Department of Defense
Chemical Biological Defense Program

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CBDP Advanced Planning Briefing to Industry

April 4, 2007

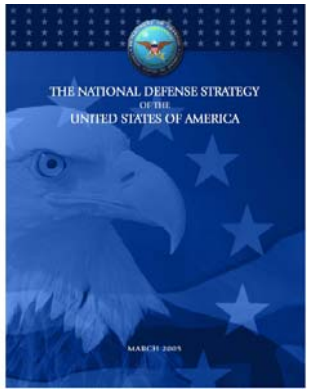
ATSD(NCB)'s Program Stragtegy Guidance for the CBDP

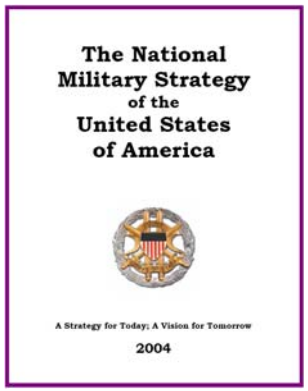
- **Provide a balanced CBDP to support National Military Strategies and Departmental objectives to improve CBRN Defense Readiness and reduce operational risk.**
  - Guided by 2006 QDR, SECDEF's FY2008-3024 Planning Guidance.
  - Provides strategic focus for the FY08-13 period.
  - Focuses on capabilities-based approaches.
  - Ensures joint integrated approaches to counter the threat.
  - Addresses lessons learned from Operations Enduring and Iraqi Freedom.
  - Addresses post-September 11, 2001 challenges.
  - Supports Transformation, Acquisition Reform and Strengthening Interagency Links.

- **Build a comprehensive fiscal plan wherein**
  ***budgets* flow from programs,**
  ***programs* from capability needs,**
  ***capability needs* from missions, and**
  ***missions* from *national security objectives*.**

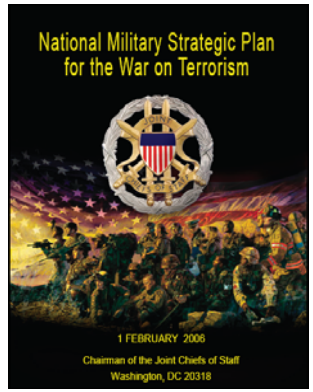
The CBDP Provides Key Capabilities Supporting Multiple National Strategies

National Security

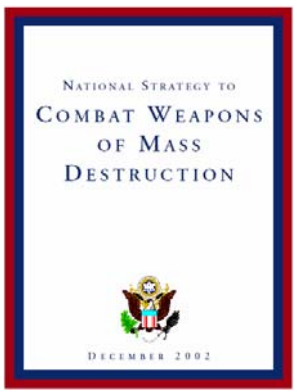


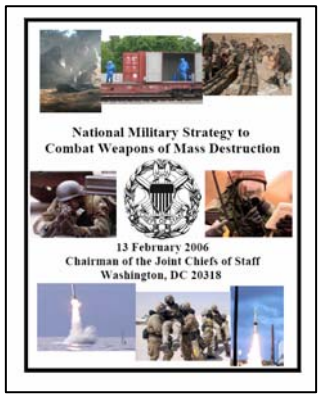


Combating Terrorism

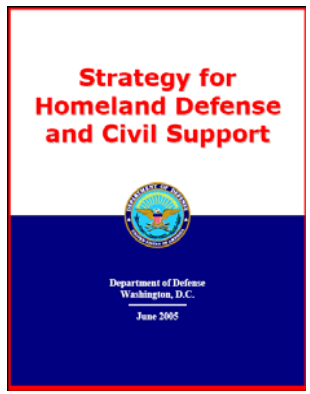


Combating WMD



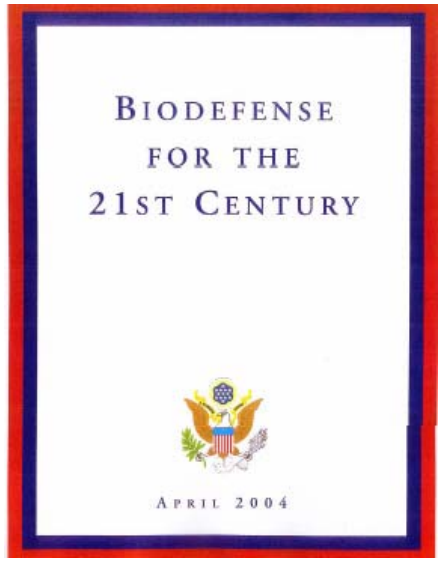


Homeland Security/Defense



National Strategies Addressing Emerging Threats

Biodefense for the 21st Century, The White House, April 2004 (NSPD-33/HSPD-10)



- **"Preventing and controlling future biological weapons threats will be even more challenging. Advances in biotechnology and life sciences—including the spread of expertise to create modified or novel organisms—present the prospect of new toxins, live agents, and bioregulators that would require new detection methods, preventive measures, and treatments. These trends increase the risk for surprise"**
- **"The proliferation of biological materials, technologies, and expertise increases the potential for adversaries to design a pathogen to evade our existing medical and non-medical countermeasures. To address this challenge, we are taking advantage of these same technologies to ensure that we can anticipate and prepare for the emergence of this threat."**

Medical Countermeasures against Weapons of Mass Destruction, The White House, January 31, 2007 (HSPD-18)

- **"...capitalize upon the development of emerging and future technologies that will enhance our ability to respond flexibly to anticipated, emerging, and future CBRN threats. "**

Quadrennial Defense Review (QDR):

Vision for Combating Weapons of Mass Destruction

The future force will be organized, trained, equipped, and resourced to deal with all aspects of the threat posed by weapons of mass destruction. It will have capabilities to:

- ***detect WMD***, including fissile material ***at stand-off*** ranges;
- locate and characterize threats;
- interdict WMD and related shipments whether on land, at sea, or in the air;
- sustain operations under WMD attack; and
- render safe or otherwise eliminate WMD before, during or after a conflict.

The Department will *develop new defensive capabilities* in anticipation of the continued evolution of WMD threats. Such threats include … *genetically engineered biological pathogens*, and *next generation chemical agents*. The Department will be prepared to respond to and help other agencies to mitigate the consequences of WMD attacks.

CBDP Vision and Mission

VISION

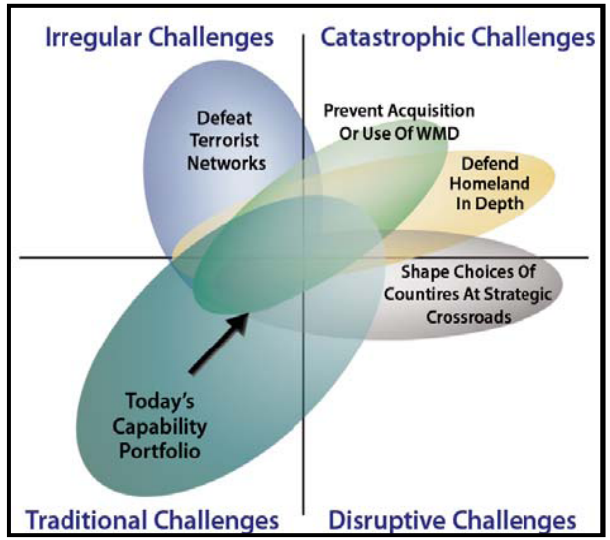
Ensure DOD operations are unconstrained by chemical and biological effects.

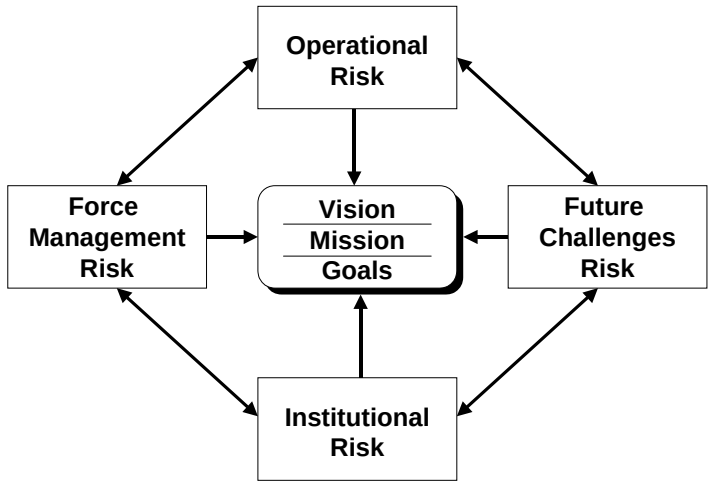
MISSION

Provide chemical and biological defense capabilities in support of the National Military Strategies.

Program Alignment with Strategy

- Utilize the Department's **risk management** framework appropriately to reduce near-term risks while developing new capabilities to meet tomorrow's challenges.
- Invest in capability development to address a **wider range of challenges**.
- Provide a risk-informed investment strategy reflecting **joint warfighting priorities**.
- Identify key outputs and appropriate balance among **near, mid, and far-term strategies** for achieving them.
- Ensure strategy-driven, **affordable and achievable** outcomes.
- Support the **transformation** process… one that not only anticipates the future but also seeks to create it.
- Support **transparent, open and agile decision making**.
- Deliver results that **support the Department-wide** strategy.





Pursue an investment strategy that seeks to reduce overall program risk, invest in revolutionary capabilities, hedge against future uncertainty and eliminate capability gaps.

The Challenge in Defining WMD Threats

- **The ability to characterize the WMD threat is complicated by:**
  - ***continued technological advances***
    - "Some hostile states are pursuing advanced weapons of mass destruction, including genetically engineered biological warfare agents that can overcome today's defenses." *
  - ***and by adversaries' active efforts to deceive the United States regarding their capabilities and intentions***
    - "It is extremely difficult to collect reliable intelligence on WMD programs and activities, which are closely guarded secrets. The prevalence of dual-use technologies and legitimate civilian applications means nuclear, chemical and biological research efforts are easy to conceal and difficult to detect and monitor. Based on the demonstrated ease with which uncooperative states and non-state actors can conceal WMD programs and related activities, the United States, its allies and partners must expect further intelligence gaps and surprises."*

* Quote from the 2006 Report of the Quadrennial Defense Review (QDR)

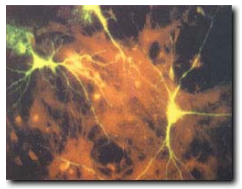
Evolution of Chemical and Biological Threats

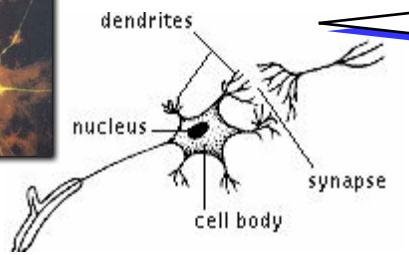
Commercial Chemical Compounds

Phosgene, Chlorine, Chloropicrin

Mustard (H) agents, Lewisite

Cholinesterase Inhibitors

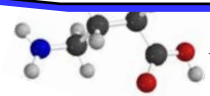




Tabun (GA)

G agents (GB, GD, GF)

V agents (VX)



Novichok agents

"Classical" Biological Agents

Bioregulators

Genetically Modified Agents

Advanced Biological Agents

1910 1920 1930 1940 1950 1960 1970 1980 1990 2000

CBDP Priorities for FY08

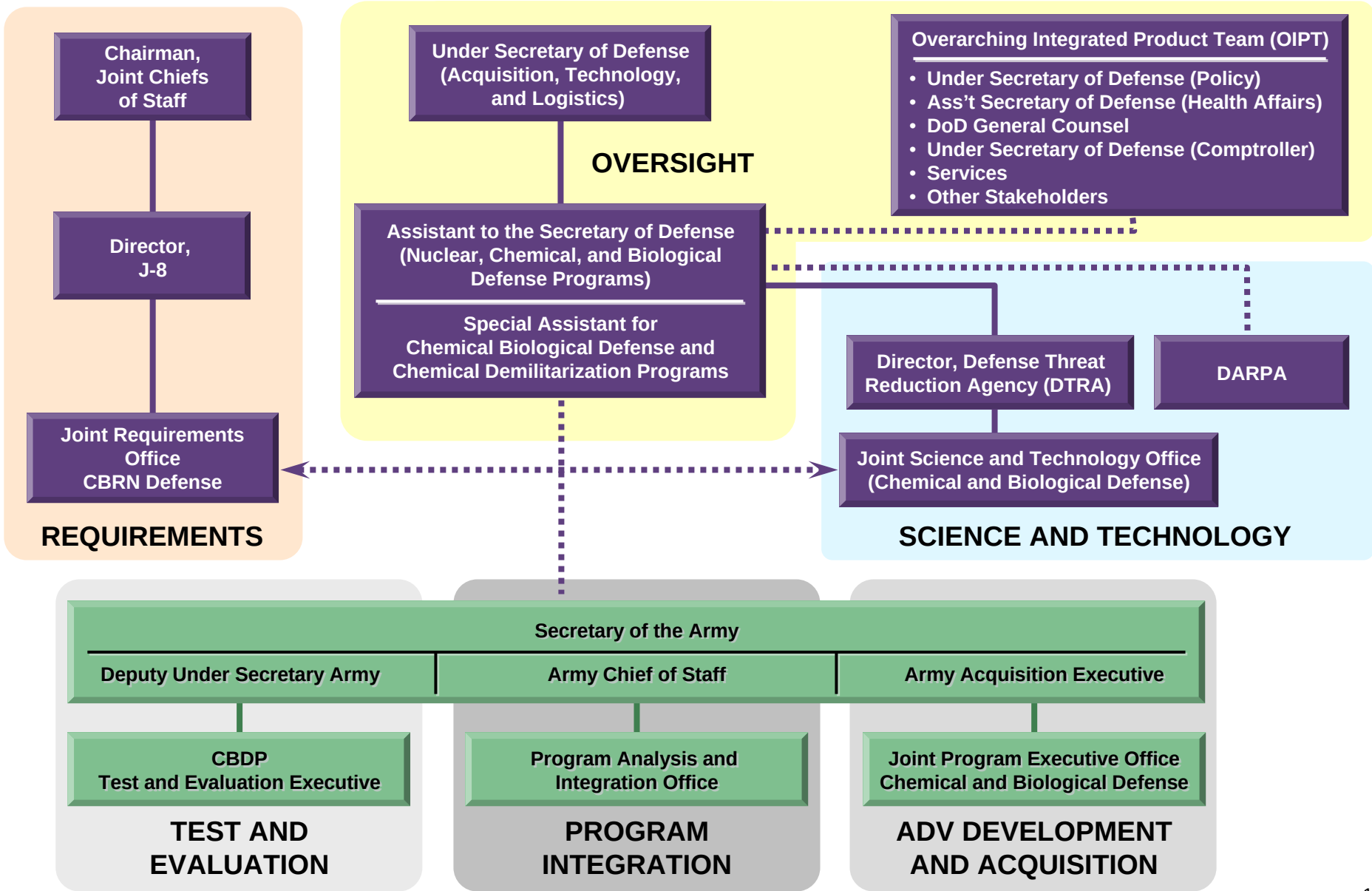
- Stable funding for the **Transformational Medical Technologies Initiative (TMTI)** to fully exploit the advanced science and technology innovation necessary to successfully counter future genetically engineered biological weapons.
- Adequate long-term investment in the **Research, Development, Test, and Evaluation (RDT&E) infrastructure** to enhance our RDT&E capabilities, including the modernization and construction of laboratories and test facilities to ensure we develop advanced countermeasures against current and emerging chemical and biological threats.
- **Consistent resources for the overall program** itself to ensure that, year after year, we are able to field the improved defensive capabilities essential to ensure our military can operate in any environment, unconstrained by chemical or biological weapons.

Background

Chemical Biological Defense Program Established by Congress

- Fiscal Year 1994 National Defense Authorization Act Public Law 103-160, Sect. 1703 (50 USC 1522)
- Oversight under a single office within the Office of the Secretary of Defense (OSD)
- Research, development, and acquisition funding consolidated into defense-wide accounts

CBDP Organization



CBDP Process

- Combatant Commanders
- Services

ATSD(NCB) Oversight

Joint Requirements Office (JRO)

Required Capabilities

Capability Needs

Prioritized Needs

Test & Evaluation Executive

Joint Combat Developer

Joint Science & Technology Office for CB Defense

Science &Tech Gaps

Joint Program Executive Office (JPEO)

Mature Technologies

Capabilities to the Warfighter for All Missions

Process based on managing total program risk

Leveraging Interagency Activities are Key to Achieving National Strategies

CBDP Coordinates With:

Counterproliferation Program Review Committee (CPRC)

Technical Support Working Group (TSWG)

U.S. Coast Guard

Centers for Disease Control (CDC)

National Institute of Allergies and Infectious Diseases (NIAID)

Department of Homeland Security (DHS), S&T Directorate

Various Levels of Coordination/Cooperation Exist With:

U.S. Department of Agriculture (USDA)

Department of Health and Human Services (DHHS)

Office of Science & Technology Policy

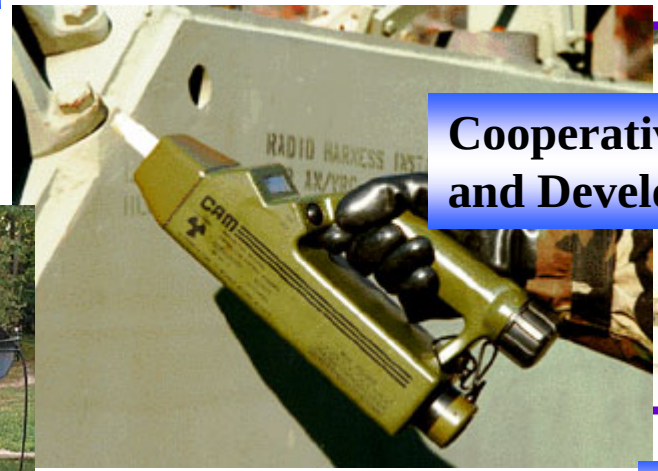
Department of Justice

National Security Council (NSC)

International Partnerships are Leveraged to Support All of Phases of CB Defense

Foreign Comparative Testing

MOUs & MOAs



Cooperative Research and Development

Foreign Military Sales

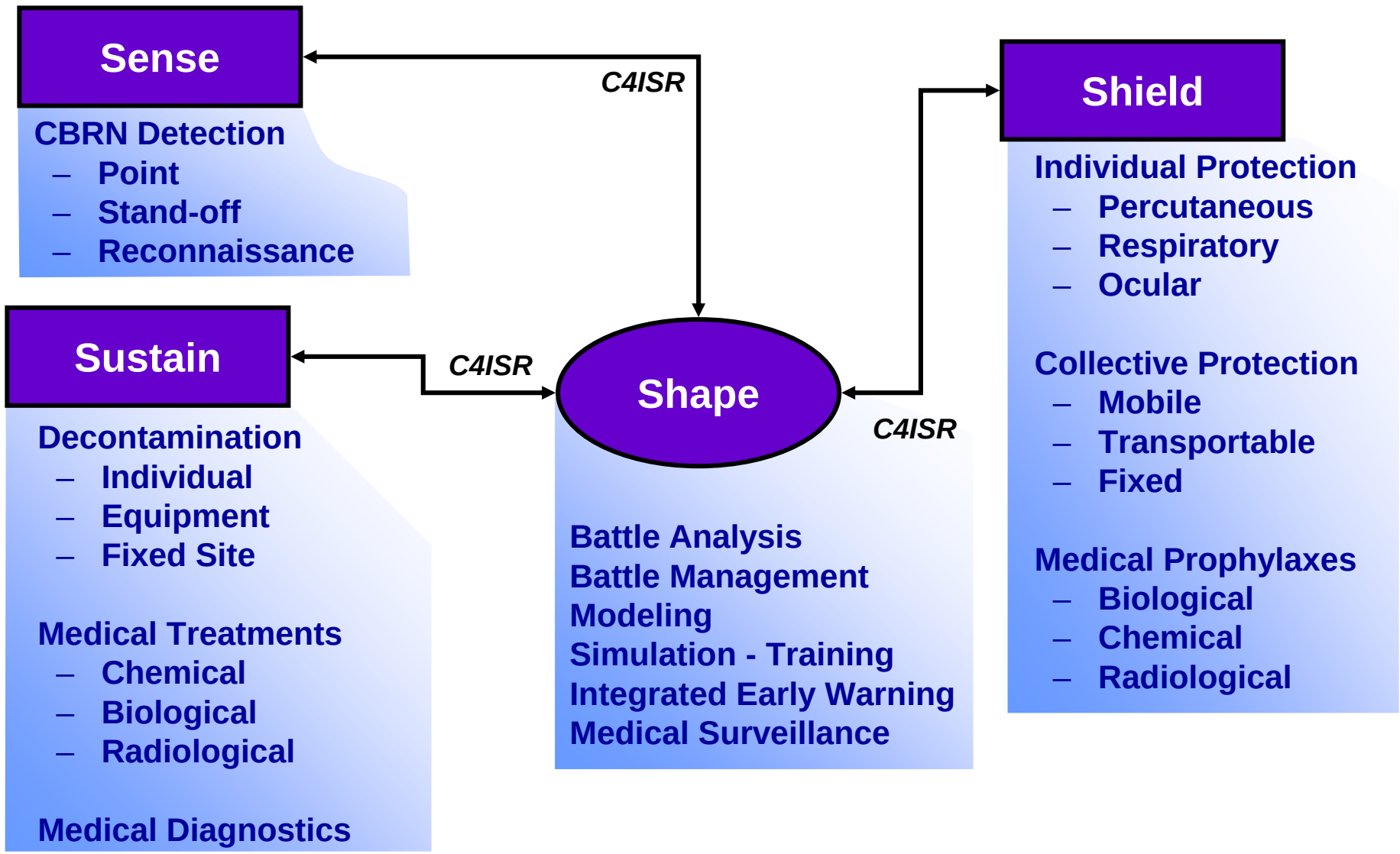
Cooperative Production

Exchange of Personnel

Loans

Exchange of Information

CBRN Defense
Operational Elements and Capabilities



Selected CB Defense Systems

SENSE

Joint Bio Point Detection System (JBPDS)

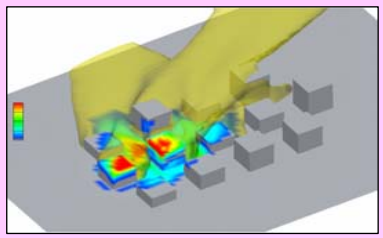
Joint Bio Standoff Detection System (JBSDS)

NBCRV

JCAD

SHAPE

Joint Warning and Reporting Network



Joint Effects Model (JEM)

Joint Operations Effects Federation (JOEF)

SHIELD

Joint Vaccine Acquisition Program

JSLIST

JSGPM

CB Protected Shelter

SUSTAIN

Joint Bio Agent Identification & Diagnostic System (JBAIDS)

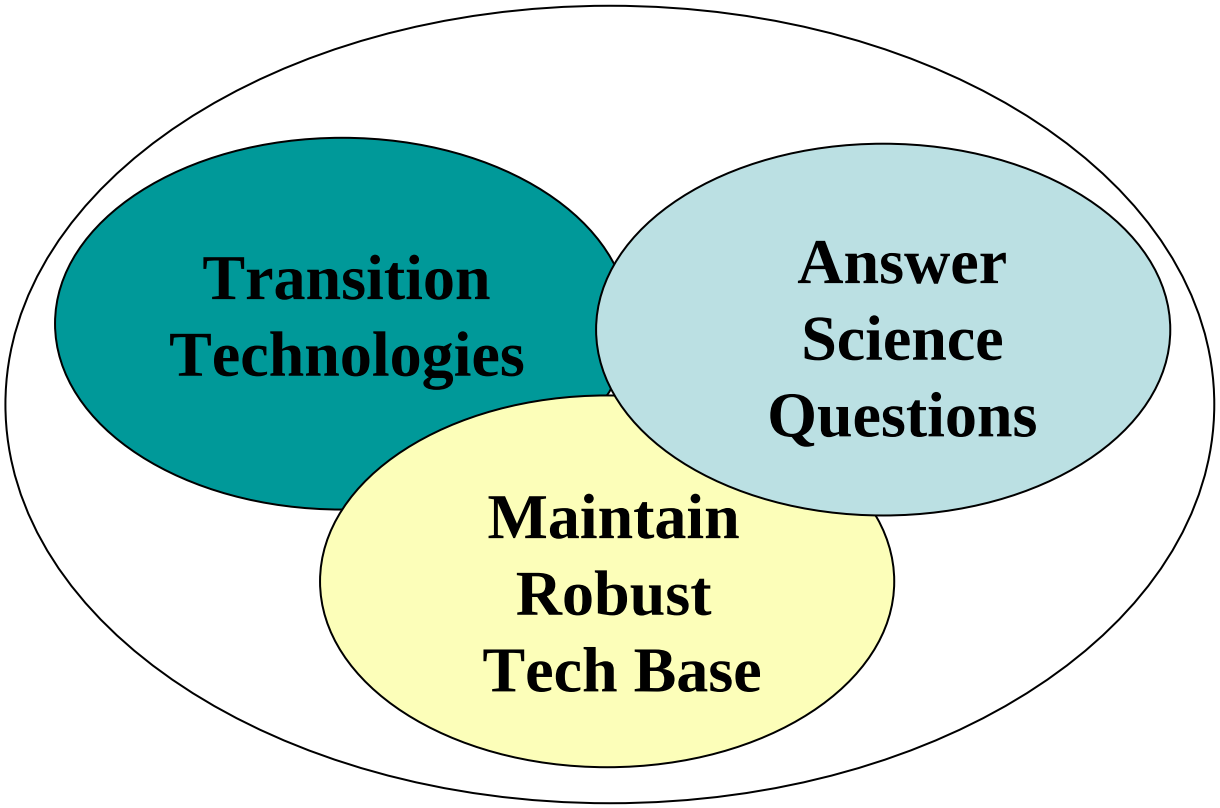
Antidote Treatment, Nerve Agent Autoinjector (ATNAA)

Joint Service Transportable Decon System

New Technologies for New Threats

- **Traditional technologies may not defeat advanced threats**
  - Currently licensed vaccines are not substantially more effective than those developed by Edward Jenner in the 18th century.
- **Research and Development efforts must evolve with the threat**
  - Develop hardware/platforms for both military and civilian use
  - Variants are distinguishable by platform, and software modifications: ***Common technologies – different platforms*.**
  - Establishment of Standards are crucial but the traditional physical model may not provide the best solution
    - For detection, approach needs to be sliding scale that optimizes sensitivity, probability of detection, false positive rate, and response time, known as ROC (Receiver Operating Characteristic) Curves
- **Leverage private sector to transform WMD protection and defeat capabilities to leapfrog WMD threat generations**

Overarching Objectives



CBDP Science & Technology (S&T) Initiatives

- **Identify and Exploit Revolutionary Technologies**
  - Transformational Medical Technologies Initiative (TMTI)
  - Transformational Countermeasures Technology Initiative (TCTI)
  - Nanotechnology Initiative
- **Recapitalization of S&T Infrastructure**
  - Test & Evaluation Facilities
  - NTA Test Chamber
  - U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) Recapitalization

Initiatives will enhance CBD S&T capabilities.

CBDP Priorities for FY08

- Stable funding for the **Transformational Medical Technologies Initiative (TMTI)** to fully exploit the advanced science and technology innovation necessary to successfully counter future genetically engineered biological weapons.
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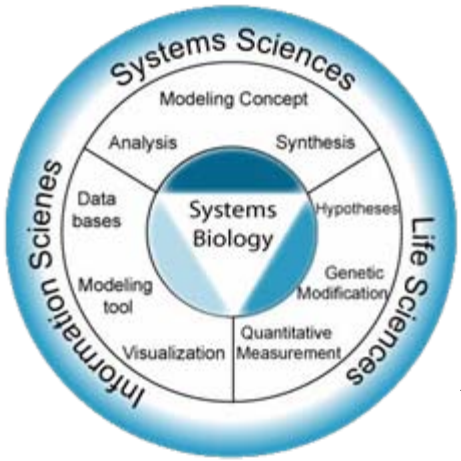
- **Consistent resources for the overall program** itself to ensure that, year after year, we are able to field the improved defensive capabilities essential to ensure our military can operate in any environment, unconstrained by chemical or biological weapons.

TMTI is a major medical innovation

Thrust Areas for Research

- *Genomic Identification*
- *Small Molecule Drugs*
- *Protein Based Therapeutics/Biologics*
- *Host Immune Enhancement*
- *Nucleotide Therapeutics*

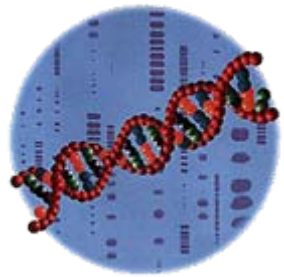
Overarching Research Approach



Microarray Technology
Bioinformatics
Proteomics
Metabolomics
Genomics
siRNA

Product Goals

Platform Technologies



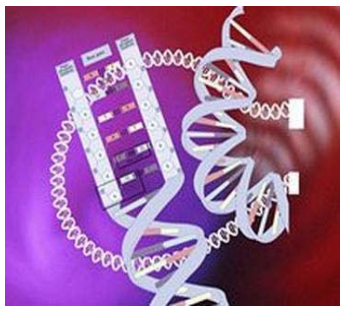
Genetic Sequencing of Pertinent Threat Agents

Broad Spectrum Counter-measures

An innovative approach using revolutionary technologies to expedite the development of products to counter emerging biological threats

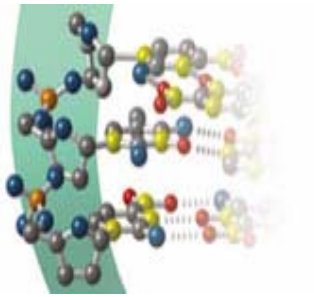
Synopses of Thrust Areas

Genomic Identification



7 projects:
- 3 bioinformatics platforms
- 2 pathogen target ID
- 2 host target ID

Small Molecule/ Drugs



8 projects:
- 6 anti-bacterial
- 2 anti-viral
- Fast track: re-label FDA approved Rx or late development candidates

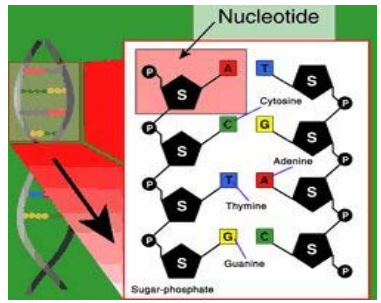
Protein-Based Therapeutics/ Biologics

4 projects:
- 2 anti-viral mAbs
- 2 host-directed

Host Immune Enhancement

3 projects:
- 1 anti-bacterial model
- 1 anti-viral platform
- 1 in negotiation

Nucleotide Therapeutics



8 projects:
- 1 anti-bacterial
- 2 anti-viral

- **The funded projects for FY06 are organized into the appropriate Thrust Areas based on the types of product being developed.**
- **The source selection board for FY07 met 16 March 2007; award decisions in April.**

TMTI Performance Metrics and Benchmarks

Industry standard metrics will be applied to each funded TMTI project and across Thrust Areas:	– Cost – Schedule – Performance
Benchmarks of successful complex DoD programs incorporated into TMTI management include:	– Funding and program stability – Program responsibility of lifecycle from development through operations support – Continuity of key personnel and technical expertise – Good management practice (communication, independent internal evaluations and contracting practices that value innovation)
Benchmarks from the pharmaceutical industry incorporated into TMTI management include:	– Clearly defined and widely acknowledged mission focus – Limiting unknowns and risk elements to early stages, when possible – Identifying Project Go/No-Go/Modification decision points

TMTI: The way ahead

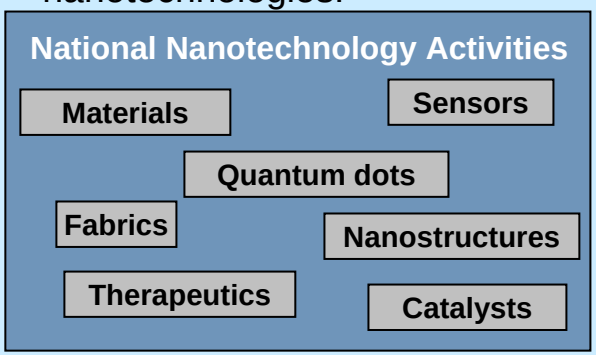
- **Need to balance investments between early- and late-term projects**
- **Coordination with other agencies (DHHS, DHS, and others) for an effective national effort**
  - **DoD may play key role in transitioning technologies from laboratory concepts to field-ready systems, especially medical systems**
- **Broad-spectrum, dual-benefit approaches will need to be evaluated in all areas**

Nanotechnology Initiative

Joint Science & Technology Office (JSTO) nanotechnology initiative is a two-phased effort.

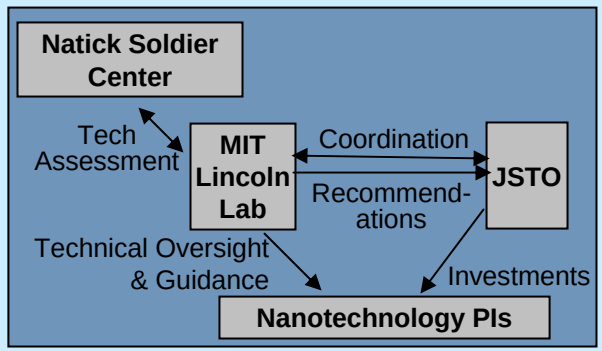
Phase I

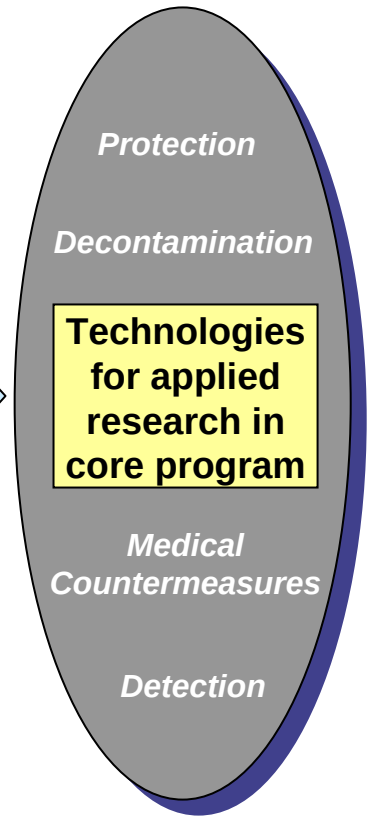
- **Objective:** Conduct a survey of nanotechnologies with application to CBD needs.
- Team from MIT-LL and Natick Soldier Center will conduct the survey.
- Recommendations will be provided to JSTO on applicable nanotechnologies.



Phase II

- **Objective:** Develop a solid S&T base of nanotechnology applied to all aspects of CBD needs.
- Multidisciplinary team will advise nanotechnology program Principal Investigators (PIs).
- Nanotechnology developments will continue to be monitored.

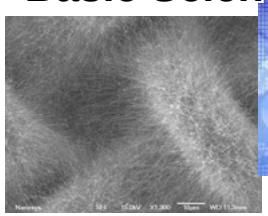




Leverages significant interagency investments for potential CBD applications.

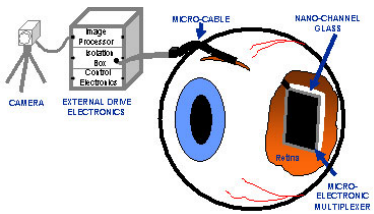
Transformational Countermeasure Technologies Initiative (TCTI)

Basic Science Advances

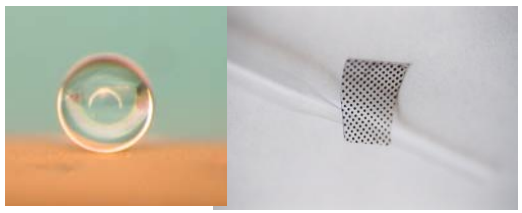


Nano-catalytic self-decon material

Bio-engineered Countermeasures



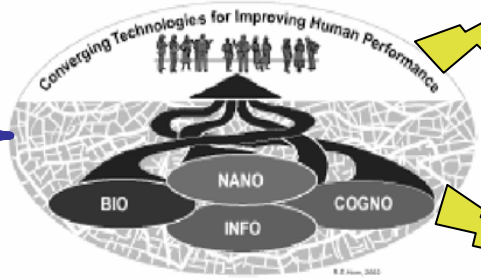
Meta-data information interface



Nano-scale protective coatings and fabrics

Integrated Cross-Cutting Technologies

- **Multi-threat defense**
- **Integral design concept**
- **Interactive digital multi-faceted data architecture**



Nanotechnology-Biotechnology-Information Technology-Cognitive Sciences (NBIC)

Broad Spectrum Applications

Future Combat Systems

- **Hierarchical systems of systems**
- **Non-intrusive; minimal logistics**

Achieves An Integrated System Using Revolutionary Technologies While Maintaining the Highest Levels of Performance and Being Invisible to the User

CBDP Priorities for FY08

- Stable funding for the **Transformational Medical Technologies Initiative (TMTI)** to fully exploit the advanced science and technology innovation necessary to successfully counter future genetically engineered biological weapons.

- Adequate long-term investment in the **Research, Development, Test, and Evaluation (RDT&E) infrastructure** to enhance our RDT&E capabilities, including the modernization and construction of laboratories and test facilities to ensure we develop advanced countermeasures against current and emerging chemical and biological threats.

- **Consistent resources for the overall program** itself to ensure that, year after year, we are able to field the improved defensive capabilities essential to ensure our military can operate in any environment, unconstrained by chemical or biological weapons.

Recapitalization of S&T Infrastructure

- **Initiative underway to recapitalize and revitalize CBD S&T infrastructure, which is required to:**
  - Counter expanding threats from novel and emerging threats.
  - Exploit advances in technology.
  - Speed the technology transition into systems acquisition programs.

U.S. Army Medical Research Institute of Infectious Diseases

Exterior

BL-4 Lab

Edgewood Chemical Biological Center's Advanced Chemistry Lab

Lab Exterior

Filtration System

Lab Interior

CBDP Major Range & Test Facility Base (MRTFB)
Dugway Proving Ground
Key Facilities

Life Sciences Test Facility

Combined Chemical Test Facility

Material Test Facility

Test Grids (Simulant)

Defensive Test Chamber

CBDP Funds only MRTFB facilities

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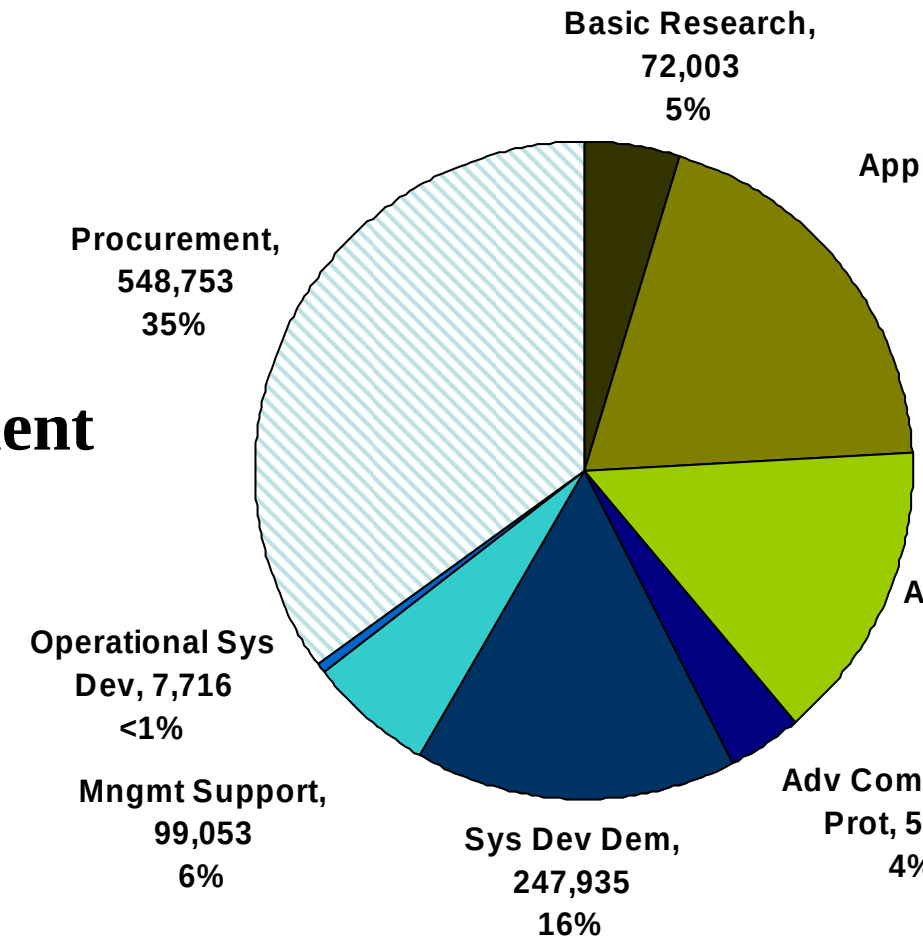
Chemical Biological Defense Program

Based on FY08 President's Budget Request (February 2007)

$1.570 Billion



Procurement

Science & Technology Base

Advanced Development

CBDP: The Way Ahead

- **Need to build on current strengths…**
  - Integrated collection of systems
  - Multi-disciplinary approaches
  - Well developed doctrine and concepts for the military in operational environments
- **…while recognizing a changing environment**
  - Laboratory and other infrastructure may need overhaul
  - Operational environment must consider homeland security
  - Emerging and non-traditional threats may be critical
  - Congress will continue to play an active role
  - Industry may be increasingly important, though DoD-unique assets need to be identified and maintained

CBDP: The Way Ahead

- **…and Planning for the Future**
  - Need to balance investment between current risks (operational and procurement needs) and future risks (S&T and infrastructure)
  - Coordination with other agencies (DHHS, DHS, and others) for an effective national effort
    - DoD may play key role in transitioning technologies from laboratory concepts to field-ready systems, especially medical systems
  - Broad-spectrum, dual-benefit approaches will need to be evaluated in all areas