

**Department of Defense:  
Chemical Biological  
Defense Program**

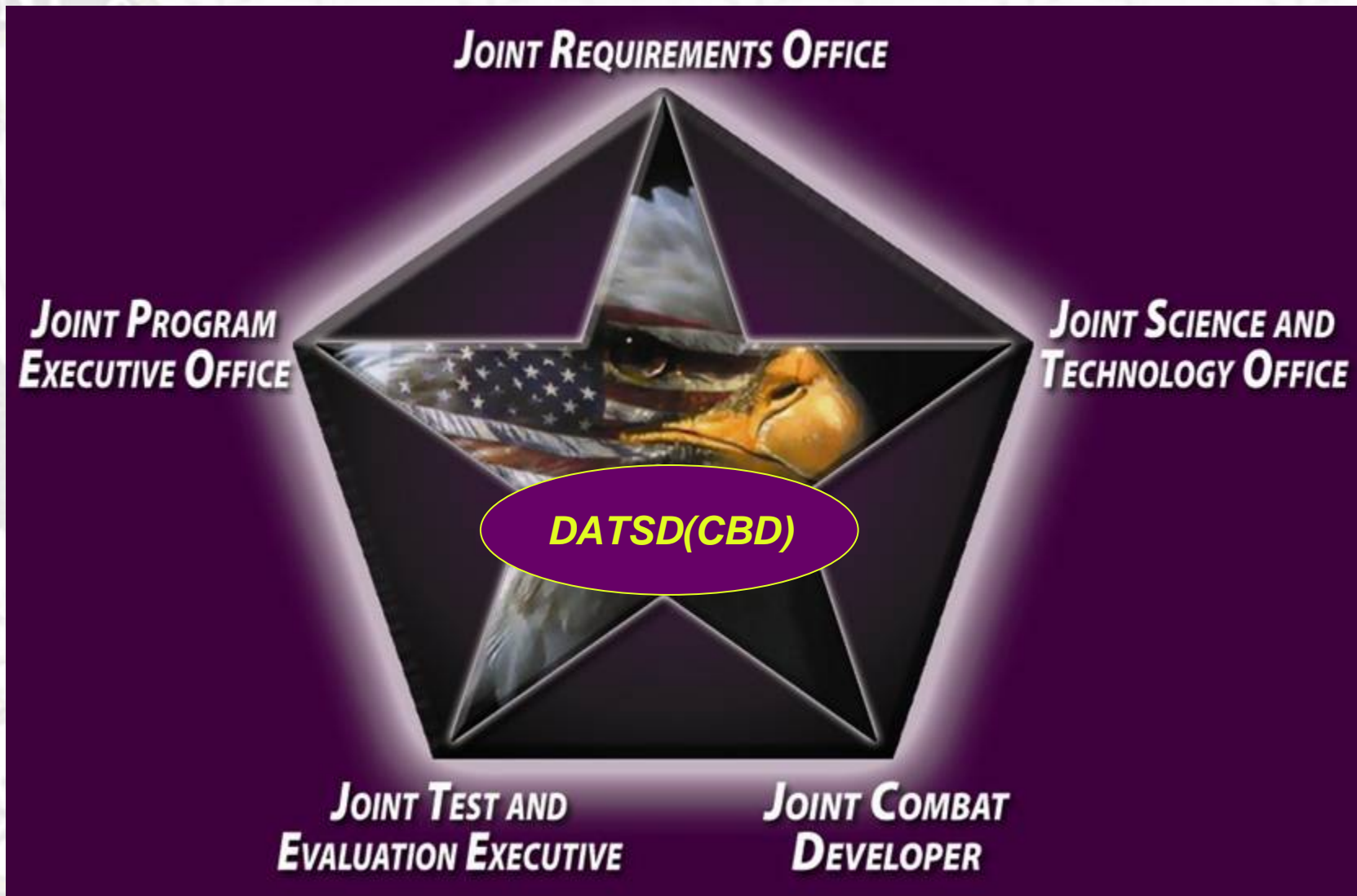
***National Defense Industrial Association  
Chemical Biological Roundtable Breakfast  
February 25, 2005***

**Klaus Schafer, MD, MPH  
Deputy Assistant to the Secretary of Defense  
for Chemical and Biological Defense, DATSD(CBD)**

# **CBDP: Great News Story**

- **First Input Under New Management Structure**
  - **First Alignment of Life-cycle Cost and Testing (from S&T through Acquisition)**
  - **Major T&E Investment**
  - **Moving More into Experimentation & Rigorous Analysis**
- **Significant Interagency Collaboration**
- **One of Few Growth Areas in DoD Budget**
  - **\$2.1 Billion Increase over FYDP in President's Budget**
  - **Aligns with President's Global War on Terror**
  - **Increased Emphasis in Future Technologies**
    - **High Investment in S&T in FY06**
      - ❖ **Infrastructure Rebuild**
      - ❖ **Non Traditional Chemical Agents**
      - ❖ **Genetically Engineered Threats**
      - ❖ **New Sensor Approaches**
      - ❖ **Systems Biology Approach to Medical Countermeasures**

# Chemical and Biological Defense Program (CBDP) Program Organization



# CBDP Major Players



**Dr. Dale Klein**  
ATSD(NCB)



**Dr. Klaus Schafer**  
DATSD(CBD)



**RADM Michael Mathis**  
JRO BRND



**BG Steve Reeves**  
JPEO CB



**Dr. Charles Galloway**  
Director, JSTO



**Mr. Walter Hollis**  
Joint T&E Executive Agent



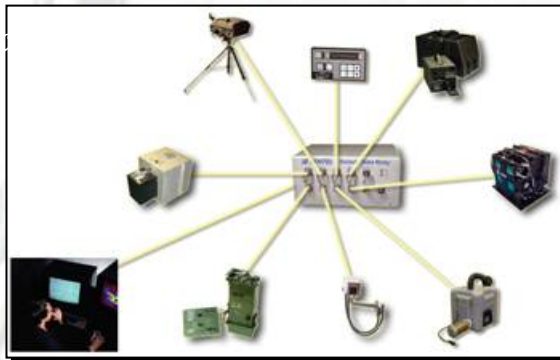
**BG Stan Lillie**  
Joint Combat Developer

# CBRN Defense Critical Roles

## Combating Weapons Of Mass Destruction



*Installation P*



## Combating Terrorism

## Homeland Security Support

# OSD-CBD Perspective

- **Think About What We Are Asked To Do?**
  - **What Have You Done Today/This Week/This Past Year?**
  - **Can We Say We Have Made Strides To Protect Our Forces?**
  - **From Peacetime in Garrison through War and Home again?**
- **Build On Current Strengths...**
  - **Systems Approach To Everything**
  - **Multi-disciplinary Teams**
  - **Everything Focuses on Incident Management (Decision Making – Resourcing to Protect People or Save Lives)**
    - Let's not forget the first part of that is Prevention and Avoidance
  - **Laboratory / Infrastructure Overhaul**
  - **DoD Still A Key Player, But No Longer The Biggest Investment**
  - **Operational Environment Must Consider Homeland**
  - **Emerging And Non-traditional Threats May Be Critical**

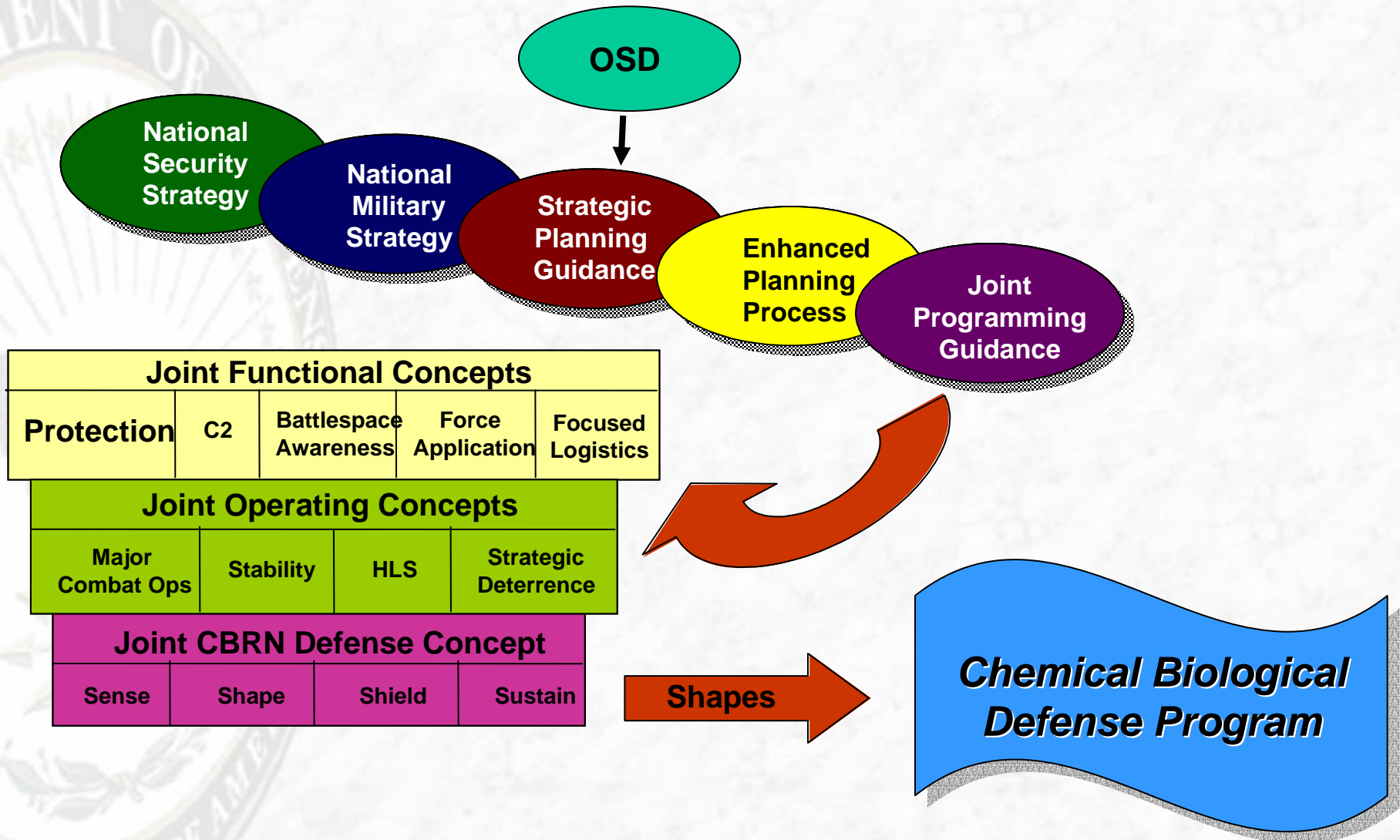


# OSD-CBD Perspective

- **Implementing Integration at OSD level**
  - **Impact on Exercises, Doctrinal Development, Plans, Training**
- **Focus Areas**
  - **Prevention/Pretreatments**
  - **Countermeasures**
  - **Data Integration/Incident Management/Resourcing**
  - **Networking Data**

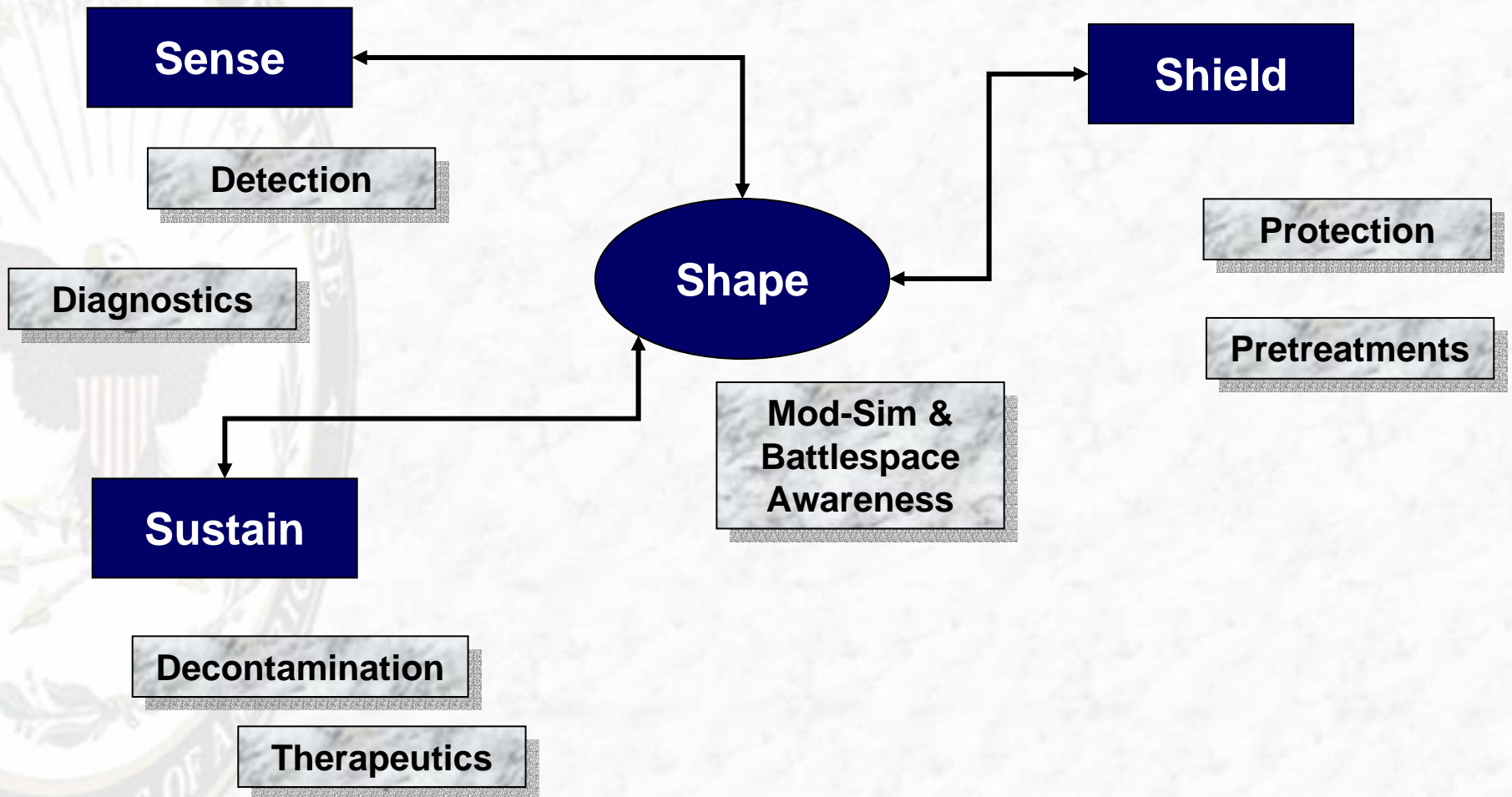


# CBRN Defense Program Policy Drivers





# CBDP Program Battlefield Capability Areas



# System of Systems Approach to Counter the Threat

*Sustained Combat Power* →

**CB Threats & Hazards**

Agent Delivery

Doses on Target

Downwind Dispersal

Doses Absorbed

Symptoms



Medical Pretreatment



Contamination Avoidance and NBC Battle Management (Detection, Identification, Reconnaissance & Warning)



Individual & Collective Protection



Installation Force Protection



Medical Treatment



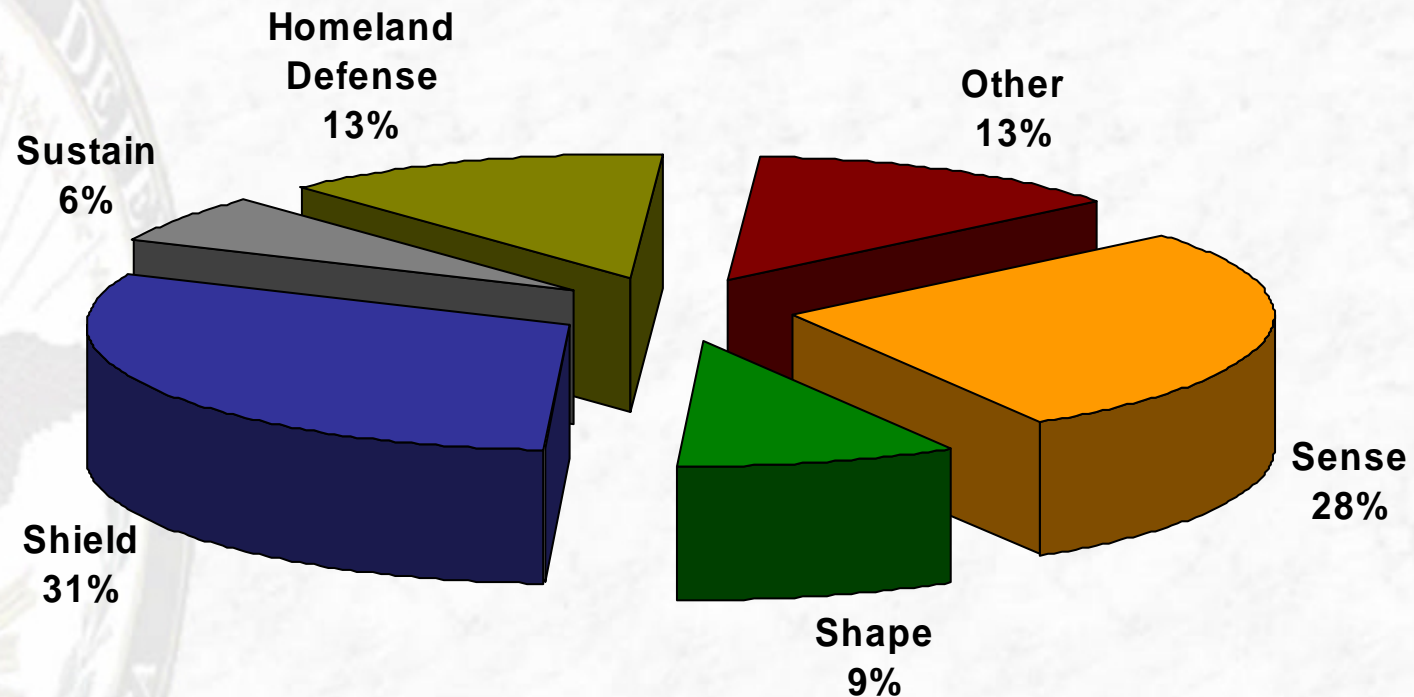
Information Systems



Decontamination, Restoration

# FY06 Resource Allocation

## Capability Areas



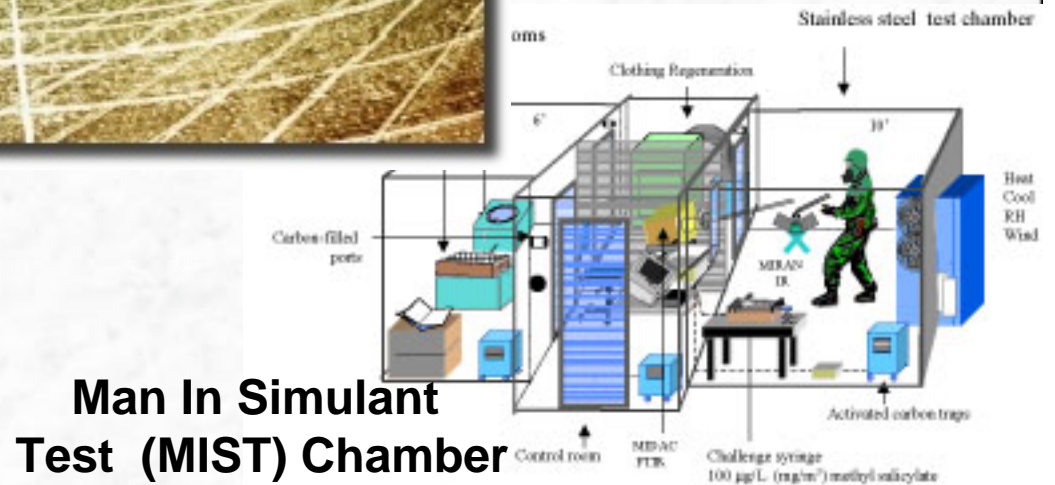
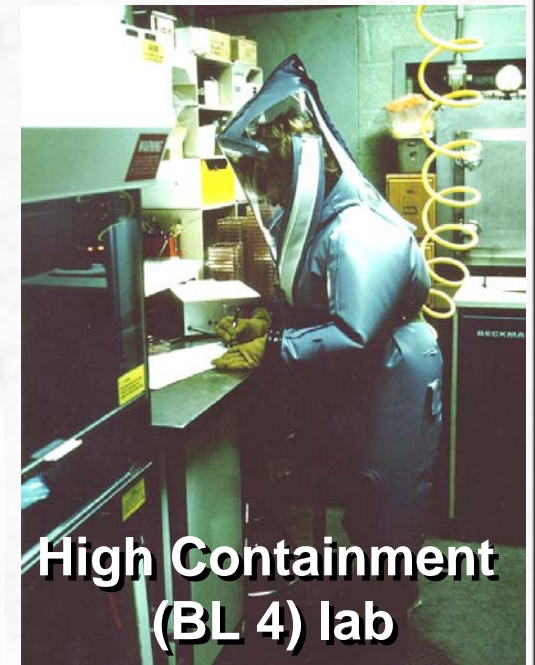
■ Sense ■ Shape ■ Shield ■ Sustain ■ Homeland Defense ■ Other

***Total Funding FY06: \$1.5B***

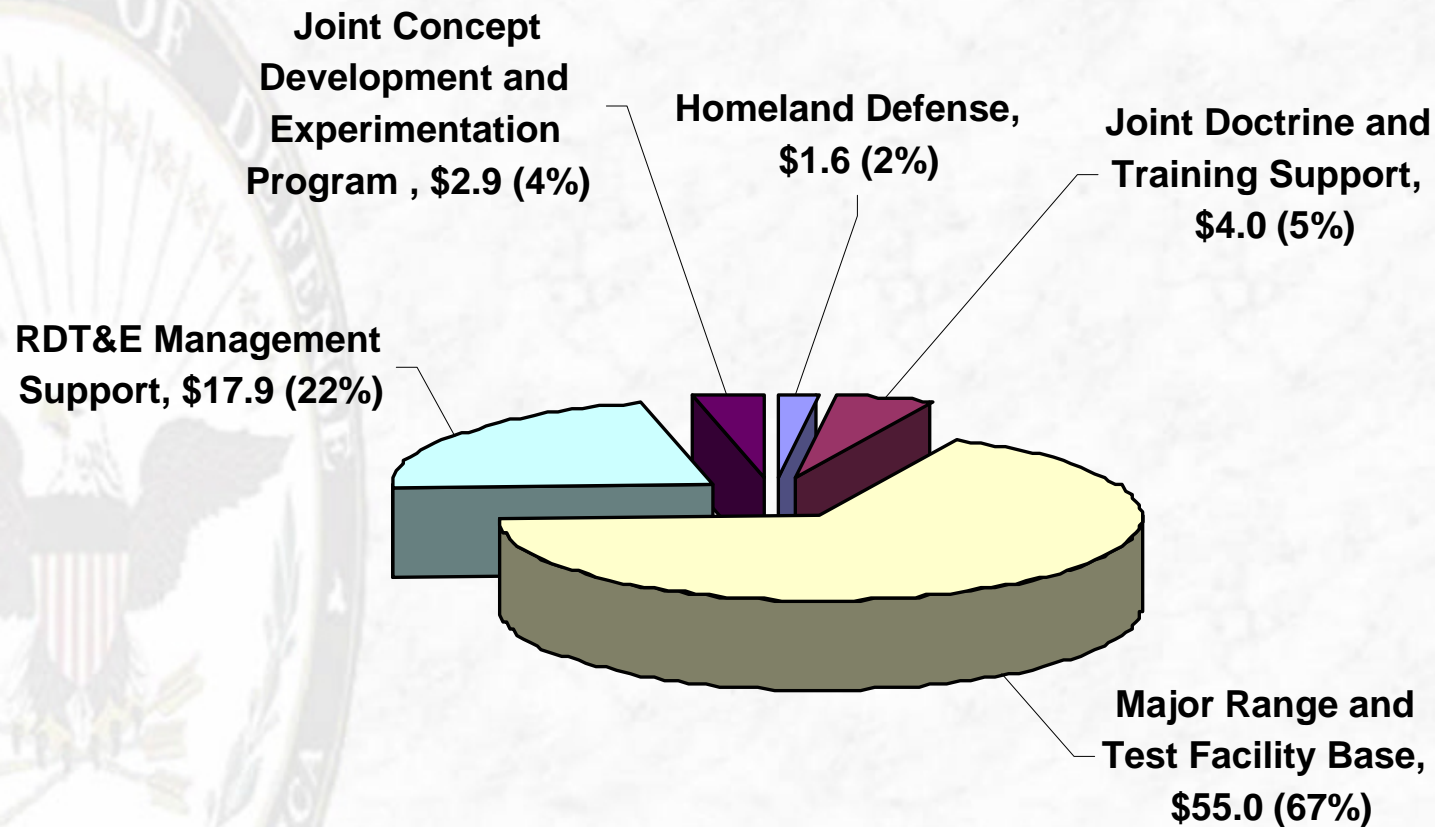
# Enhanced Planning Process (EPP): Key Results

<b>Infrastructure Improvements</b>	<b>RDT&amp;E Areas of Additional Emphasis</b>
<ul style="list-style-type: none"><li>• <b>CB T&amp;E Facilities</b></li><li>• <b>NTA Test Chamber</b></li><li>• <b>USAMRIID (DHP)</b></li></ul>	<ul style="list-style-type: none"><li>• <b>S&amp;T for NTA detection</b></li><li>• <b>Bio point and standoff detection</b></li><li>• <b>Medical Prophylaxis</b></li><li>• <b>Battle Analysis</b></li><li>• <b>Decontamination</b></li><li>• <b>Bio Defense Initiatives</b></li><li>• <b>Chem point detection</b></li></ul>

# T&E Infrastructure Investment

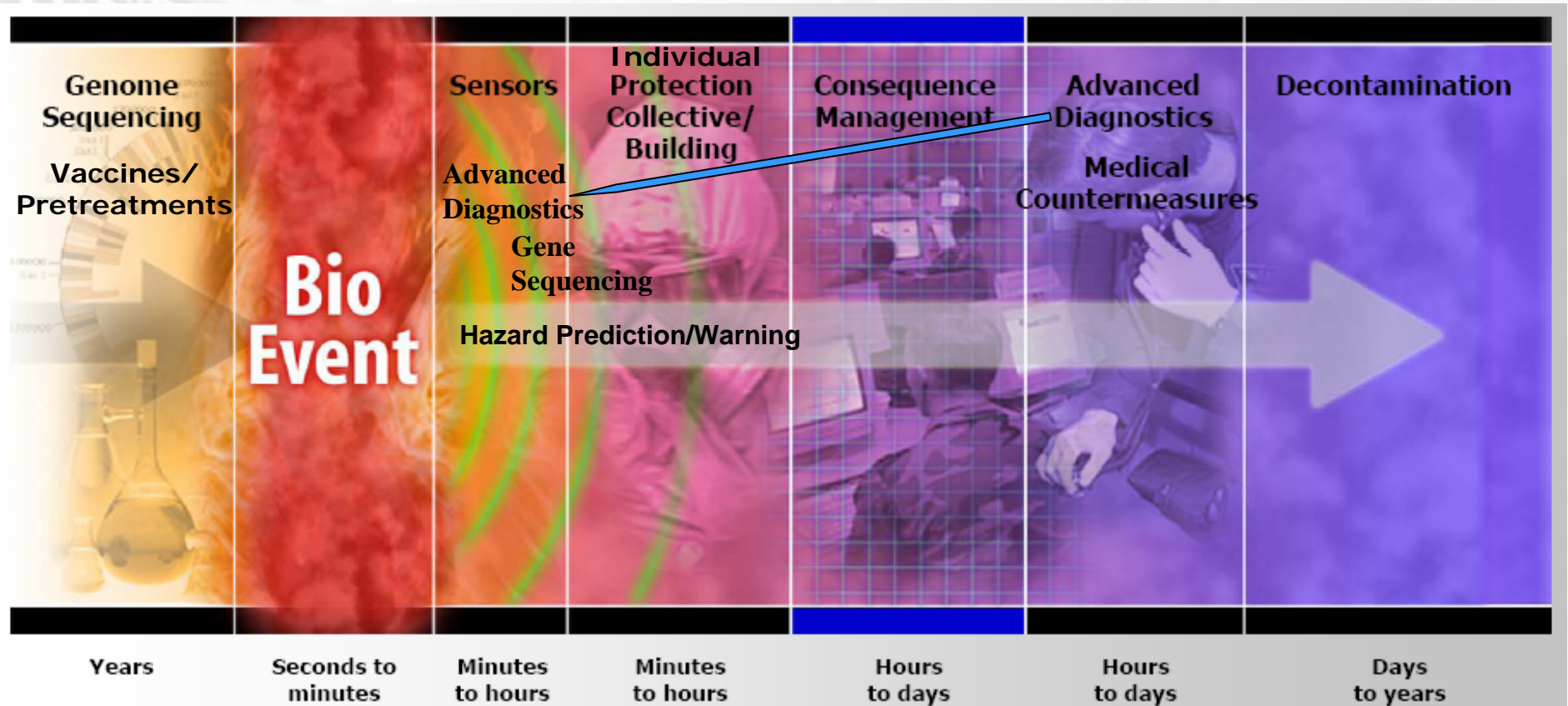


# RDT&E Management Support (\$ in millions)



**Provides critical support for  
T&E Infrastructure**

# DoD Biological Defense Efforts



## Leveraging the State-of-the-Art

- Proteomics
- Genomics
- Metabolomics
- Toxicogenomics
- Multi spectral analysis
- Bioinformatics
- PCR/Immuno assays
- Bioscavengers
- Microarrays
- Nanomaterials
- Broad spectrum disinfectants
- Anti viral/Antisense therapeutics
- Multi agent vaccines
- Epidemiology
- Self decontaminating coatings
- Host response pathways

## Partnerships & Cooperation to Leverage the State-of-the-Art

- Service Labs
- International
- Industry
- Academia
- Other Federal Agencies

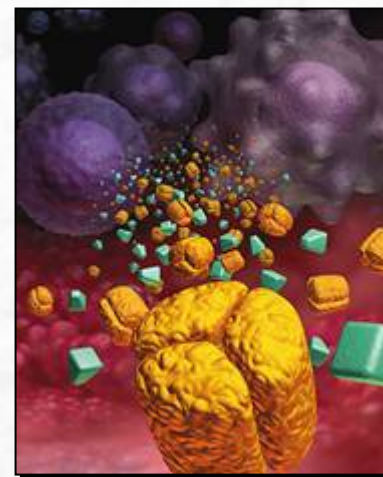
# Transformational Strategy

- **Established New Technical Senior Biodefense Group**
  - Leverage/Evaluate Expert Panel Candidate Technologies
  - Identify Optimal Candidate Technologies and Science
    - Scientific Analysis
- **Create Cooperative Effort: Gov't, Industry, Academia**
  - Develop Candidates with Seed Funds in FY06
  - Partner with Interagency & Industry in FY07 and Beyond
  - Fund BioTechnology Solutions in FY07 and Beyond
    - Internal DOD Strategy
    - External Partners
- **Identify Biologics Rapid Throughput Mechanism**
  - Parallel Processing of Technologies and Candidates
  - Downselect to Candidate Development



# Senior Panel for Emerging Threats (Biodefense 2025)

- **Panel Drawn from Varied Scientific Backgrounds**
  - **Genetics, Proteomics, Metabolomics, Toxicogenomics, Microarrays, Bioinformatics, Multi-spectral Analysis, Vaccinomics, Nanotechnologies, and “Luminaries” From Cross Functional Other Scientific Disciplines**
  - **Provide White Papers and Develop Concepts for Response to Emerging Threats**
- **FY06 Research Focus:**
  - **Determine Effectiveness of Spore Germination Inhibitors Leading to a Broad Array of Studies on Discovery and Characterization of Genetic Elements of Pathogenicity and Virulence of Genetically Engineered Threats. Studies to Address:**
    - **Toxin Virulence Factors**
    - **Broad-spectrum Anti-viral Compounds**
    - **Common Pathways of Virulence and Host Protection**
    - **Feasibility of Using Microarray-based Resequencing Technologies for Rapid Detection, Threat Assessment and Attrition of Genetically Engineered Biological Threats**



# Senior Biodefense 2025 Panel

- **Honorable Richard Danzig, Chair**
- **Leroy Hood, PhD (Institute for Systems Biology)**
- **Craig Venter, PhD (Venter Institute)**
- **David Relman, (The Relman Lab, Stanford)**
- **Ivar Giaever, PhD (Rensselaer)**
- **Dorothy Margolskee, MD, Prospect Ventures, Inc, (former Merck)**
- **Paul Reider, PhD, Chief Chemist, Amgen, Inc, (former Merck)**
- **George Georgiou, PhD (Center for Biomedical Engineering, U.T. Austin)**

# Future Emphasis: Systems Biology

## Today's Threats

*Anthrax*  
*Smallpox*  
*Botulinum*  
*Plague*  
*Tularemia*  
*Ebola/Filo*  
*Hemorrhagic Fever*  
*Encephalitis*  
*SARS*  
*Influenza*  
*Ricin/SEB, others*

## Modes of Action

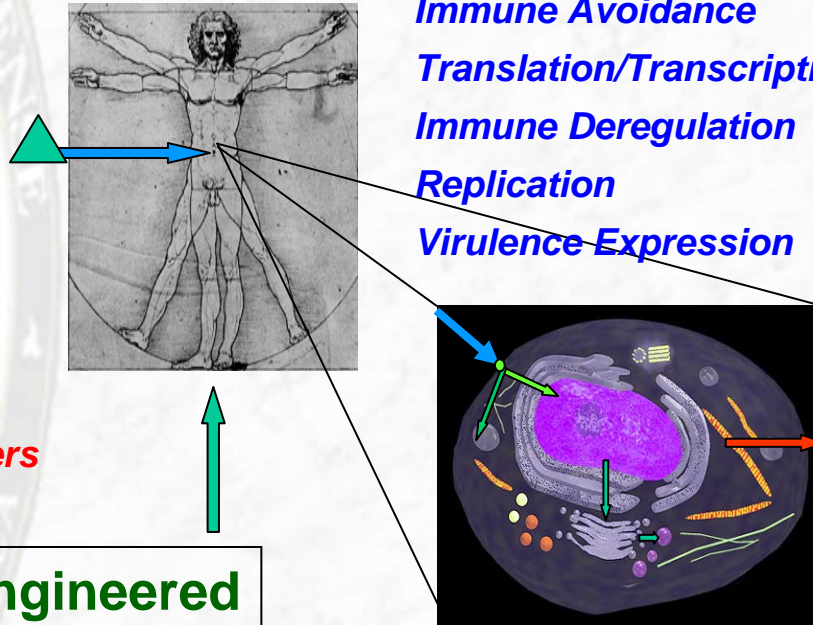
*Receptor Binding*  
*Signal Transduction*  
*Decoys*  
*Immune Avoidance*  
*Translation/Transcription*  
*Immune Deregulation*  
*Replication*  
*Virulence Expression*

## Parallel Systems Approach

## Solutions

### Target Agent Commonalities

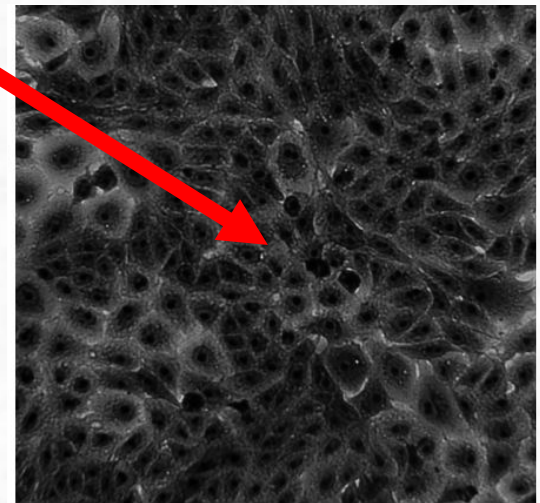
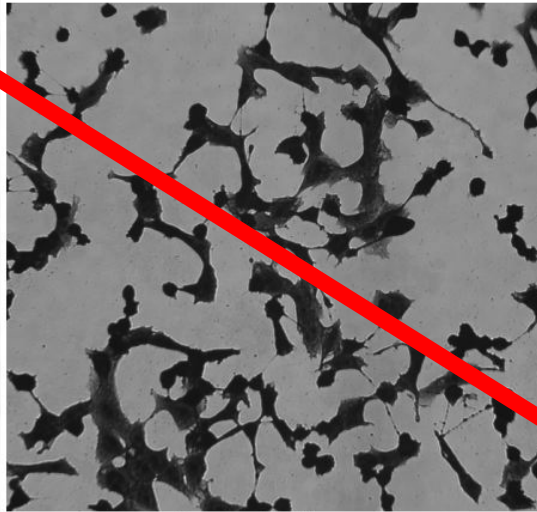
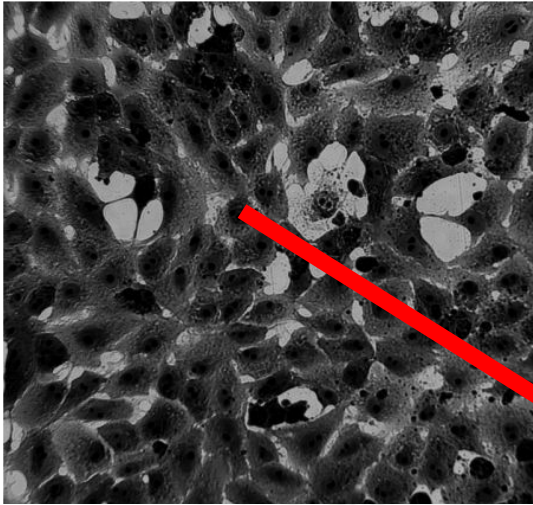
- Block Key Receptors
- Inhibition by Small Molecules
- Modulate Immunity
- Change Gene Expression
- Block Protein Actions
- Modulate Physiologic Impacts



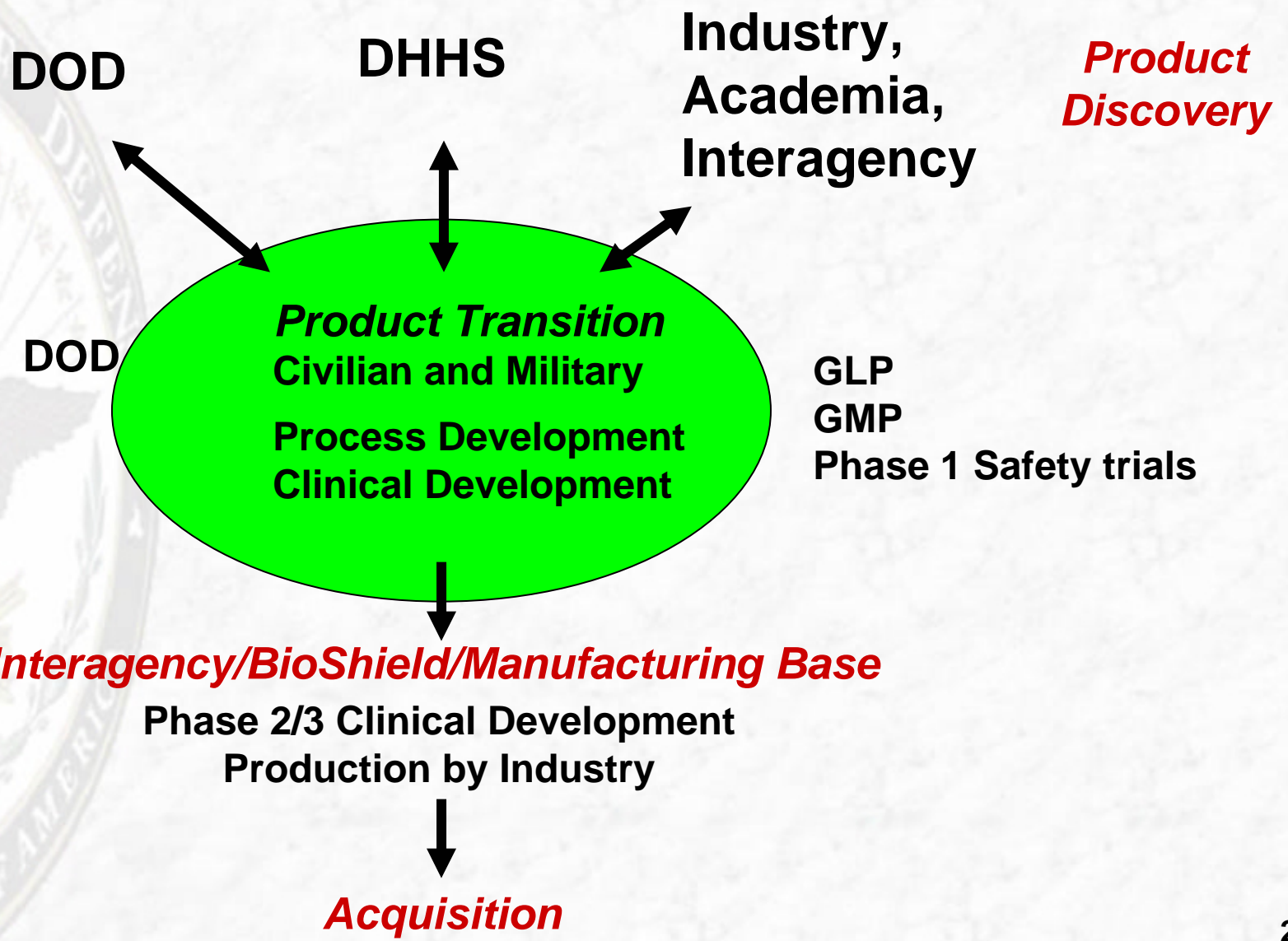
**Bioengineered**

One **PIECE** at a time → Process Analysis → Broad Spectrum

# Viral Disease



# Product Life Cycle Plan



# CB Defense Initiative Fund for FY05

- **\$20 Million was Appropriated**
- **FY05 Initiative Fund Recipients:**
  - **EOS (Epidemic Outbreak Surveillance) Project Silent Guardian**
    - **Provide a Surveillance Tool to Select Medical Treatment Facilities. The Detection Capability From EOS Uses the Respiratory Pathogen Microarray (RPM) to Enable Robust, Rapid Pathogen Identification for a Subset of Pathogens That Result in Febrile Respiratory Illness, Including Bio-threat Agents, thus Facilitating Potential Response Before Widespread Onset of Symptoms.**
  - **Bioscavenger for Chemical Agent Prophylaxes:**
    - **Funding to Initiate Clinical Trials for a Preventive Countermeasures for Nerve Agents. This Capability May Allow Significant Operational Improvement Over Current Countermeasures, Which Rely on Post-exposure Therapeutics (That Is, Atropine, Diazepam, 2-PAM Cl).**

**Initiative Fund provides flexibility to address rapidly changing technology**

# Advanced Diagnostics

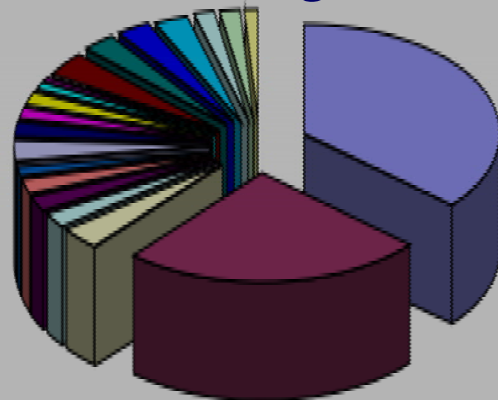
## Respiratory Pathogen Microarray (RPM)

- ❑ Z-chip from concept to delivery  
(Operational 7 Jun 2003)
- ❑ Common and biowarfare agents
- ❑ Iterative design and process
- ❑ Delivery, evaluation, and validation

### Common Pathogens

- ❑ Adenovirus
- Influenza
- ❑ Coronavirus
- ❑ West Nile
- Parainfluenza
- RSV
- Rhinovirus
- ❑ Strept. pyogenes
- Chlam. pneumoniae
- Myco. pneumoniae
- Bord. pertussis
- Neiss. meningitidis
- Strept. pneumoniae

### EOS Pathogen Pie



### Characteristics

Characteristics	RPM v1
Physical Size	1.25 cm <sup>2</sup>
Array Dimensions	500x500
Number of Features	240,000
Feature Size	24 μ
Pathogens	
common viruses	10
common bacteria	6
others, controls, vectors	1
bio-threat agents	6
Tiled Gene Segments	61
Nucleotide Queries (bp)	29,508
Average Tile Length (bp)	485

### Biowarfare Pathogens

- Smallpox
- Anthrax
- Plague
- ❑ Tularemia
- Ebola Virus
- Lassa Fever



**240,000  
different  
diagnostic  
tests / chip**

# Interagency Activities

- **CBDP Coordinates With:**
  - **Defense Advanced Research Projects Agency (DARPA) Biological Warfare Defense Programs**
  - **Counterproliferation Program Review Committee (CPRC)**
  - **Technical Support Working Group (TSWG)**
  - **Department of Homeland Security (DHS), Science & Technology Directorate**
  - **National Institute of Allergies and Infectious Diseases (NIAID)**
  - **Centers for Disease Control (CDC)**
  - **U.S. Coast Guard**
- **Various Levels of Coordination/Cooperation Exist with:**
  - **National Security Council**
  - **Office of Science & Technology Policy**
  - **Department of Health and Human Services (including the Food and Drug Administration, and the Centers for Disease Control and Prevention)**
  - **U.S. Department of Agriculture**
  - **Department of Justice**



# **CBDP: The Way Ahead**

- **Build on Current Strengths...**
  - **Integrated Collection of Systems**
  - **Multi-disciplinary Approaches**
  - **Well Developed Doctrine and Concepts for the Military in Operational Environments**
- **Recognize A Changing Environment**
  - **Laboratory and Other Infrastructure Getting an Overhaul**
  - **DoD a Key Player, but No Longer the Biggest Investment Within the Federal Government**
  - **Operational Planning Considers Homeland and Terrorist Threats**
  - **Emerging and Non-traditional Threats Are Critical**
  - **Industry Increasingly Important, Though DoD-unique Assets Must be Maintained**

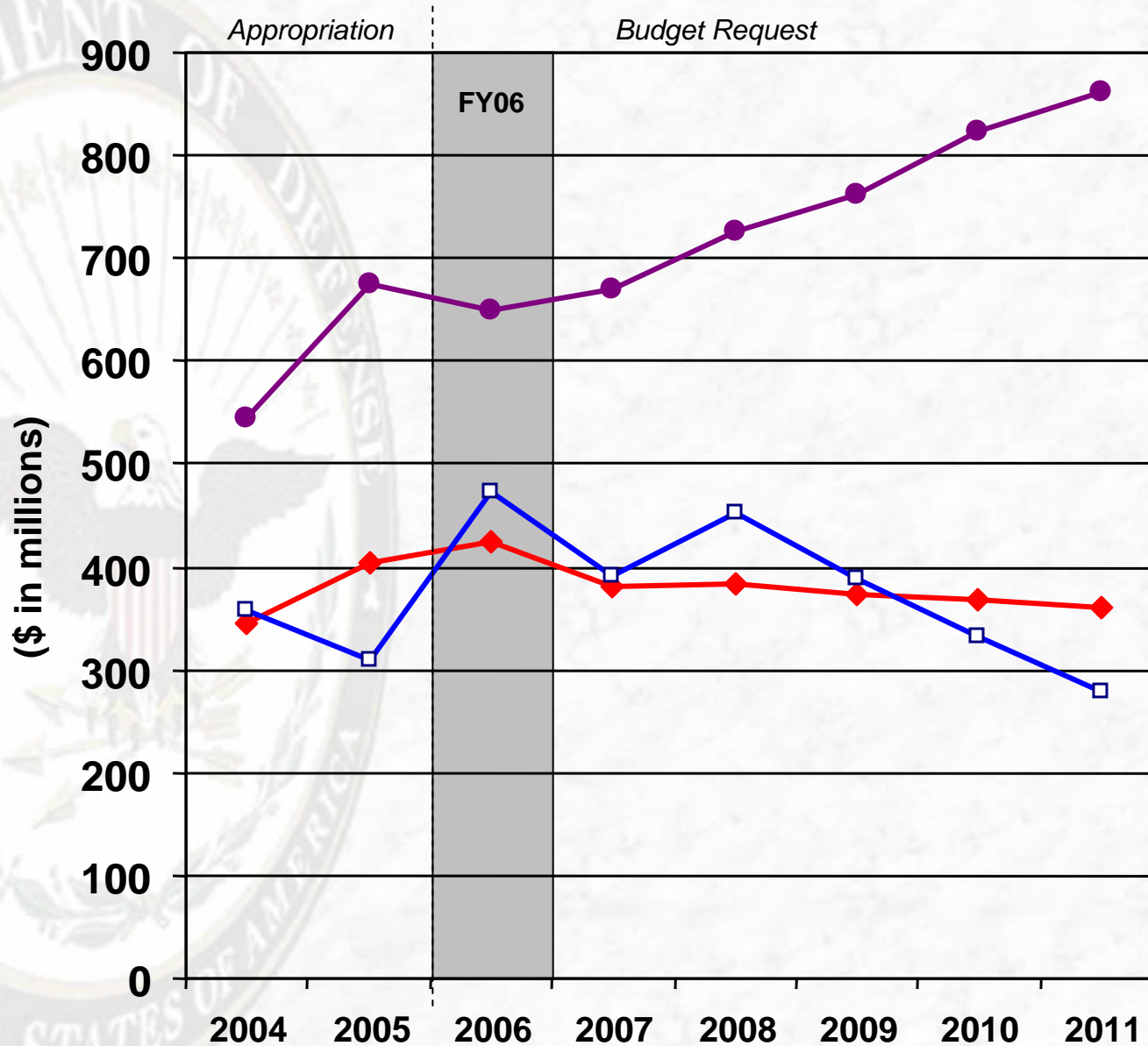
# **CBDP: The Way Ahead**

- **Plan for the Future**
  - **Balance Investment Between Current Risks (Operational and Procurement Needs) and Future Risks (S&T and Infrastructure)**
    - **FY06 Budget Submission Includes Results of EPP**
      - ❖ **Realignment of Existing Programs**
      - ❖ **\$2.1 Billion Over the FY06-11 Period for S&T, Advanced Development, and T&E Infrastructure Improvements**
  - **Develop Broad-spectrum, Dual-benefit Approaches**
  - **Coordinate with Other Agencies (DHHS, DHS, and Others) for an Effective National Effort**
    - **DoD Plays Key Role in Transitioning Technologies from Laboratory Concepts to Field-ready Systems, Especially Medical Systems**
- **Integrate within DoD & with Interagency Community**  
**Key**

# **CBDP: Opportunities**

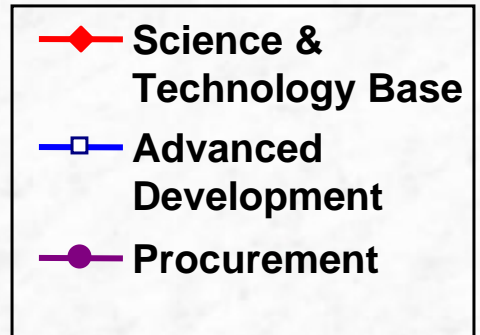
- **ColPro: Tech Readiness Eval Late Summer/Fall**
  - Joint Expeditionary ColPro system filtration technology
- **Sensitive Decon:**
  - Aircraft and Interior Decon
  - Sensitive Equipment
- **JCAD/JSLSCAD already restructured**
  - Opportunities over the next couple of years
- **Bio-Tactical Program '06**

# CB Defense Program Structure: FY06 PB



## FY06 Highlights

- Near-Term Shift in Emphasis to Address Future Challenges (NTAs, Emerging Threats) and Improve the T&E Infrastructure
- Long term trend to Provide Advanced Capabilities to the Warfighter



A tropical beach scene with several tall palm trees in the foreground and middle ground. The ocean is visible in the background under a blue sky with some clouds. A thatched umbrella is on the beach. The word "Questions?" is written in large yellow letters across the center of the image.

# Questions?

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