WMD - CIVIL SUPPORT TEAMS	2299	1764	2449

**FY 2003 Accomplishments:**

- 1300 WMD CST - Initiated evaluation of commercially produced level A and B suit ensembles being used by the National Guard Bureau (NGB) WMD-CST and the United States Army Reserve (USAR) Reconnaissance and Decontamination Platoons.
- 999 WMD CST - Initiated a joint evaluation with the Navy and Air Force to assess capabilities to meet the NGB WMD-CST Analytical Laboratory System (ALS) Block I requirements.

**Total** 2299

**FY 2004 Planned Program:**

- 1365 WMD CST - Continue to evaluate Chemical / Biological detection / identification technologies for insertion into WMD CST Tables of Distribution and Allowances (TDA).

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**FY 2004 Planned Program (Cont):**

- 399 WMD CST - Develop modifications to commercial systems and technologies in response to specific WMD CST operational requirements.

**Total** 1764

**FY 2005 Planned Program:**

- 1449 WMD CST - Continue evaluation and testing of new commercial products being considered in response to WMD CST requirements.
- 755 WMD CST - Develop modifications to commercial systems and technologies in response to specific WMD CST operational requirements.
- 245 WMD CST - Implement modified requirements and transition processes and continue to participate in analysis of alternatives and for follow-on technology insertion options.

**Total** 2449

	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
SBIR/STTR	0	30	0

**FY 2004 Planned Program:**

- 30 SBIR - Small Business Innovative Research

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**FY 2004 Planned Program (Cont):**  
**Total      30**

<b>C. <u>Other Program Funding Summary:</u></b>	<b><u>FY 2003</u></b>	<b><u>FY 2004</u></b>	<b><u>FY 2005</u></b>	<b><u>FY 2006</u></b>	<b><u>FY 2007</u></b>	<b><u>FY 2008</u></b>	<b><u>FY 2009</u></b>	<b><u>To Compl</u></b>	<b><u>Total Cost</u></b>
CA4 CONTAMINATION AVOIDANCE (ACD&P)	22084	22642	14938	2494	2495	12493	2503	Cont	Cont
CM5 HOMELAND DEFENSE (SDD)	956	5974	24274	389	0	0	0	0	31593
CM6 HOMELAND DEFENSE (RDT&E MGT SUPPORT)	1520	1558	1568	1555	1552	0	0	0	7753
JA0004 WMD - CIVIL SUPPORT TEAM EQUIPMENT	14055	8793	0	0	0	0	0	0	22848

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COST (In Thousands)	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	Cost to	Total Cost
	Actual	Estimate	Estimate	Estimate	Estimate	Estimate	Estimate	Complete	
CP3 COUNTERPROLIFERATION SUPPORT (ATD)	10815	4208	5257	4563	4114	3194	3259	Continuing	Continuing

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

**Project CP3 COUNTERPROLIFERATION SUPPORT (ATD):** The mission of the Counterproliferation Program (CP) is to address shortfalls in the DoD capability to defend against and counter the proliferation of Weapons of Mass Destruction (WMD). By focusing on near term results, the CP accelerates delivery of new tools, equipment, and procedures to combat forces. Under the passive defense pillar, CP enhances the efforts of the CBDP. This program defends our forces against WMD by demonstrating and transitioning mature technology. Efforts include planning and development of Advanced Concept Technology Demonstrations (ACTD), such as the Restoration of Operations (RestOps) and Contamination Avoidance at Seaport of Debarkation (CASPOD) in addition to Joint Warfighter Experiments (JWE).

**B. Accomplishments/Planned Program**

	<b><u>FY 2003</u></b>	<b><u>FY 2004</u></b>	<b><u>FY 2005</u></b>
ACTD Planning and Development	1745	2822	5257

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		PROJECT <b>CP3</b>
<p><b>FY 2003 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>• 1745 ACTD-PD - Evaluated FY04 and FY05 ACTD candidates. Supported the evaluation of the Large Frame Aircraft Decontamination Demonstration for RestOps ACTD. Supported the completion of transition planning for RestOps ACTD.</li> </ul> <p><b>Total 1745</b></p> <p><b>FY 2004 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 500 CASPOD - Developed test techniques, tactics, and procedures (TTP) for the use of the CASPOD ACTD technologies. Acquired test equipment, provided test participants and evaluators. Developed environmental compliance documentation for tests and preliminary demonstration.</li> <li>• 2322 ACTD-PD - Perform technology demonstrations and maturity evaluation on Contaminated Surface Detector (CSD) in preparation for the CUGR ACTD in FY05.</li> </ul> <p><b>Total 2822</b></p> <p><b>FY 2005 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 3757 ACTD-PD - Initiate technology maturity evaluations for selection of technologies for future ACTD candidates.</li> <li>• 1500 ACTD-PD - Initiate planning for ACTD candidates, explore potential CONOPS with ACTD candidates technologies.</li> </ul> <p><b>Total 5257</b></p>		
<p>Project CP3/Line No: 033 <span style="float: right;">Page 24 of 51 Pages <span style="float: right;">Exhibit R-2a (PE 0603384BP)</span></span></p>		

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	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
ACTD Development and Demonstration	5567	1315	0

**FY 2003 Accomplishments:**

- 2189 RestOps - Conducted RestOps ACTD lessons learned study and completed report on RestOps ACTD. Initiated transition planning for technology acquisition from the RestOps ACTD.
- 1986 CASPOD - Performed technical testing of technologies for the CASPOD ACTD.
- 867 CASPOD - Developed test techniques, tactics, and procedures (TTP) for the use of the CASPOD ACTD technologies. Acquired test equipment, provided test participants and evaluators. Developed environmental compliance documentation for tests and preliminary demonstration.
- 525 RestOps - Performed Large Frame Aircraft Decontamination Demonstration (LFADD) project.

**Total** 5567

**FY 2004 Planned Program:**

- 1315 ACTD-PD - Develop CONOPS and procedures for Biological Warfare fusion cell for the Biological Warfare Countermeasures Initiative (BWCI) Counter Bio project in preparation for United States Pacific Command (PACOM) FY05 demonstration.

**Total** 1315

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	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
ACTD PLANNING AND DEVELOPMENT	3503	0	0

**FY 2003 Accomplishments:**

- 3503 RESTOPS - Completed evaluation of technologies in final demonstration. Transition continues in FY04 to CP4 for residual support projects.

**Total** 3503

	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
SBIR/STTR	0	71	0

**FY 2004 Planned Program:**

- 71 SBIR - Small Business Innovative Research

**Total** 71

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<b>C. <u>Other Program Funding Summary:</u></b>									
	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>To Compl</u>	<u>Total Cost</u>
CP4 COUNTERPROLIFERATION SUPPORT (ACD&P)	12463	14836	17075	24313	25462	26059	26633	Cont	Cont

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BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA3 - Advanced Technology Development (ATD)</b>	PE NUMBER AND TITLE <b>0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ATD)</b>	PROJECT <b>TB3</b>
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COST (In Thousands)	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	Cost to	Total Cost
	Actual	Estimate	Estimate	Estimate	Estimate	Estimate	Estimate	Complete	
TB3 MEDICAL BIOLOGICAL DEFENSE (ATD)	34677	45944	55621	39416	39440	42499	38625	Continuing	Continuing

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

**Project TB3 MEDICAL BIOLOGICAL DEFENSE (ATD):** This project funds preclinical development of safe and effective prophylaxes and therapies (vaccines and drugs) for pre- and post-exposures to biological threat agents. This project also supports the advanced technology development of diagnostic devices to rapidly diagnose exposure to biological agents in clinical samples. A broad range of technologies involved in the targeting and delivery of prophylactic and therapeutic medical countermeasures and diagnostic systems is evaluated so that the most effective countermeasures are identified for development. Entry of candidate vaccines, therapeutics, and diagnostic technologies into development is facilitated by the development of technical data packages that support the Food and Drug Administration (FDA) Investigational New Drug (IND) and licensure processes and DoD acquisition regulations. Categories for this project include Defense Technology Objectives (DTOs); science and technology program areas in medical biological defense (diagnostic technology, bacterial therapeutics, toxin therapeutics, viral therapeutics, bacterial vaccines, toxin vaccines, and viral vaccines), directed research efforts; and efforts to transition promising medical biological defense technologies from the Defense Advanced Research Projects Agency (DARPA).

**B. Accomplishments/Planned Program**

	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Therapeutics	6740	10063	18537

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**FY 2003 Accomplishments:**

- 910 Therapeutics, Bacterial - Conducted comparative assessment for safety and efficacy of immunomodulators and other types of broad-spectrum compounds against multiple bacterial threat agents.
- 3888 Therapeutics, Toxin - Prepared sufficient amounts of lead inhibitors of botulinum toxin and staphylococcal enterotoxin B (SEB) intoxication for testing ex vivo or in vivo. Evaluated feasibility of drugs approved by FDA for septic shock as adjunct SE therapeutics using in vitro assays.
- 1742 Therapeutics, Viral - Evaluated the combined approach of antiviral drug therapy and immunotherapy in treatment of disease from filoviruses and further characterized three new antiviral targets against Ebola. Continued evaluating formulations or prodrugs to overcome problems with metabolism, bioavailability, or pharmacokinetics of compounds with otherwise acceptable antiviral profiles for orthopox viruses.
- 200 Therapeutics, Viral, Therapy for Smallpox and Other Pathogenic Orthopox Viruses (DTO CB54) - Began assessment and development of a clinical study site where sufficient monkeypox exists naturally in order to characterize the clinical course and pathogenesis of monkeypox.

**Total** 6740

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**FY 2004 Planned Program:**

- 1420 Therapeutics, Bacterial - Continue the assessment of selected compounds for safety and efficacy against multiple bacterial threat agents in small animal models.
- 3520 Therapeutics, Toxin - Standardize in vivo concept model systems for assessment of therapeutic efficacy and surrogate endpoints of human clinical efficacy for SE intoxication. Test FDA-approved drugs for septic shock as adjunct SE therapeutics in vivo.
- 1323 Therapeutics, Viral - Complete the evaluation of one antiviral drug formulation for orthopox viruses. Continue evaluating second drug formulation or prodrugs for orthopox viruses.
- 400 Therapeutics, Viral, Therapy for Smallpox and Other Pathogenic Orthopox Viruses (DTO CB54) - Complete the assessment of the clinical study site to determine feasibility for use in a field trial of cidofovir to treat human monkeypox. Complete an initial dose seeking study using an oral form of cidofovir in the monkeypox primate model.
- 2600 Therapeutics, Toxin, Therapeutic Strategies for Botulinum Neurotoxins (DTO CB59) - Initiate ex vivo evaluation of lead compounds in model systems for therapeutic efficacy. Standardize in vivo concept model systems for assessment of therapeutic efficacy and surrogate endpoints of human clinical efficacy for botulinum neurotoxin (BoNT) intoxication.
- 800 Therapeutics, Viral, Therapeutic Strategies for Treating Filovirus (Marburg and Ebola Viruses) Infection (DTO CB63) - Determine the basis for the pathogenesis of filovirus-induced shock or toxemia in animal models and identify potential mediators.

**Total** 10063

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**FY 2005 Planned Program:**

- 3090 Therapeutics, Bacterial - Advance the assessment of selected compounds for safety and efficacy against multiple bacterial threat agents in non-human primates. Enhance aerobiology capabilities and animal model development to facilitate bacterial therapeutics research.
- 6208 Therapeutics, Toxin - Conduct proof-of-concept studies in animal models with lead compounds shown to have potential as inhibitors of SEs. Enhance aerobiology capabilities and animal model development to facilitate toxin therapeutics research.
- 2329 Therapeutics, Viral - Finish characterization of genes identified in random homozygous knock-out screening and their evaluation as drug targets. Finish screening for inhibitors of ribonucleic acid (RNA) polymerase. Evaluate novel targets obtained from proteomic studies. Continue evaluating new drug formulations or prodrugs for orthopox viruses. Enhance aerobiology capabilities and animal model development to facilitate viral therapeutics research.
- 540 Therapeutics, Viral, Therapy for Smallpox and Other Pathogenic Orthopox Viruses (DTO CB54) - Complete technical data package supporting FDA approval of a labeled indication for pre- and post-exposure treatment for smallpox with intravenous (IV) cidofovir by the drug license holder.
- 4430 Therapeutics, Toxin, Therapeutic Strategies for Botulinum Neurotoxins (DTO CB59) - Continue to evaluate high affinity recombinant human antibodies against BoNT in vivo. Develop surrogate endpoints of human clinical efficacy for BoNT therapeutics. Evaluate neuronal drug delivery systems for leading BoNT treatment modalities in vitro and ex vivo.
- 1940 Therapeutics, Viral, Therapeutic Strategies for Treating Filovirus (Marburg and Ebola Viruses) Infection (DTO CB63) - Identify and test leading antiviral technology candidates in appropriate animal model systems.

**Total** 18537

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	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Diagnostics	4035	4463	14104

**FY 2003 Accomplishments:**

- 2435 Diagnostic Technologies - Continued comparing alternative diagnostic technologies in laboratory-based and field-based studies prior to transition to the field medical laboratory. Compared overlapping diagnostic technologies that can be integrated into a single comprehensive platform capable of identifying a broad range of biological threat agents in clinical specimens in laboratory-based and field-based studies. Continued to develop, evaluate, and transition diagnostic assays out of the technology base in support of the Joint Biological Agent Identification and Diagnostic System (JBAIDS) acquisition program.
- 1600 Diagnostic Technologies, Improved Immunodiagnostic Platform (DTO CB47) - Identified immunodiagnostic technology options offering performance and design characteristics capable of addressing operational requirements of the JBAIDS acquisition program. Demonstrated technical capability for detection of at least three biological agents (including toxins) in three biological matrices within two hours with the immunodiagnostic technology options. Conducted comparative laboratory evaluation trial of the immunodiagnostic technology options and identified top performing immunodiagnostic platform based on results of the laboratory evaluation trial.

**Total**    4035

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**FY 2004 Planned Program:**

- 1163 Diagnostic Technologies - Continue to compare alternative diagnostic technologies in laboratory-based and field-based studies prior to transition to the field medical laboratory. Continue to compare overlapping diagnostic technologies that can be integrated into a single comprehensive platform capable of detecting and identifying a broad range of biological threat agents in clinical specimens in laboratory-based and field-based studies. Continue to develop, evaluate, and transition diagnostic assays out of the technology base in support of the JBAIDS acquisition program.
- 2100 Diagnostic Technologies, Improved Immunodiagnosics Platform (DTO CB47) - Complete interlaboratory evaluation of top performing immunodiagnostic technology option. Perform a multi-center evaluation trial of the top performing immunodiagnostic platform and prepare a technical data package detailing results of the multi-center trial. Recommend immunodiagnostic technologies for incorporation into JBAIDS acquisition program.
- 1200 Diagnostic Technologies, Methodology to Facilitate Development of Biological Warfare Threat Agent Detection and Medical Diagnostic Systems (DTO CB56) - Develop a technical data package format for delivering assays and reagents, in concert with the advanced developer.

**Total** 4463

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**FY 2005 Planned Program:**

- 7659 Diagnostic Technologies - Continue to compare alternative diagnostic technologies in laboratory-based and field-based studies prior to transition to the field medical laboratory. Initiate a detailed analysis of alternatives for an advanced integrated diagnostic system capable of detecting and identifying a broad range of biological threat agents in clinical specimens in laboratory-based and field-based studies using a combination of appropriate technologies. Continue to develop, evaluate, and transition diagnostic assays out of the technology base in support of the JBAIDS acquisition program. Analyze clinical samples obtained from human vaccinees receiving biodefense vaccines to evaluate host responses to the immunizations.
- 1445 Diagnostic Technologies, Methodology to Facilitate Development of Biological Warfare Threat Agent Detection and Medical Diagnostic Systems (DTO CB56) - Deliver four nucleic acid detection/diagnostic assays and/or supporting reagents to the advanced developer. Deliver four antigen detection assays and/or supporting reagents to the advanced developer.
- 5000 Diagnostics Technologies, IT Medical Surveillance - Demonstrate how to integrate medical surveillance information and potential CB threat agent information obtained through medical surveillance, with non-medical detection information; and work toward defining a draft Concept of Operations (CONOPS) for the application of these technologies.

**Total** 14104

	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Vaccines	10167	9865	12980

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**FY 2003 Accomplishments:**

- 1700 Vaccines, Bacterial, Medical Countermeasures for Brucella (DTO CB31) - Demonstrated effectiveness of candidate vaccine in non-human primate challenge model for protective efficacy against a single pathogenic Brucella species. Collected information for preparation of a technical data package supporting transition of the live, attenuated Brucella vaccine candidate out of technology base.
- 800 Vaccines, Viral, Medical Countermeasures for Encephalitis Viruses (DTO CB24) - Demonstrated that the lead Venezuelan equine encephalitis (VEE) vaccine candidate, V3526, induced protection against the three VEE virus subtypes of concern (IA/B, IE, and IIIA), which would significantly reduce the complexity of a multivalent VEE vaccine. Completed analyses of the stability, safety, and efficacy (potency) of V3526 in mouse and non-human primate models. Determined the surrogate protection marker to be serum-neutralizing antibody in the non-human primate model. Completed the technical data package for the V3526 vaccine candidate and handed it off to the advanced developer.
- 1102 Vaccines, Alternative Delivery Methods for Recombinant Protein Vaccines (DTO CB32) - Performed initial efficacy studies for single recombinant protein delivered by alternate route(s). Proposed monovalent vaccine formulations for intranasal, inhalational, and/or transdermal delivery systems. Proposed in vitro correlate of immunity for surrogate endpoint of clinical efficacy.
- 1000 Vaccines, Bacterial, Recombinant Plague Vaccine Candidate (DTO CB34) - Continued expanded studies in non-human primates for immunogenicity and efficacy and downselected the best non-human primate model. Continued studies to optimize vaccine production and formulation to support entry of the vaccine candidate into component advanced development. Completed a revised technical data package based on completed studies, to facilitate transition of the vaccine candidate out of technology base.

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**FY 2003 Accomplishments (Cont):**

- 1749 Vaccines, Bacterial - Initiated a comparison of the safe and most efficacious vaccine candidates against select agent exposures. Analyzed study data to determine best glanders vaccine candidate(s). Incorporated data for Brucella and plague vaccine candidates into technical data packages. Continued assay support and studies on adjuvants and formulations in support of rPA and recombinant plague F1-V vaccine candidates progress through component advanced development; continued to evaluate the efficacy of rPA immunity against B. anthracis strains of diverse geographic origins; and continued long-term rPA efficacy studies in rabbits and non-human primates.
- 555 Vaccines, Toxin - Completed the scale up process development of botulinum toxin serotype C vaccine candidate. Conducted process development work for botulinum toxin serotypes D and G vaccine candidates in the Pichia yeast expression system.
- 1815 Vaccines, Viral - Tested promising vaccine strategies in non-human primates for the ability to protect against filoviruses (Marburg and Ebola viruses). Continued research studies for the development of vaccine candidates for eastern and western equine encephalitis virus (EEE and WEE).
- 1446 Vaccines, Vaccine Stabilization - Developed chemical and physical methods to detect molecular changes in various candidate biodefense vaccine platforms and constructs that are responsible for loss of antigenicity at elevated temperatures. Confirmed that these changes confer the loss of vaccine activity under storage and shipping conditions. Developed accelerated stability high-throughput assays based upon these molecular changes found to be responsible for the vaccine's loss of antigenicity. Conducted screening of vaccine excipients for stabilization of proteins and viral particles.

**Total** 10167

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<p><b>FY 2004 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 2113 Vaccines, Bacterial - Continue to perform animal studies which support transition of potential Brucella vaccine candidates to advanced development. Perform studies to address the mechanism of protective cellular immunity induced by selected vaccine candidates. Continue studies supporting rPA and recombinant plague F1-V vaccine candidates clinical trials and progress toward licensure. Complete developmental work on the mouse potency assay in support of rPA vaccine candidate advanced development.</li> <li>• 252 Vaccines, Toxin - Produce and characterize inactivated BoNT light chain vaccine candidates and large-scale truncations of BoNT holotoxins. Clone and express existing BoNT vaccine candidates using selected plant-based expression systems. Initiate studies exploring multivalent vaccine technologies for protection against multiple botulinum neurotoxin serotypes.</li> <li>• 1800 Vaccines, Alternative Delivery Methods for Recombinant Protein Vaccines (DTO CB32) - Propose formulation/device/route for delivery of combinations of multiple recombinant proteins. Perform definitive efficacy studies on monovalent vaccine in second animal model. Evaluate in vitro correlate of immunity.</li> <li>• 2100 Vaccines, Toxin, Recombinant Ricin Vaccine (DTO CB46) - Complete toxicity assays, activity assays, and rodent efficacy studies for lead recombinant ricin toxin A-chain (rRTA) vaccine candidates. Conduct laboratory stability studies of the lead rRTA candidate. Evaluate lead candidate with in vitro models for vascular leak syndrome. Conduct efficacy studies in non-human primates with the lead rRTA vaccine candidate.</li> </ul>		
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**FY 2004 Planned Program (Cont):**

- 2900 Vaccines, Viral, Western and Eastern Equine Encephalitis (WEE/EEE) Vaccine Constructs for a Combined Encephalitis Vaccine (DTO CB58) - Initiate the evaluation of candidate vaccine platforms/constructs against a minimum of one of the alphaviruses of concern (WEE or EEE) in the mouse efficacy model. Continue research for the development of live attenuated mutant viruses as vaccine candidates for EEE virus infection. Establish aerosol WEE animal efficacy models for evaluating vaccine candidates.
- 700 Vaccines, Viral, Vaccine Technologies for Protection Against Filovirus (Marburg and Ebola Viruses) Exposure (DTO CB60) - Develop and improve animal models for evaluating vaccine candidates for protection against Ebola and Marburg viruses.

**Total** 9865

**FY 2005 Planned Program:**

- 2928 Vaccines, Bacterial - Continue to perform animal studies which support development of selected vaccine candidates against bacterial threat agents. Continue technology base studies in support of the development and eventual FDA licensure of the rPA and recombinant plague F1-V vaccine candidates. Enhance aerobiology capabilities and animal model development to facilitate research toward the development of bacterial vaccines.
- 1617 Vaccines, Toxin - Initiate evaluation of inactivated BoNT light chain vaccine candidates as well as large-scale truncations of BoNT holotoxins in animal models. Continue studies on multivalent vaccine candidates to protect against multiple BoNT serotypes, including cloning and expression of genes for novel multivalent vaccine candidates. Enhance aerobiology capabilities and animal model development to facilitate research toward the development of toxin vaccines.

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**FY 2005 Planned Program (Cont):**

- 500 Vaccines, Viral - Enhance aerobiology capabilities and animal model development to facilitate research toward the development of viral vaccines.
- 1890 Vaccines, Alternative Delivery Methods for Recombinant Protein Vaccines (DTO CB32) - Demonstrate proof-of-concept for lead alternate vaccine delivery system(s). Complete preclinical research studies and prepare recommendations to support transition of commercial technology for alternate vaccine delivery out of the technology base.
- 1680 Vaccines, Toxin, Recombinant Ricin Vaccine (DTO CB46) - Complete a comprehensive review of results with lead candidate, including potency, efficacy, adjuvant studies, toxicity, and pathology results in rodents. Complete efficacy studies and evaluate pathology in non-human primates with the lead vaccine candidate.
- 3070 Vaccines, Viral, Western and Eastern Equine Encephalitis (WEE/EEE) Vaccine Constructs for a Combined Encephalitis Vaccine (DTO CB58) - Continue evaluating the short-term efficacy of various vaccine platforms and constructs in available animal models. Determine the compatibility of selected vaccine platforms/constructs with Venezuelan equine encephalitis (VEE) vaccine candidate V3526.
- 1295 Vaccines, Viral, Vaccine Technologies for Protection Against Filovirus (Marburg and Ebola Viruses) Exposure (DTO CB60) - Test leading vaccine candidates in worst-case scenarios (viral challenge dose, route, pre-existing vector immunity, and variation in viral challenge strain).

**Total** 12980

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	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
DARPA Transition	12000	16700	10000

**FY 2003 Accomplishments:**

- 12000 Defense Advanced Research Projects Agency (DARPA) Program Transition - Continued expansion and definition of medical biological defense technologies transitioned from the DARPA. Completed lead optimization of a small molecule antibiotic, completed in vitro and in vivo safety and efficacy studies, and continued IND enabling studies. Developed two additional B-cell lines and extended the B-cell based diagnostic sensor technology to include toxin agents. Evaluated superantigen toxin antagonists in vitro assays. Used plant expression vectors to create transgenic whole-plant systems expressing plague vaccine antigens. Produced monoclonal antibodies directed against Ebola virus in transgenic plants (plantibodies). Optimized two classes of bacterial RNA-binding compounds with broad-spectrum antimicrobial activity. Applied DNA shuffling technology to identify novel antigens that show protection in mice against at least two encephalitic alphaviruses. Identified and evaluated biomarkers for protection by a synthetic lipid A analog (aminoalkyl glucosaminide 4-phosphate) in mouse and non-human primate models. Developed small molecular structures that inhibit botulinum neurotoxin A (BoNT A) at nanomolar concentrations. Completed mechanism of action and lead optimization studies of a new class of antibiotics that target DNA-methylation in anthrax.

**Total 12000**

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**FY 2004 Planned Program:**

- 16700 Defense Advanced Research Projects Agency (DARPA) Program Transition - Continue expansion and definition of medical biological defense technologies transitioned from the DARPA. Complete chemical manufacturing and control studies and file an IND application for a small-molecule antibiotic effective against anthrax. Develop additional B-cell lines and evaluate the B-cell based diagnostic sensor technology on clinical samples. Develop a blood assay for the superantigen toxin antagonists. Optimize plant lines and obtain milligram-quantities of plague vaccine antigens from multiple plant species for in DNA shuffling in non-human primates for protection against three encephalitic alphaviruses.

**Total** 16700

**FY 2005 Planned Program:**

- 10000 Defense Advanced Research Projects Agency (DARPA) Program Transition - Conclude characterization and process development of candidate vaccines, therapeutics, and diagnostic technologies to determine if any are sufficiently mature to transition to development. Develop five additional B-cell lines and complete development and performance testing of a 16-channel B-cell based diagnostic sensor. Establish formulation for an orally bioavailable superantigen toxin antagonist.

**Total** 10000

	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Medical Biological Warfare Defense	1735	4076	0

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**FY 2003 Accomplishments:**

- 1735 Medical Biological Warfare Defense, Bioadhesion Research to Combat Biological Warfare - Generated recombinant anthrax antigens, native protective antigen, lethal factor, and capsular antigens and developed conjugated vaccine formulations. Constructed covalent conjugates and nanoparticles displaying various combinations of anthrax antigens and determined immunogenicity in animals. Conjugated various combinations of anthrax toxins and capsular materials and determined the optimal conjugate for generating protective immune responses.

**Total** 1735

**FY 2004 Planned Program:**

- 4076 Medical Biological Warfare Defense, Bioadhesion Research to Combat Biological Warfare - Continue to generate recombinant anthrax antigens, native protective antigen, lethal factor, and capsular antigens and continue to develop conjugated vaccine formulations. Continue to construct covalent conjugates and nanoparticles displaying various combinations of anthrax antigens and determine immunogenicity in animals. Continue to conjugate various combinations of anthrax toxins and capsular materials and determine the optimal conjugate for generating protective immune responses.

**Total** 4076

	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
SBIR/STTR	0	777	0

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**FY 2004 Planned Program:**

- 777 SBIR - Small Business Innovative Research

**Total 777**

<b>C. <u>Other Program Funding Summary:</u></b>								<b><u>To</u> <u>Compl</u></b>	<b><u>Total</u> <u>Cost</u></b>
MB4 MEDICAL BIOLOGICAL DEFENSE (ACD&P)	<b><u>FY 2003</u></b>	<b><u>FY 2004</u></b>	<b><u>FY 2005</u></b>	<b><u>FY 2006</u></b>	<b><u>FY 2007</u></b>	<b><u>FY 2008</u></b>	<b><u>FY 2009</u></b>	Cont	Cont
MB5 MEDICAL BIOLOGICAL DEFENSE (SDD)	36057	64743	34968	45128	38518	18788	9553	Cont	Cont

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BUDGET ACTIVITY <b>RDT&amp;E DEFENSE-WIDE/ BA3 - Advanced Technology Development (ATD)</b>				PE NUMBER AND TITLE <b>0603384BP CHEMICAL/BIOLOGICAL DEFENSE (ATD)</b>				PROJECT <b>TC3</b>	
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COST (In Thousands)	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	Cost to	Total Cost
	Actual	Estimate	Estimate	Estimate	Estimate	Estimate	Estimate	Complete	
TC3 MEDICAL CHEMICAL DEFENSE (ATD)	11197	11045	13489	12534	12615	12808	13075	Continuing	Continuing

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

**Project TC3 MEDICAL CHEMICAL DEFENSE (ATD):** This project supports the investigation of new medical countermeasures to include prophylaxes, pretreatments, antidotes, skin decontaminants and therapeutic drugs to protect U.S. forces against known and emerging chemical warfare threat agents. Capabilities are maintained for reformulation, formulation, and scale-up of candidate compounds using current good laboratory practices. 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 development 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 and DoD acquisition regulations. Categories for this project include Defense Technology Objectives (DTOs), science and technology program areas (Nerve Agent Defense, Vesicant Agent Defense and Chemical Warfare Agent (CWA) Defense), and directed research efforts (Low Level CWA Exposure and Non-Traditional Agents(NTAs)).

**B. Accomplishments/Planned Program**

	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Nerve Agent Defense	4268	9092	9657

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<p><b>FY 2003 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>• 980 Nerve Agent Defense, Nerve Agent Anticonvulsants - Selected optimal anticholinergic drug for inclusion with midazolam anticonvulsant and established optimal treatment protocol in non-human primates.</li> <li>• 2088 Nerve Agent Defense, Biological Scavenger - Completed physiological pharmacokinetic model studies of expected human efficacy with various bioscavengers. Verified adequacy of transgenic animal model to produce recombinant enzyme scavenger.</li> <li>• 1200 Nerve Agent Defense, Improved Oxime (DTO CB48) - Conducted efficacy studies of candidate oxime(s) against traditional nerve agents and non-traditional agents (NTAs) in guinea pigs. Initiated down selection process. Synthesized appropriate quantities of each oxime for required studies.</li> </ul> <p><b>Total</b> 4268</p> <p><b>FY 2004 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 662 Nerve Agent Defense, Nerve Agent Anticonvulsants - Determine efficacy of midazolam anticonvulsant and anticholinergic drug combinations against seizures and lethality produced by all current threat agents in the guinea pig model.</li> <li>• 2610 Nerve Agent Defense, Biological Scavenger - Initiate evaluation of human protein recombinant scavenger. Utilize transgenic animal model to produce adequate amounts of recombinant enzyme scavenger for preclinical testing.</li> <li>• 520 Nerve Agent Defense, Neuroprotection - Assess potential neuroprotectant treatments for nerve agent-induced brain pathology in guinea pig model.</li> </ul>		
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<b>FY 2004 Planned Program (Cont):</b>		
<ul style="list-style-type: none"> <li>• 4300 Nerve Agent Defense, Improved Oxime (DTO CB48) - Initiate efficacy and pharmacokinetic (PK) studies of candidate oxime(s) for use against traditional nerve agents and NTAs in non-human primates and safety/toxicity studies in two species. Continue the down selection process.</li> <li>• 1000 Nerve Agent Defense, Non-Traditional Nerve Agent Medical Countermeasures (DTO CB57) - Evaluate the efficacy of candidate bioscavengers for protection against non-traditional nerve agents in multiple animal models.</li> </ul>		
<b>Total</b>	9092	
<b>FY 2005 Planned Program:</b>		
<ul style="list-style-type: none"> <li>• 750 Nerve Agent Defense, Nerve Agent Anticonvulsants - Assess application of emerging therapy for organophosphate insecticide poisoning to nerve agent exposure. Continue testing of midazolam and anticholinergic drug combinations against seizures and lethality produced by all current threat agents. Initiate PK evaluations of selected anticonvulsants.</li> <li>• 3107 Nerve Agent Defense, Biological Scavenger - Complete evaluation of human protein recombinant scavenger as a nerve agent countermeasure. Initiate preparation of technical data package for transition out of the technology base.</li> <li>• 300 Nerve Agent Defense, Neuroprotection - Initiate PK evaluations of selected neuroprotectants.</li> <li>• 5500 Nerve Agent Defense, Improved Oxime (DTO CB48) - Complete efficacy, safety/toxicity and PK studies of candidate oxime(s) for use against traditional nerve agents and NTAs. Down select the leading candidate oxime(s). Prepare a technical data package that supports FDA requirements for an IND application and for transition of the best improved, broad-spectrum candidate oxime(s) out of the technology base.</li> </ul>		
<b>Total</b>	9657	
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	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Vesicant Agent Defense	4860	717	1832

**FY 2003 Accomplishments:**

- 338 Vesicant Agent Defense, Vesicant Medical Countermeasures - Completed preclinical studies of selected vesicant therapy candidate compounds.
- 522 Vesicant Agent Defense, Cutaneous Therapeutics - Evaluated commercially licensed wound healing medical therapeutics for sulfur mustard (HD)-induced injuries.
- 4000 Vesicant Agent Defense, Medical Countermeasures for Vesicant Agents II (DTO CB30) - Completed preclinical safety and efficacy studies of selected vesicant countermeasure candidate compounds. Completed PK studies of vesicant countermeasure candidates. Performed additional studies necessary to completely characterize candidate therapy. Initiated preparation of a technical data package to support FDA requirements for an IND application.

**Total** 4860

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**FY 2004 Planned Program:**

- 334 Vesicant Agent Defense, Vesicant Medical Countermeasures - Pursue development of protective agent against HD-induced skin lesions.
- 383 Vesicant Agent Defense, Cutaneous Therapeutics - Begin efficacy tests of promising treatment strategies.

**Total** 717

**FY 2005 Planned Program:**

- 1300 Vesicant Agent Defense, Vesicant Medical Countermeasures - Initiate PK evaluations of selected antivesicants.
- 532 Vesicant Agent Defense, Cutaneous Therapeutics - Continue screening of promising treatment strategies, and prioritize successful strategies for further in-depth study.

**Total** 1832

	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Chemical Warfare Agent Defense	2069	1049	2000

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<p><b>FY 2003 Accomplishments:</b></p> <ul style="list-style-type: none"> <li>• 730 Chemical Warfare Agent Defense, Inhalation Therapeutics - Evaluated therapeutic agents for pulmonary edema produced by whole-body exposure to CWAs in animal models.</li> <li>• 245 Chemical Warfare Agent Defense, Medical Diagnostics - Evaluated hand-held cholinesterase monitor for clinical use.</li> <li>• 294 Chemical Warfare Agent Defense, Skin and Wound Decontamination - Pursued development of polyurethane immobilized cholinesterases and chemical agent hydrolyzing enzymes as skin and wound decontaminants for organophosphate CWAs. Developed protocols supporting the sponge decontamination concept and the detoxification of medically sensitive skin project. Evaluated formulations for efficacy.</li> <li>• 800 Chemical Warfare Agent Defense, Non-Traditional Agents (NTAs) - Compared all nerve agents for induction of neurochemical changes. Evaluated efficacy of anticonvulsants against NTAs. Evaluated current nerve agent medical decontamination procedures against percutaneous NTAs.</li> </ul> <p><b>Total</b> 2069</p> <p><b>FY 2004 Planned Program:</b></p> <ul style="list-style-type: none"> <li>• 314 Chemical Warfare Agent Defense, Medical Diagnostics - Develop and test a non-invasive prototype instrument that measures blood gases via finger, ear, or toe.</li> <li>• 435 Chemical Warfare Agent Defense, Skin and Wound Decontamination - Continue development of skin and wound decontaminants for organophosphate CWAs. Continue to expand decontamination and detoxification efforts by developing HD decontaminants.</li> </ul>		
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**FY 2004 Planned Program (Cont):**

- 300 Chemical Warfare Agent Defense, Low Level CWA Exposure - Evaluate the efficacy of the FDA-approved oxime treatment, pralidoxime chloride (2-PAM), against biochemical and behavioral effects induced by repeated low level exposure to chemical warfare nerve agents in guinea pigs.

**Total** 1049

**FY 2005 Planned Program:**

- 400 Chemical Warfare Agent Defense, Medical Diagnostics - Continue testing devices that measure blood gases via finger, ear, or toe.
- 300 Chemical Warfare Agent Defense, Skin and Wound Decontamination - Continue development of concepts for nerve agent and HD skin and wound decontamination.
- 1300 Chemical Warfare Agent Defense, Low Level CWA Exposure - Evaluate the effects of selected pretreatment and/or therapeutic medical countermeasures, to include the FDA-approved Soman Nerve Agent Pretreatment Pyridostigmine (SNAPP), on the detrimental actions of low dose chemical warfare nerve agent exposure in guinea pigs.

**Total** 2000

	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
SBIR/STTR	0	187	0

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**FY 2004 Planned Program:**

- 187 SBIR - Small Business Innovative Research

**Total 187**

<b>C. <u>Other Program Funding Summary:</u></b>	<b><u>FY 2003</u></b>	<b><u>FY 2004</u></b>	<b><u>FY 2005</u></b>	<b><u>FY 2006</u></b>	<b><u>FY 2007</u></b>	<b><u>FY 2008</u></b>	<b><u>FY 2009</u></b>	<b><u>To Compl</u></b>	<b><u>Total Cost</u></b>
MC4 MEDICAL CHEMICAL DEFENSE (ACD&P)	1642	3760	14780	4499	4539	4564	4614	Cont	Cont
MC5 MEDICAL CHEMICAL DEFENSE (SDD)	1778	1439	1423	7163	7199	7555	6269	Cont	Cont

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