



# **Chemical and Biological Defense Program (CBDP): Capabilities for Countering the Threat**

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**April 26, 2005**

| Report Documentation Page                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                    |                                     |                            | Form Approved<br>OMB No. 0704-0188                  |                                 |
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| 1. REPORT DATE<br><b>26 APR 2005</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                    | 2. REPORT TYPE                      |                            | 3. DATES COVERED<br><b>00-00-2005 to 00-00-2005</b> |                                 |
| 4. TITLE AND SUBTITLE<br><b>Chemical and Biological Defense Program (CBDP): Capabilities for Countering the Threat</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                    |                                     |                            | 5a. CONTRACT NUMBER                                 |                                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                    |                                     |                            | 5b. GRANT NUMBER                                    |                                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                    |                                     |                            | 5c. PROGRAM ELEMENT NUMBER                          |                                 |
| 6. AUTHOR(S)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                    |                                     |                            | 5d. PROJECT NUMBER                                  |                                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                    |                                     |                            | 5e. TASK NUMBER                                     |                                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                    |                                     |                            | 5f. WORK UNIT NUMBER                                |                                 |
| 7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)<br><b>Army Medical Research and Material Command, Chemical Biological Defense Program (CBDP), Fort Detrick, MD, 21702</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                    |                                     |                            | 8. PERFORMING ORGANIZATION REPORT NUMBER            |                                 |
| 9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                    |                                     |                            | 10. SPONSOR/MONITOR'S ACRONYM(S)                    |                                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                    |                                     |                            | 11. SPONSOR/MONITOR'S REPORT NUMBER(S)              |                                 |
| 12. DISTRIBUTION/AVAILABILITY STATEMENT<br><b>Approved for public release; distribution unlimited</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                    |                                     |                            |                                                     |                                 |
| 13. SUPPLEMENTARY NOTES<br><b>The original document contains color images.</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                    |                                     |                            |                                                     |                                 |
| 14. ABSTRACT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                    |                                     |                            |                                                     |                                 |
| 15. SUBJECT TERMS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                    |                                     |                            |                                                     |                                 |
| 16. SECURITY CLASSIFICATION OF:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                    |                                     | 17. LIMITATION OF ABSTRACT | 18. NUMBER OF PAGES<br><b>26</b>                    | 19a. NAME OF RESPONSIBLE PERSON |
| a. REPORT<br><b>unclassified</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | b. ABSTRACT<br><b>unclassified</b> | c. THIS PAGE<br><b>unclassified</b> |                            |                                                     |                                 |



# Outline



- **Recent Highlights**
- **Program Organization**
- **Program Guidance and Direction**
- **Summary**





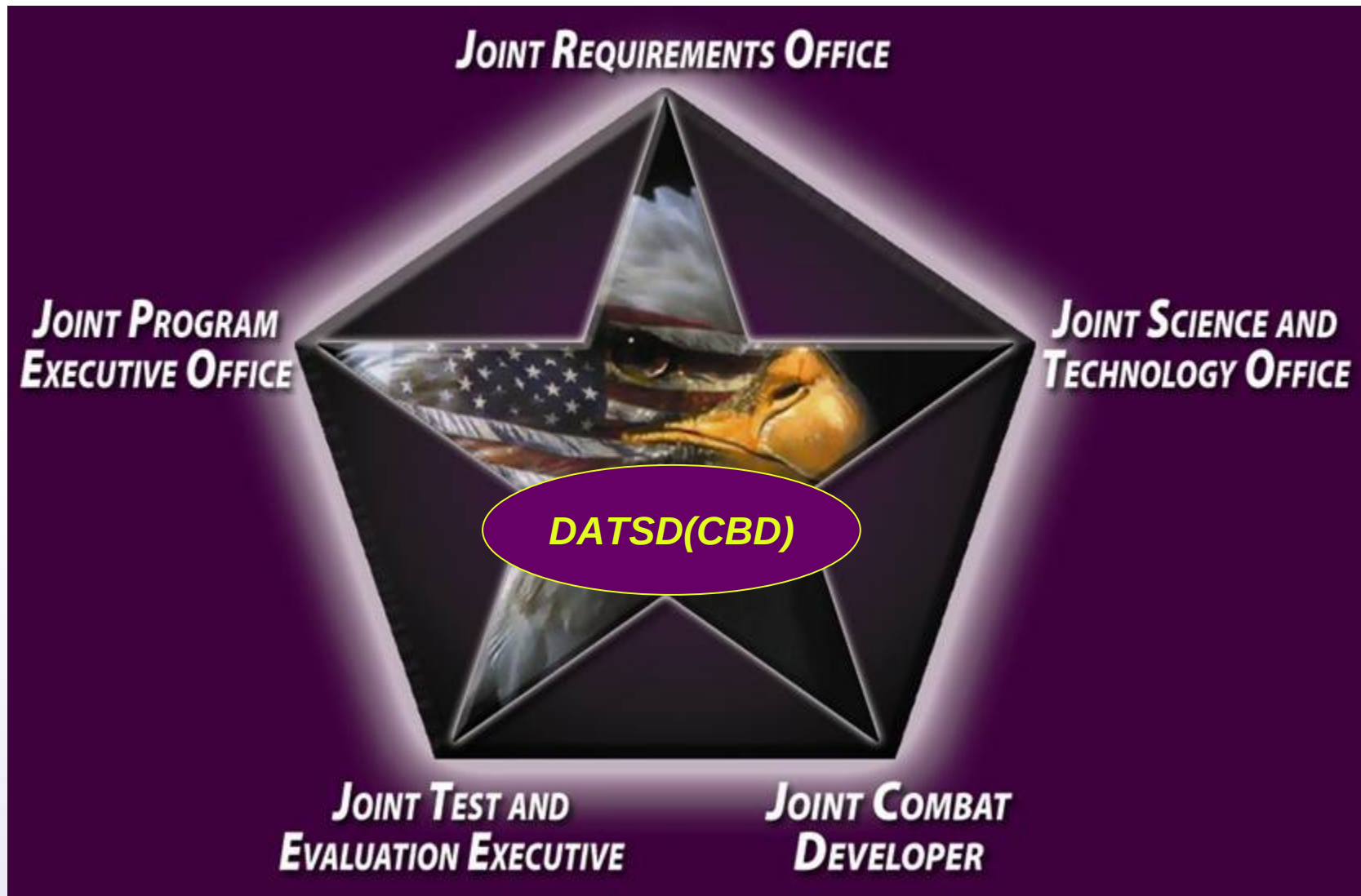
# **CBDP: Great News Story**



- **FY06 Budget submission**
  - First input under new management structure
  - First alignment of life-cycle cost and testing (from science & technology 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 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)



**Dr. Barry Fridling**  
JRO-CBRND  
(Acting)



**BG Steve Reeves**  
JPEO-CBD



**Dr. Charles Galloway**  
Director, JSTO



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



**BG Stan Lillie**  
Joint Combat Developer



# An Integrated Systems Approach to Counter the Threat





# CBRN Defense Program Strategic Environment



- Defense of the Homeland
- Global War on Terror
- DOD Role in Bioshield
- Proliferation of Weapons of Mass Destruction
- Challenge of Non-Traditional CBRN Agents
- Biosurety



**“The *greatest threat* before humanity today is the possibility of *secret and sudden attack* with *chemical, or biological, or nuclear weapons*”**

*President George W. Bush  
Remarks at the National Defense University, 11 February 2004*



# Chemical Biological Defense Program Paradigm Shift



*Prior to the transformation*, the *major focus* to provide improved capabilities for the warfighter to survive, fight, and win on any battlefield contaminated with chemical and biological weapons.

The current paradigm shift directs both a *broadening and deepening* of the CBDP.

- CBRN consequence management (about 1997)
- Force protection (in 1999)
- Homeland Defense (in 2002)
- Visibility of “radiological and nuclear” aspects of the program (2003)
- Inclusion of the US Coast Guard
- Transition from *Threat Based* to *Capabilities Based* Process

➤ This broadening requires a carefully developed program strategy to *ensure that warfighter capabilities are maintained and advanced* concurrently with these added missions.



# **Chemical and Biological Defense: *Strategic Framework***





## DoD Mission



**Provide integrated chemical and biological defense capabilities to effectively execute the National Military Strategy.**





# Strategic Imperatives



- **Eliminate technological surprise.**
- **Make the threat irrelevant.**
- **Detect the threat.**
- **Protect against the threat.**
- **Eliminate the threat.**





# Enabling the Vision



- **Doctrine**
- **Organization**
- **Training**
- **Materiel**
- **Leader development**
- **Personnel**
- **Facilities**

**Oversight – Coordination – Integration**



# Transforming

- New Team Focused on:
  - Defining Equities Across DoD
  - Streamlining Processes
  - Synchronizing Effort
  - Improving Efficiency
  - Optimizing Capability
  - Promoting Interoperability

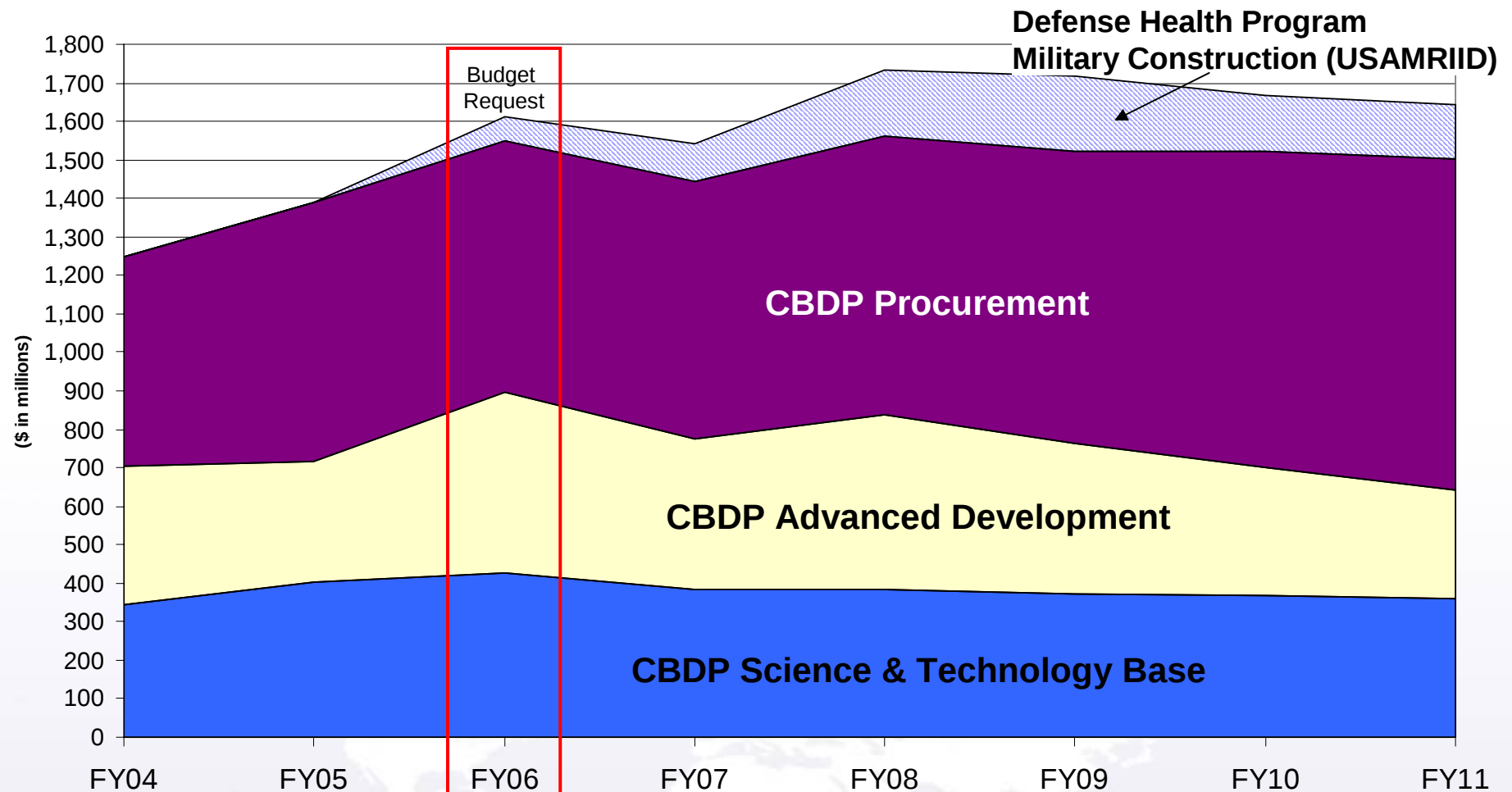


**BOTTOM LINE:**  
***EFFECTIVE SOLUTIONS***  
***IN THE HANDS OF THE USER***



# FY06 President's Budget

(DoD CB Defense Program + Defense Health Program for Construction of USAMRIID Improvements)



## 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



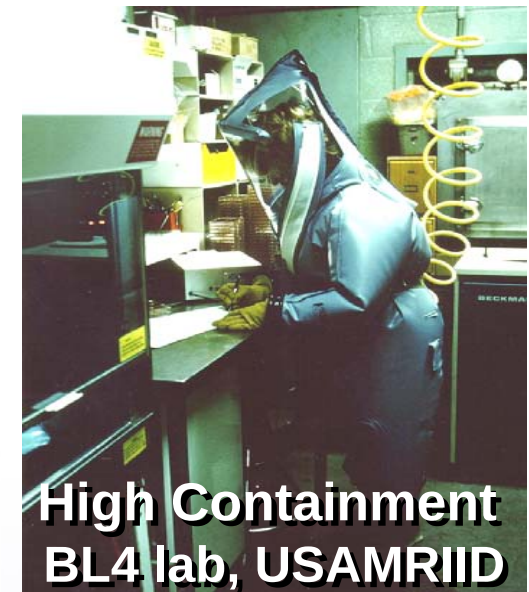
# Enhanced Planning Process (EPP) Results



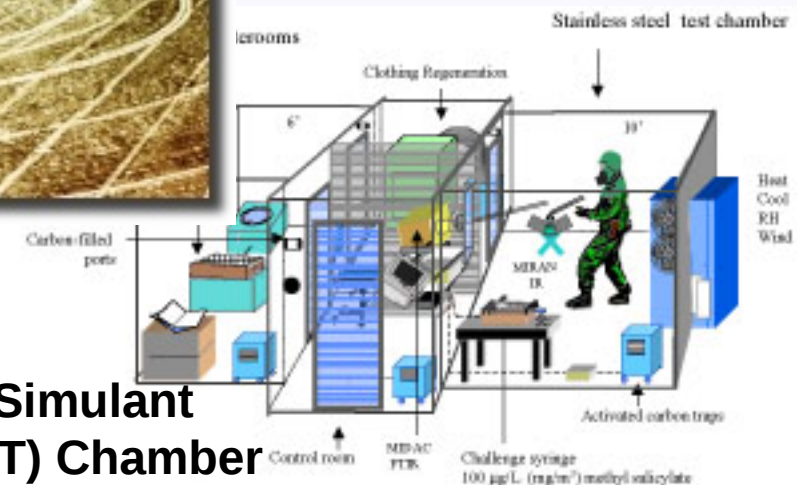
| <b>T&amp;E Infrastructure Improvements</b>                                                                                  | <b>RDT&amp;E Improvements</b>                                                                                                                                               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



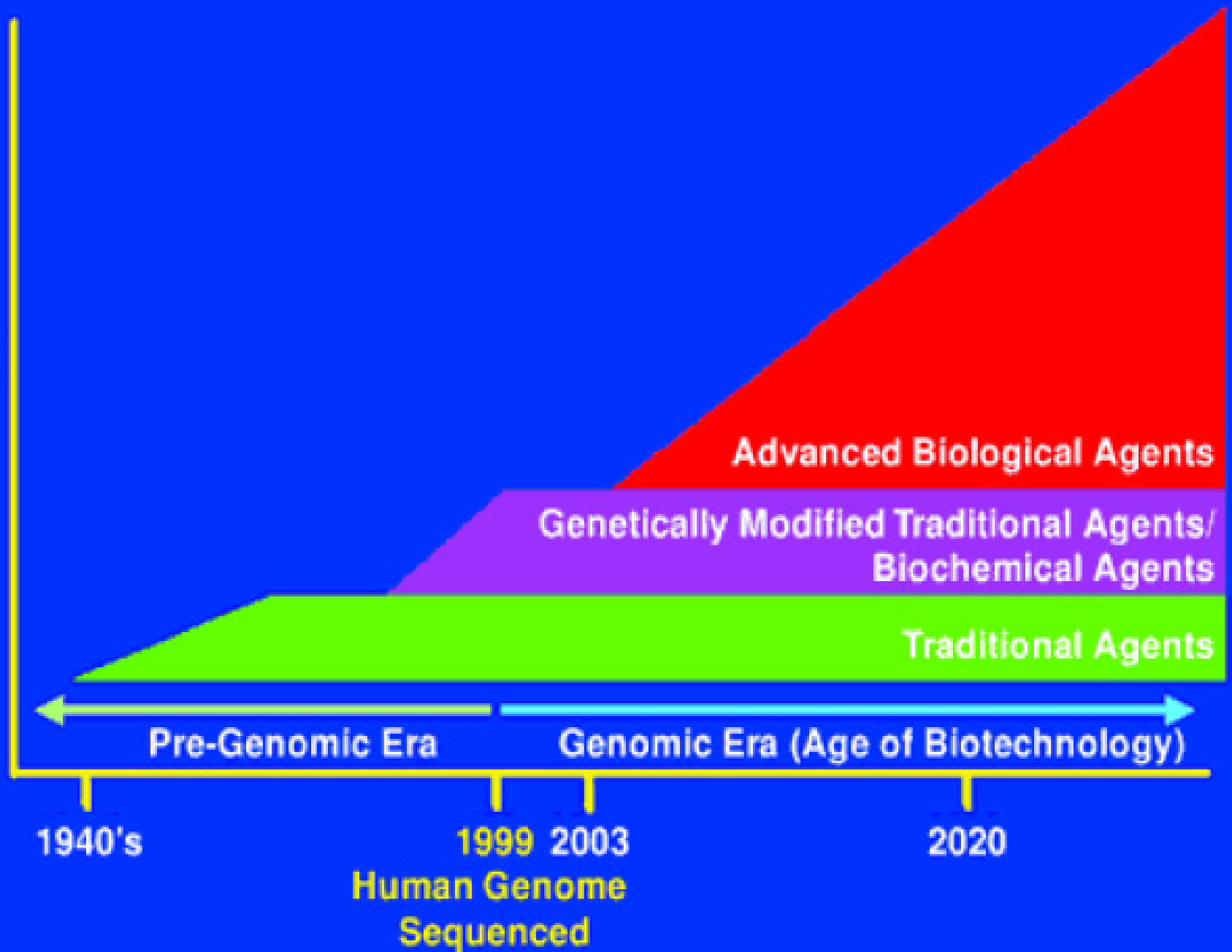
# T&E Infrastructure Investment



Man In Simulant  
Test (MIST) Chamber



Threat





# The Problem



*Slow drug development process leads to economic and social catastrophe jeopardizing national security*



**Attack with new threat**

**DHS funds to NIAID**

**Early Stage Research**

10+ years

**Lead Discovery**

2+ years

**Preclinical Development**

2-5 years

**Clinical Development  
Production Models**

5-8 years

**FDA Approval**

1 year

**Production Procurement**

10+ years > \$800M



**Safe & effective countermeasure**

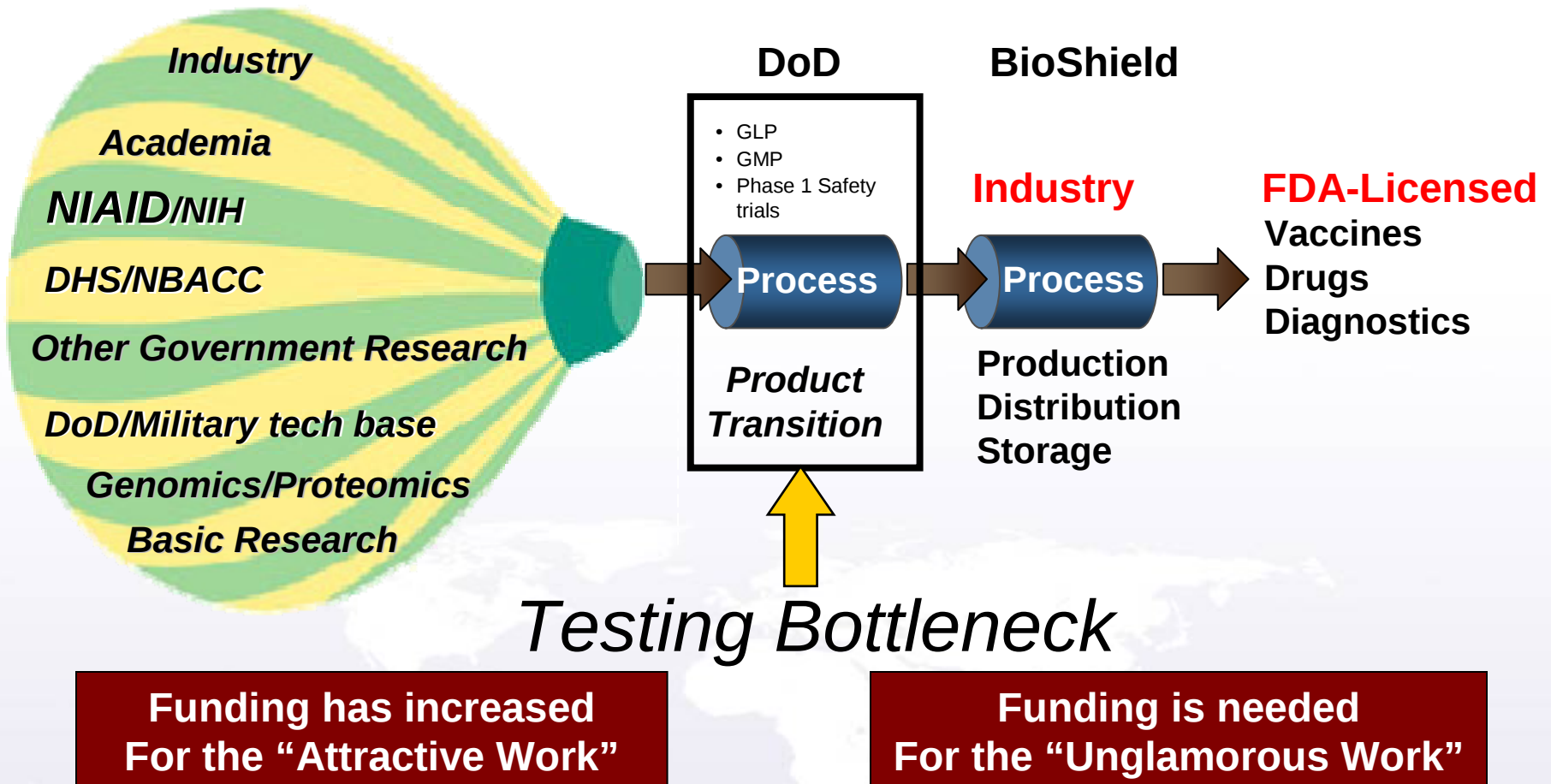
**Bioshield**

**No national strategy, clear responsibility or federal funding to shorten this cycle**



## R&D - Test and Evaluation

### Vaccine/Drug Discovery Vaccine/Drug Development





# 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

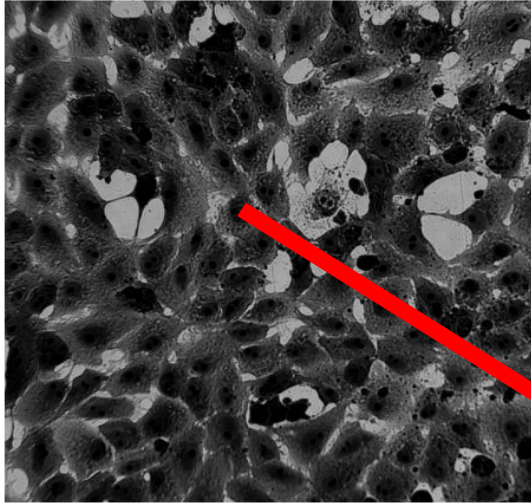
- Block Key Receptors
- Inhibition by Small Molecules
- Modulate Immunity
- Change Gene Expression
- Block Protein Actions
- Modulate Physiologic Impacts

**Bioengineered**

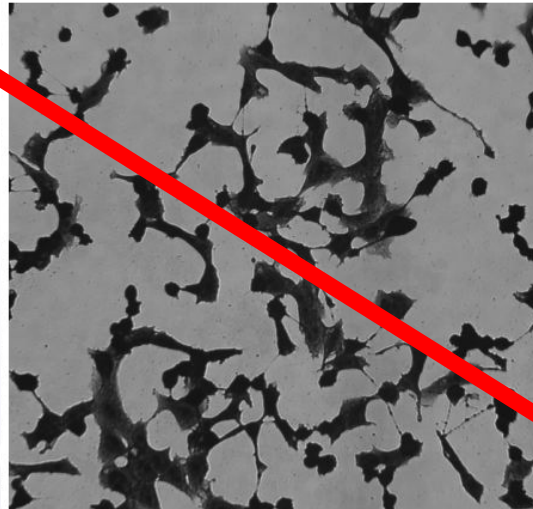
One **PIECE** at a time → Process Analysis → Broad Spectrum



# Viral Disease

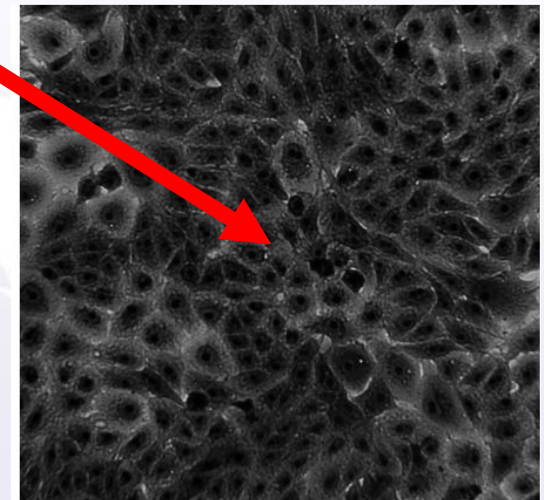


**Healthy Cells  
(Untreated)**



**Cells Infected with SARS  
(Untreated)**

**Cells Infected with SARS  
(Treated with 20 $\mu$ M of  
TRS2 PMO)**





# Broad Spectrum Therapies for Novel Biodefense Threats



- **\$100M funding in FY06**
  - Budget Activities BA1-BA5
  - 76% in Science and Technology Base
- **Transformational Approaches will be applied – leverage genomics, proteomics and systems biology data explosion**
- **Technical and program advisory leadership from team of nationally recognized experts**
  - BW defense, microbiology, drug development
  - Will draw heavily from commercial and academic performers
- **Basic Research/Science (\$28M)**
  - Directed at common pathways (modes of action) in pathogen host response
  - Find novel intervention points



# Broad Spectrum Therapies for Novel Biodefense Threats (Cont'd)



- **Applied Research/Science (\$18M)**
  - Directed at expanding technologies
  - Speed the cycle from discovery to license application
- **Advanced Science/Tech Development (\$30M)**
  - Aimed at quick wins based on new compounds and technology approaches demonstrating current success
  - Strategy to deliver products with IND approval (Phase 1 trials) for BioShield acceptability and further investment
- **Advanced Component Development and System Demonstration (\$24M)**
- **Ultimate goal is defeat of genetically engineered biological threat**



# Emerging Threats: Path Forward



- **Anticipate the threat**
- **Deliver New capabilities Short Term and Long Term**
- **Exploit Existing Med CM as Well as Survey Existing Therapeutics**
- **Major Investments Needed in Host-pathogen Infection Process to Identify Common Targets for Broad-spectrum Drugs**
- **Push Developments to Diagnostics, Therapeutics and Pretreatment Portfolios**
- **Needs to Harness all of the Major Bioinformatics and Molecular Biology Breakthroughs**



## Conclusion

- **Finish What we Started on Classic Threats**
  - **Legacy Products Need Investment to Take These Threats Away from the Enemy**
- **The Good Old Days are over**
  - **Next Generation Threats Need New Thinking, Bold Approaches and Harnessing Information Revolution in Biology**
- **Best Approach for Long-term Threats is Looking for Common Virulence Pathways**
  - **Defeat Next Generation Threats by Attacking Problem at the Common Host Response Pathways**



# Questions?

<http://www.acq.osd.mil/cp>