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Capitalizing Opportunity℠

Development and Procurement of Biotechnology for Emerging Disease and Engineered Threats in the Public Health Preparedness Sector

John M. Clerici

john@tibercreekpartners.com

Public Health Preparedness Funding Key Considerations

How to Pursue Non-Dilutive Funding
- What does it take and how long?

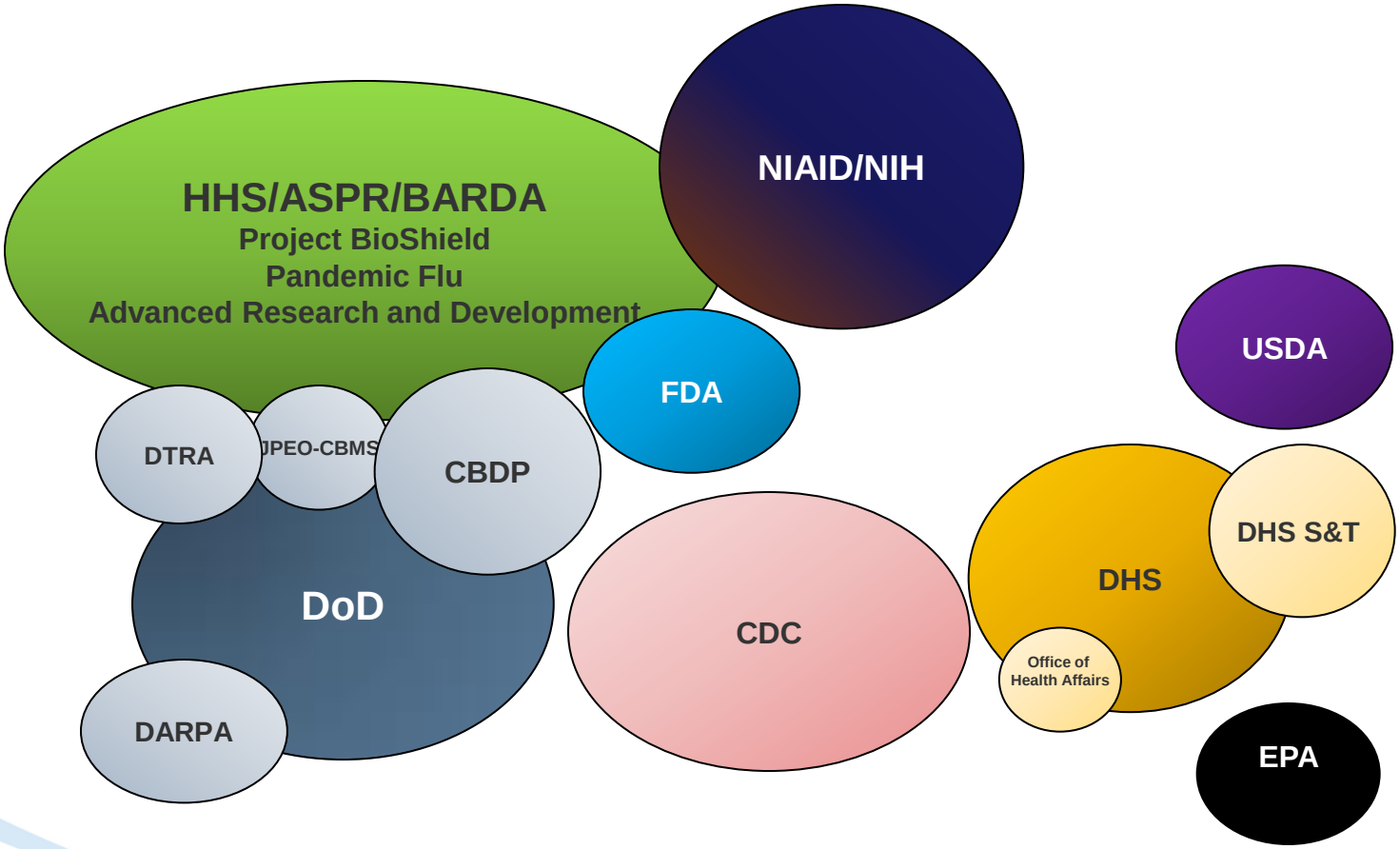
Proposals and Requirements
- The government “red tape”

Commercial Strategy
- How does non-dilutive funding fit with your business strategy?

Alternative Sources
- Working with charities and foundations

Collaboration Maintenance
- Maintaining relationships with non-dilutive funding partners

Public Health Preparedness Spending
US Government



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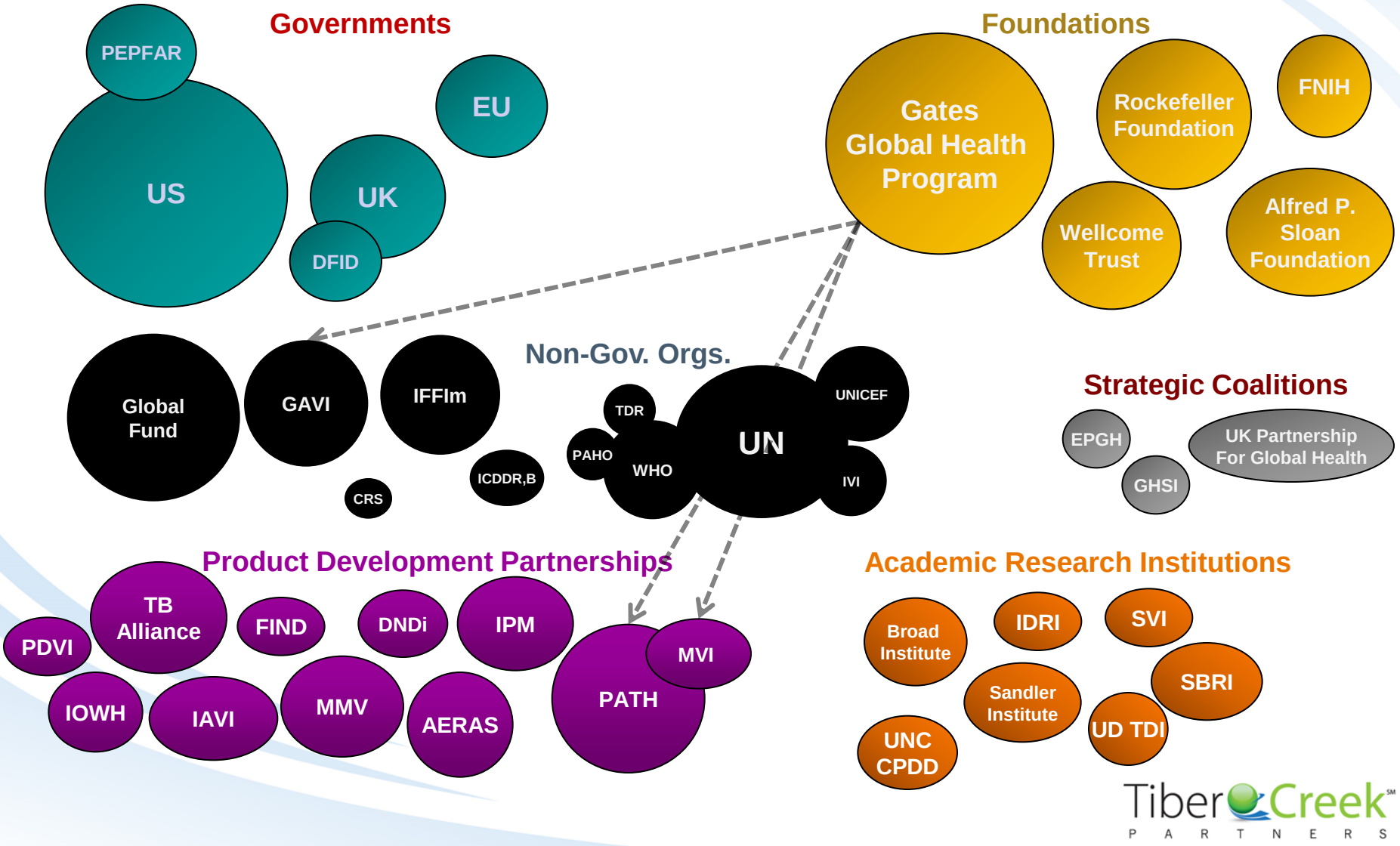
Global Public Health Initiatives
Scope of Opportunity



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Where's the Money in Infectious Disease?

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Where's the Money in Infectious Disease?

Agency or Activity	*Amount of Funds*	*Timeframe*	*Function of Funds*
BioShield/HHS	$2.8 Billion ($5.6 B from 2004-2010)	5 Years	Procurement of medical countermeasures
H5N1/H1N1 Influenza Preparedness	$6.1 Billion (H5); $5 billion, plus (H1); $100 million, plus Universal Vaccines		Pandemic preparedness funding (includes advanced development and procurement of influenza vaccines, therapeutics, devices, and diagnostics)
BARDA Advanced Development	$400 million plus	Annual	Advanced development of medical countermeasures
DOD	$500 Million	Annual	Development and procurement of medical countermeasures
NIH/NIAID	$32 Billion/$1.79 Billion	Annual	Development of pre-clinical medical countermeasures
DHS	$12 Million	Annual	Disaster preparedness planning
TOTAL	***$20 Billion plus***		

HHS Public Health Enterprise

The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) coordinates intra-agency effort with mission to define and prioritize requirements for public health medical emergency countermeasures

- Assistant Secretary Preparedness and Response (ASPR)
  - The ASPR Office was created under the Pandemic and All Hazards Preparedness Act (PAHPA) to lead the nation in preparing for, preventing and responding to public health emergencies and disasters
- Biomedical Advanced Research and Development Authority (BARDA)
  - BARDA manages the **Procurement** of MCMs under Project BioShield and directs the **Advanced Development** of a pipeline of MCMs for chemical, biological, radiological, and nuclear agents
  - Project BioShield
    - A comprehensive effort during the George W. Bush Administration resulting in a $5.6B strategic reserve fund to **Procure** and **Develop** drugs and vaccines to protect against attack by chemical, biological, radiological, and nuclear agents

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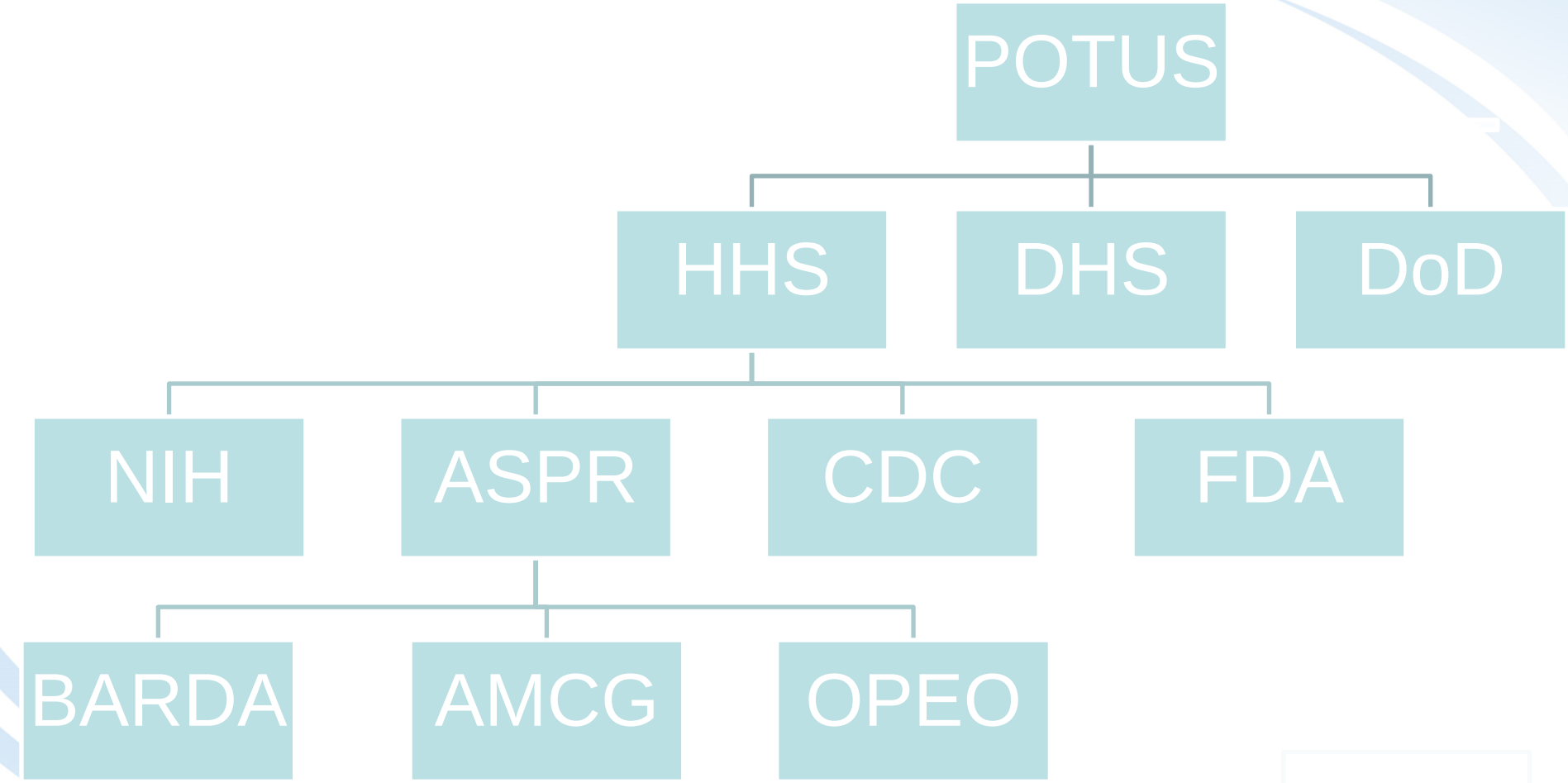
HHS Public Health Enterprise



POTUS=President of the US; DHS=Department of Homeland Security; DoD=Dept. of Defense; NIH=National Institutes of Health; CDC=Centers for Disease Control; ASPR=Assistant Secretary of Preparedness & Response; CDC=Centers for Disease Control; FDA=Food & Drug Administration; BARDA=Biomedical Advanced Research & Development Authority; AMCG=Acquisition Management, Contracts & Grants; OPEO=Office of Preparedness & Emergency Operations (OPEO

Non-Dilutive Funding Strategy

- Another BD target with unique needs
- Map technological benefits with government requirements
- Create realistic timelines for success
- Advocacy and opportunity sourcing occurs in many forums:
  - Direct interaction with decision-makers
  - Participation in industry meetings and trade associations
  - Participation in media sessions and investor conferences
  - Online outlets and through the blogosphere
- Establish and nurture resilient relationships with relevant non-government players
  - Industry collaborators and partners
  - Non-Governmental Organizations
  - Media outlets

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Non-Dilutive Funding Strategy

- Successful government strategies MUST make full use of global alliances and networks
- Significant funding opportunities exist across the USG and beyond the USG
  - Different agencies
  - NGOs
  - Charities
  - Other governments

The USG expects you to know this and exploit this!

Broad Non-Dilutive Funding Strategy

- Governments increasingly collaborating with each other as well as Non-Governmental Organization, such as:
  - UK Defence Science and Technology Lab (DSTL)
  - Public Health England (PHE)
    - Biodefense
    - Community and hospital acquired infections (HAI)
  - European Centers for Disease Control in HAI monitoring
  - Gates Foundation and World Health Organization
    - Global public health
  - PATH
    - Influenza
    - Malaria
    - Enteric disease
  - Wellcome Trust
    - Unmet medical need

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Primary Funding Opportunities

- Broad spectrum technologies (with potential commercial application)
- Significant United States Government interest in the following areas:
  - Biodefense (it's not what you imagine!)
  - Emerging Infectious Disease
  - Global Public Health
- CNS - Traumatic Brain Injury/Post-Traumatic Stress/Alzheimer's
- Rare/Orphan Disease
- Hard Sells – Any Potential Blockbuster
  - Oncology/Cardio/Pain

“Biodefense” Targets

- Food- and Waterborne Pathogens
  - Diarrheagenic E.coli
  - Shigella species
  - Salmonella
  - Listeria monocytogenes
  - Campylobacter jejuni
- Antimicrobial resistance
- Research on mechanisms of antimicrobial resistance, spread of antimicrobial resistance genes within populations
- Modification of existing antimicrobials to overcome emergent resistance
- Yellow fever
- Tuberculosis, including drug-resistant TB
- Influenza
- Rabies
- Prions
- Chikungunya virus
- SARS
- Innate immunity
- West Nile Virus
- LaCrosse
- California encephalitis
- VEE
- EEE
- WEE
- Japanese Encephalitis Virus

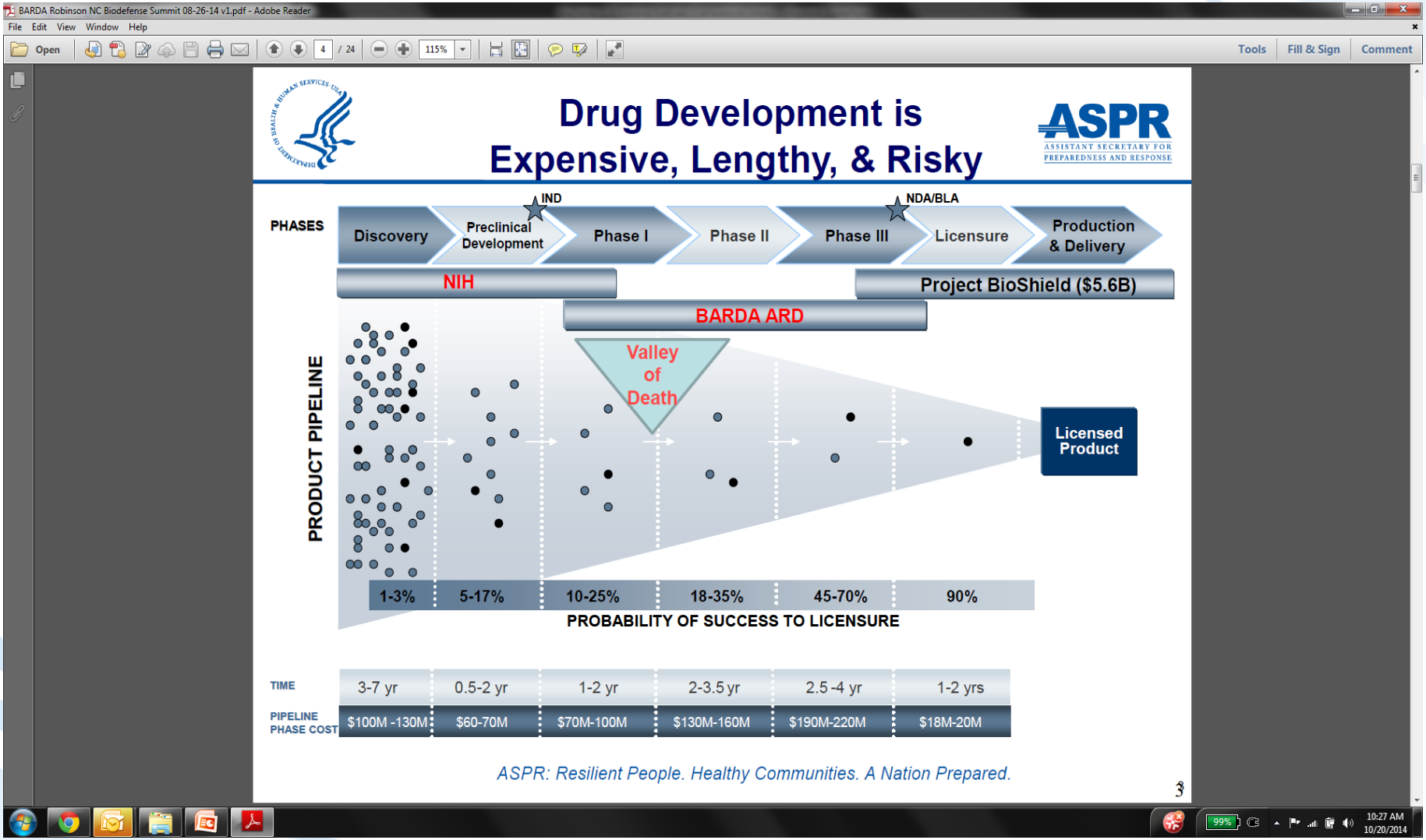
What Else is Happening in the USG?

- Presidential Combating Antimicrobial Resistance Initiative
- Affordable Care Act (ACA) Implementation
- Legislation and Policy
  - Funding shifts
  - Policy shifts
    - 21st Century Cures
    - Brooks Bill – proposed expansion of the PRV
    - BARDA expanding beyond biodefense and influenza
    - Animal health impact on human health
- Watching the experience of the international health community (learning from them?)
  - Ebola lessons learned/not learned

21st Century Cures

- Antibiotic development also features prominently in the *Cures Act*
  - Title II, Subtitle G—"Antibiotics Drug Development"—is closely modeled off a previous version of the *Cures Act* and another piece of legislation, the *Promise for Antibiotics and Therapeutics for Health (PATH) Act*.
- The bill calls for the creation of a "limited population pathway" for antibacterial and antifungal drugs.
  - The pathway would allow a sponsor of a new drug to seek approval for the product intended to treat "a serious or life-threatening disease, condition or indication" that is currently not adequately served by existing therapies.
  - The pathway could only be used if the sponsor could identify a specific population in which the medical product would be used.
  - Each drug product approved under this pathway would need to be labeled with the following statement: "This drug is indicated for use in a limited and specific population of patients."
  - The pathway also provides for the clearance of antimicrobial susceptibility testing devices, which would be used to determine if a particular microorganism is susceptible to a particular drug.
- FDA is also required to set up a website to provide recommendations on which bacteria/fungi are susceptible to specific drugs.

A Walk Through Relevant HHS Slides



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A Walk Through Relevant HHS Slides

BARDA Transitions to Project BioShield II & Pandemic Influenza II - Adobe Reader

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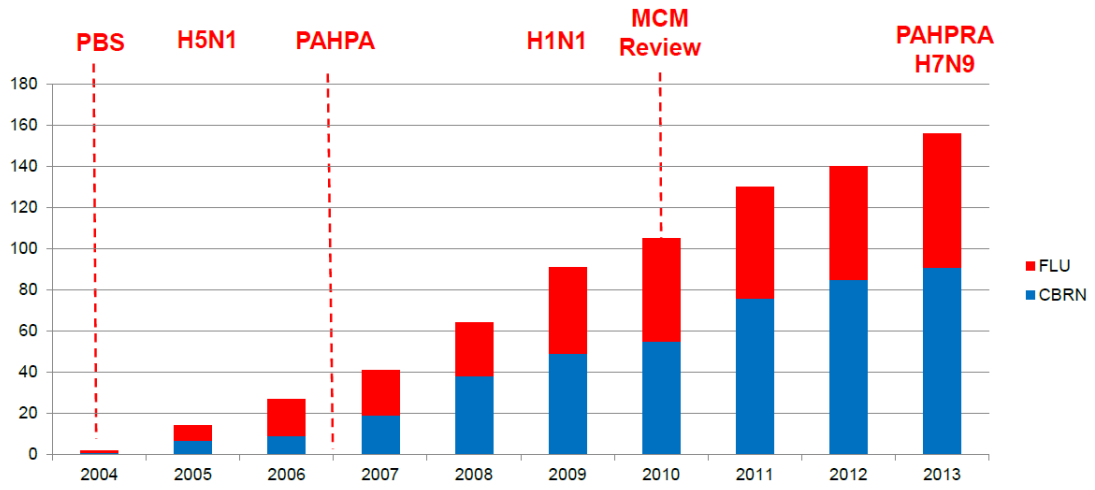
BARDA Created a Robust & Productive MCM Development Pipeline

ASPR
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

- **More than 150 MCM product candidates in development since 2004**



ASPR: Resilient People. Healthy Communities. A Nation Prepared.

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A Walk Through Relevant HHS Slides

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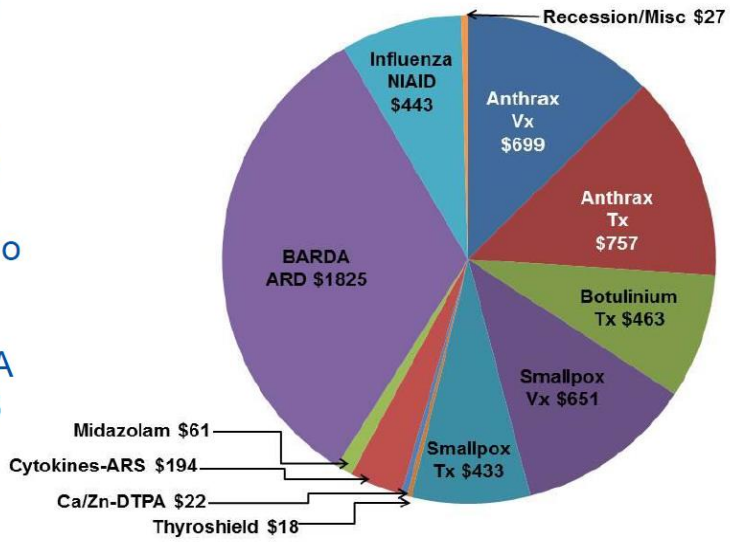
Project BioShield

ASPR
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

- Had early difficulties – but has transformed into a successful program
- Explicit goal of the program – acting as a market guarantee or AMC for developers of products for which there are no commercial markets
- Success of PBS led to PAHPA reauthorization in March 2013
- BARDA expects to procure 8 - 12 new products for the SNS between FY2014-18



Expenditures FY2004-13

ASPR: Resilient People. Healthy Communities. A Nation Prepared.

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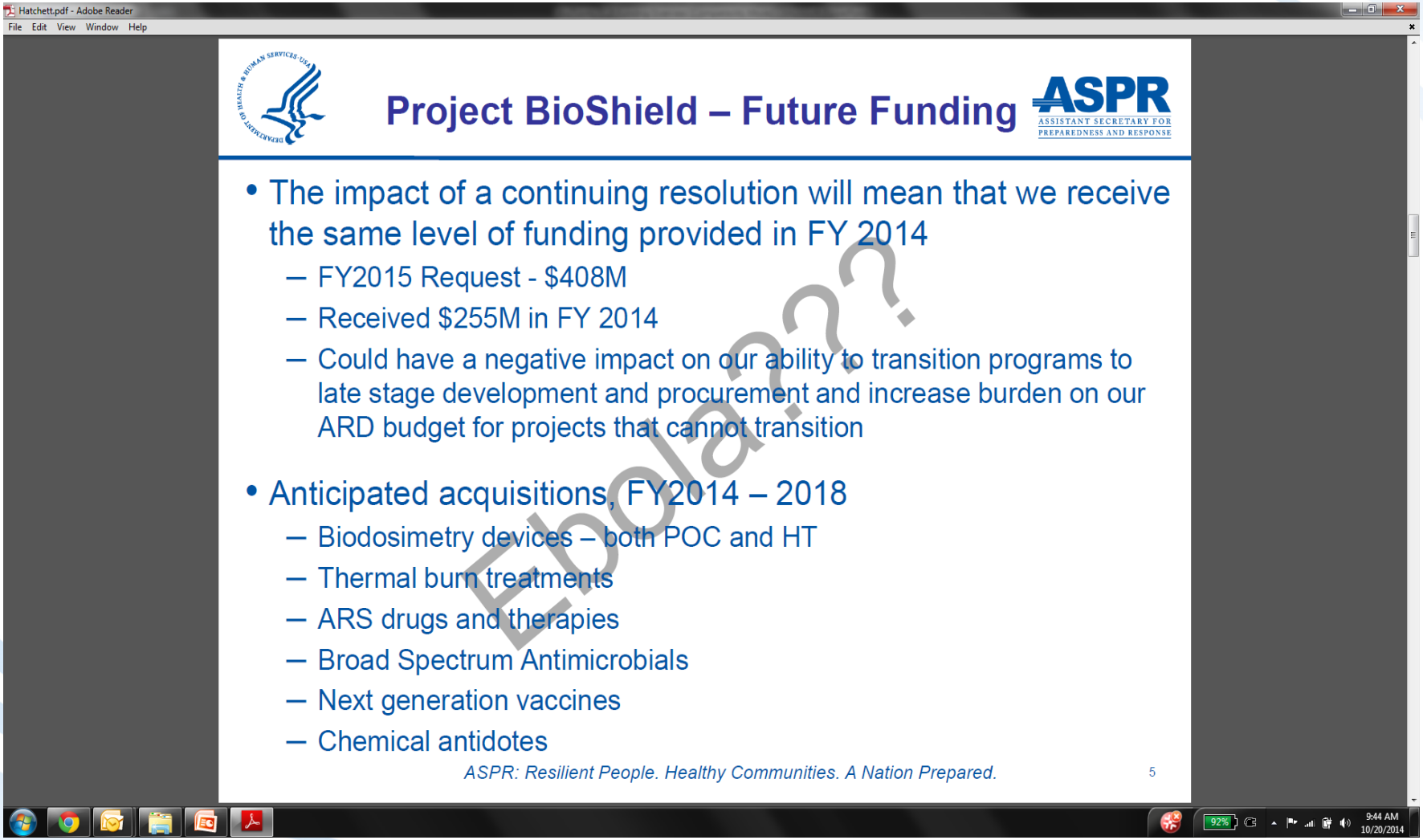

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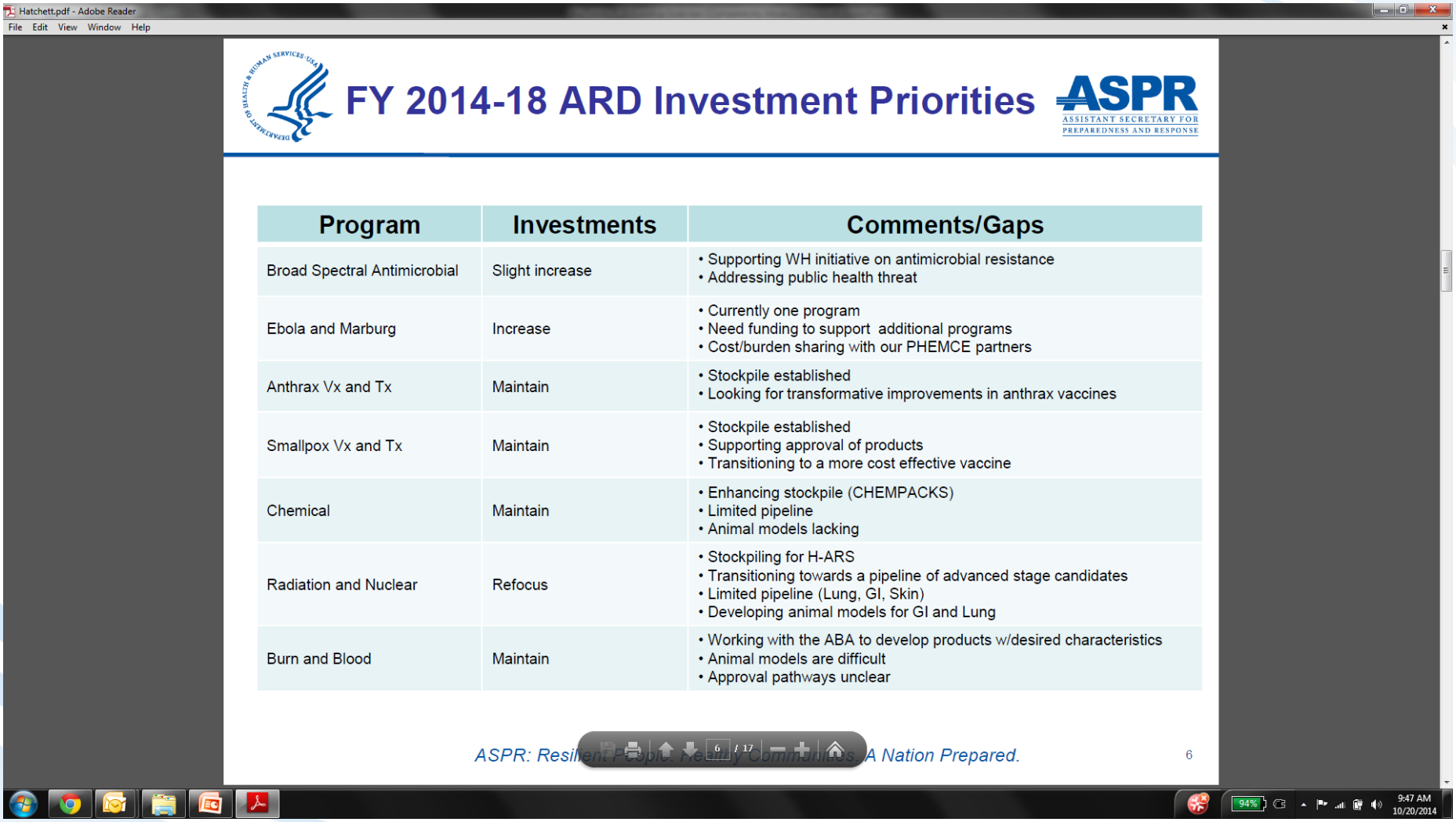

Program	Investments	Comments/Gaps
Broad Spectral Antimicrobial	Slight increase	• Supporting WH initiative on antimicrobial resistance • Addressing public health threat
Ebola and Marburg	Increase	• Currently one program • Need funding to support additional programs • Cost/burden sharing with our PHEMCE partners
Anthrax Vx and Tx	Maintain	• Stockpile established • Looking for transformative improvements in anthrax vaccines
Smallpox Vx and Tx	Maintain	• Stockpile established • Supporting approval of products • Transitioning to a more cost effective vaccine
Chemical	Maintain	• Enhancing stockpile (CHEMPACKS) • Limited pipeline • Animal models lacking
Radiation and Nuclear	Refocus	• Stockpiling for H-ARS • Transitioning towards a pipeline of advanced stage candidates • Limited pipeline (Lung, GI, Skin) • Developing animal models for GI and Lung
Burn and Blood	Maintain	• Working with the ABA to develop products w/desired characteristics • Animal models are difficult • Approval pathways unclear

What does this all mean to a for-profit biotech?

- There is A LOT of money out there
- USG Partnerships are valuable – BUT have to be managed carefully
- Commercial goals are VERY important to the funders and MUST be the top priority for the company
- “It takes a village”
- Avoid the gold-rush mentality – do your homework!

Contact Info

- **John M. Clerici**
  - (703) 795-4247
  - john@tibercreekpartners.com
- **Jennifer R. Schneider**
  - (574) 210-7468
  - jennifer@tibercreekpartners.com

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