

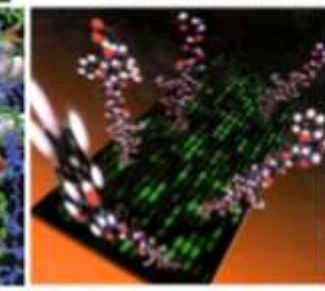
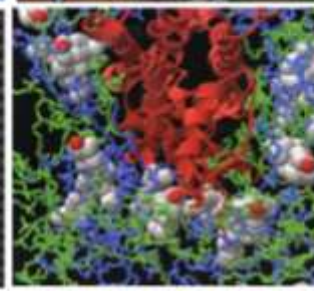
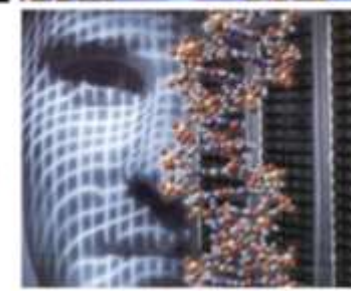
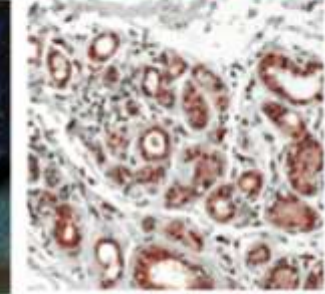
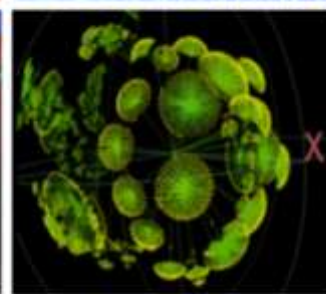
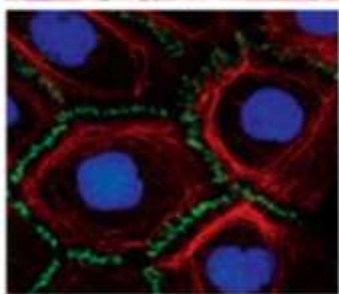
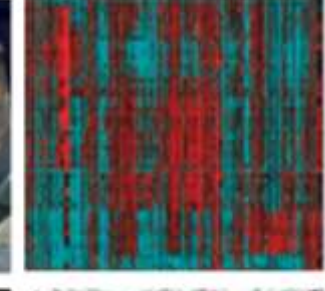
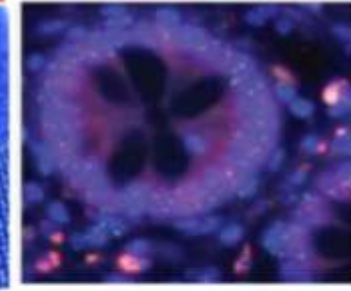
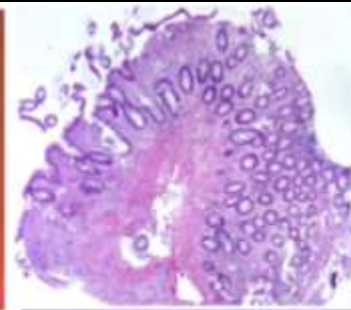
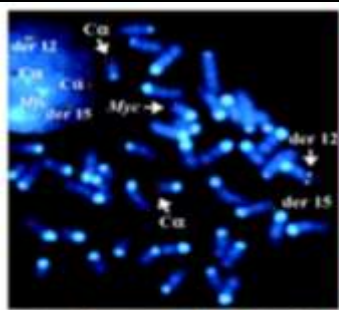
Biosecurity: Enhancing Security in an Increasingly Complex World

Dr. George Poste
Chief Scientist, Complex Adaptive Systems
and Del E. Webb Chair in Health Innovation
Arizona State University
george.poste@asu.edu
www.casi.asu.edu

**Threat Preparation for the 21st Century:
Association of University Research Parks Annual Meeting**

Tempe, Arizona 6 March 2013

Slides available @ <http://casi.asu.edu/>



Seeking Security in an Unsecure World: The Military and National Security Calculus

Expanding Conflict Zones, Political Instabilities and Terrorism



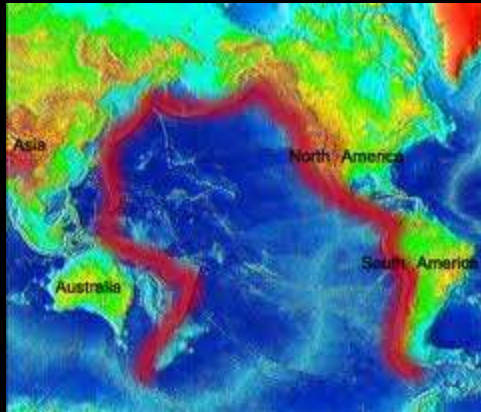
**WMD
Proliferation**

**New Power
Centers**

**US Retrenchment:
Geopolitical/Fiscal**

Seeking Security in an Unsecure World: Economic Risks to Stability and Sustainability

Natural Disasters and Future Increased Risks Due to Climate Change



**Environmental
Deterioration**

**Adequacy of
Global Food and Water**

**Critical Resources and
Non-Renewable Resources**

Seeking Security in an Unsecure World: New Technologies and Implications for National Security and Competitiveness

Cyber- Vulnerabilities



Robotic Warriors and Future War



Synthetic Biology



Miniaturization

3D Digital Mfg.

Dual-Use Biology

Biosecurity: Three Inter-related Domains

biodefense

- **combating malevolent biological assault from terrorists/nation states**
- **not just humans as targets (animals, food supply)**
- **not just bugs (dual-use biology and disruption of key body biological pathways)**

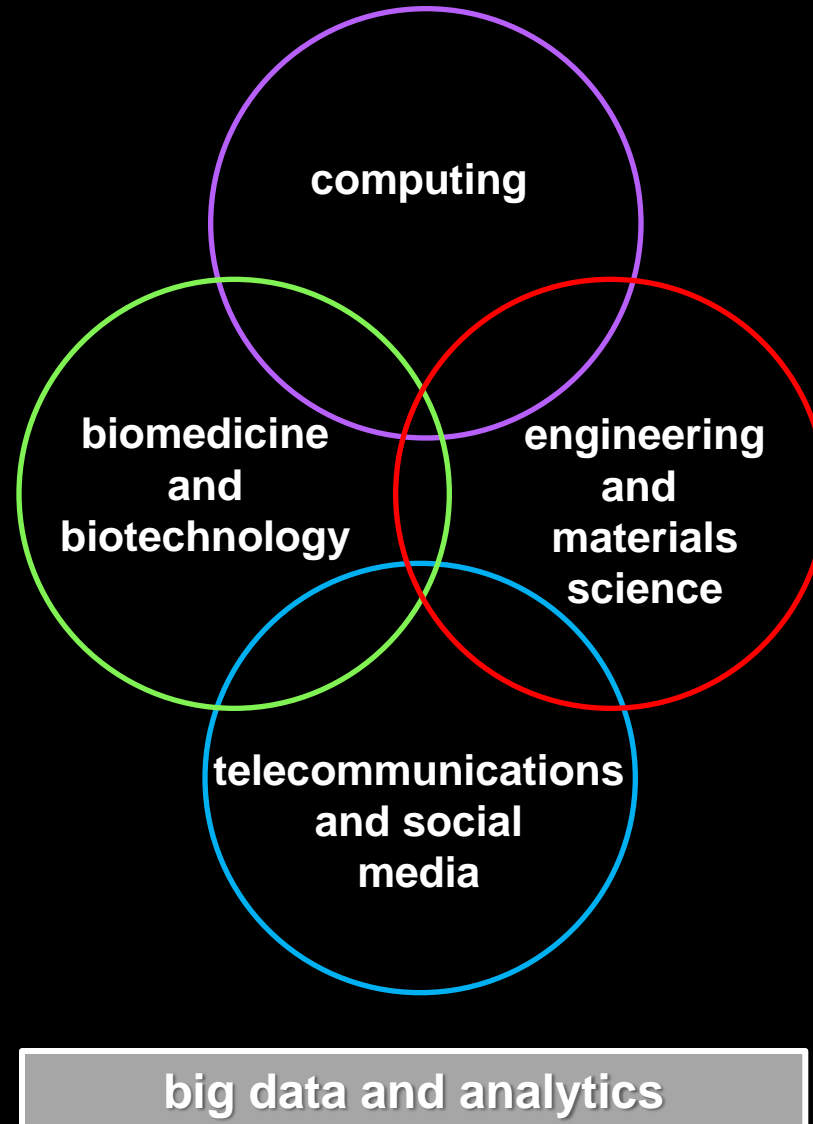
public health

- **combating naturally occurring biological threats**

dual-use technologies

- **scientific methods and knowledge which can be used for both beneficent and malevolent purposes**

Technology Convergence and the Life Sciences



Building Resilient and Agile Systems for Biosecurity

Bioterrorism

**Infectious
Diseases
of
Natural
Origin**

**Environmental,
Socio-Economic
and
Security
Impacts of
Disease**



Biosecurity

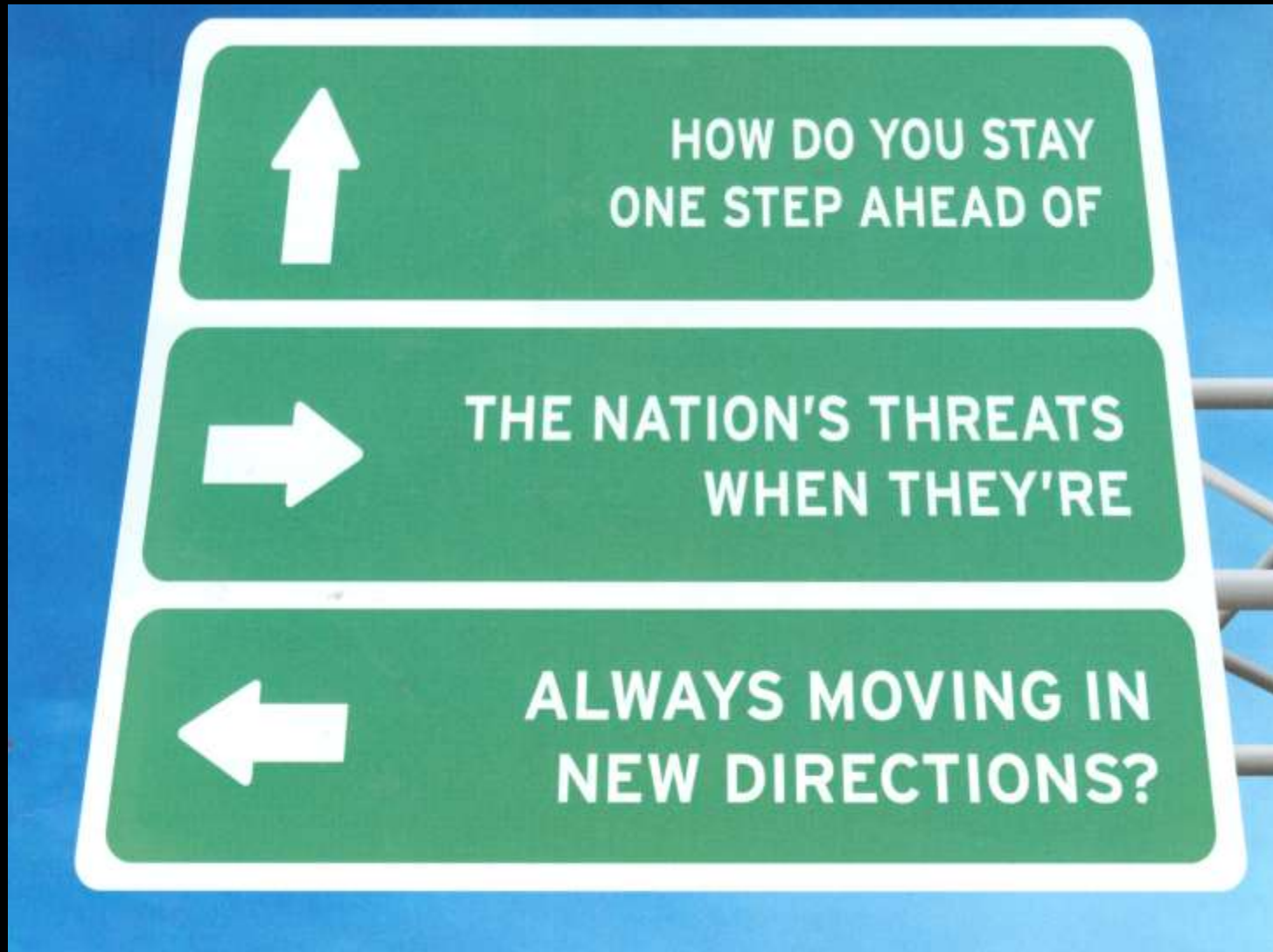
Today

- **bioterrorism: low probability, high consequence**
- **natural infections: high probability, high consequence**

2020 and beyond

- **bioterrorism**
 - **an expanded risk beyond bugs**
- **outpacing natural infectious diseases**
 - **old foes, resurgent foes and new EIDs**
- **synthetic biology**
 - **the ultimate dual-use technology**

Preparedness: Building Resilient Systems and the “All Hazards” Challenge



Immediate Assessment of Damage (Ordinance; Radiation; Chemicals) Versus Unknown Scale of Continued Damage ('Bio')





TOM BROKAW
NBC TV
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

10112+0002

09-11-01

THIS IS NEXT

TAKE PENACILIN NOW

DEATH TO AMERICA

DEATH TO ISRAEL

ALLAH IS GREAT

**“I will show you fear
in a handful of dust”
T. S. Eliot**





COMMISSION ON THE PREVENTION OF WEAPONS OF
MASS DESTRUCTION PROLIFERATION AND TERRORISM

Prevention of WMD Proliferation and Terrorism Report Card

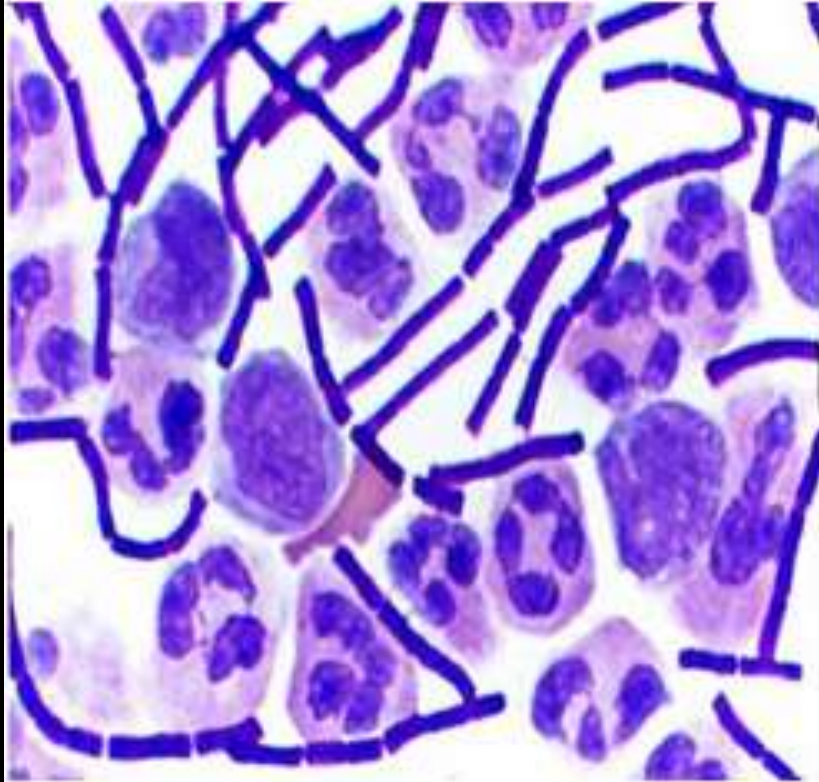
An Assessment of the U.S. Government's Progress
in Protecting the United States from Weapons of
Mass Destruction Proliferation and Terrorism

January 2010

**“Each of the three last Administrations
have been slow to recognize and respond
to the biothreat”**

A \$250 Billion 'Hit'

"Amerithrax 2001"



Project Bioshield (July 2004)



Sound-Bite Policies, Big Bucks and No Accountabilities

- **Bioshield**
- **Biowatch**
- **Medical Counter Measures Initiative**
- **National Vaccine Plan**
- **Public Health Emergency Countermeasures**
- **Creation of BARDA under PAHPA**
- **Collective Foreign Threat Assessment
Restricted Party Screening Authorities**

A Shared Global Risk: The Omnipresent Threat Posed By Microorganisms and Parasites



The Global Public Health Challenge Posed by Rapid Urbanization in Developing Countries

**High Disease
Transmission**



**Expanded Eco-niches
and Increased Zoonotic EID Risks**



**Major Deficits in Health
Infrastructure**



**Lack of
Safe Water**



Toxic Waste

The Ever Shifting Dimension of EIDs

West Nile Virus, New York 2001



Monkeypox, USA May-June 2003



West Nile Virus, Dallas, TX 2012

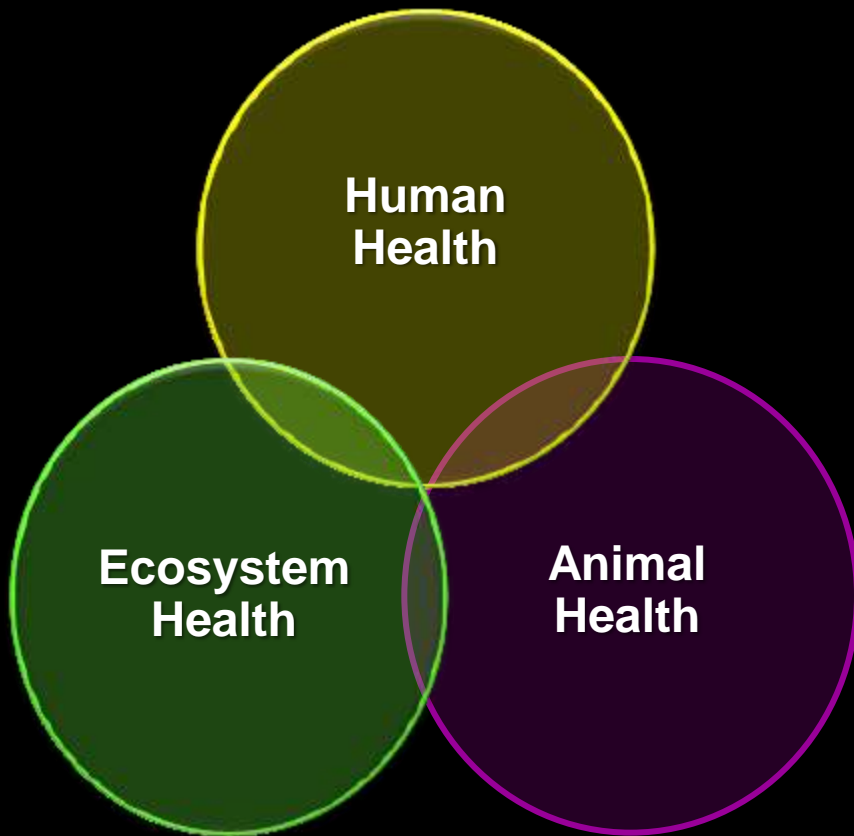


African Swine Fever, Russia 2012



The Rationale for Integration of Historically Separate Domains and Responsibilities

“One Health”



- most effective control route for zoonotic threats to humans is via the relevant animal population(s)
- knowledge of the potential impact(s) of ecosystem perturbations on emergence of novel zoonoses must be accorded high priority
- disparity in animal and human public health capacity undermines global disease control
- food chain safety

Global Transport and Trade: New Interactions of People, Animals and Product Supply Chains

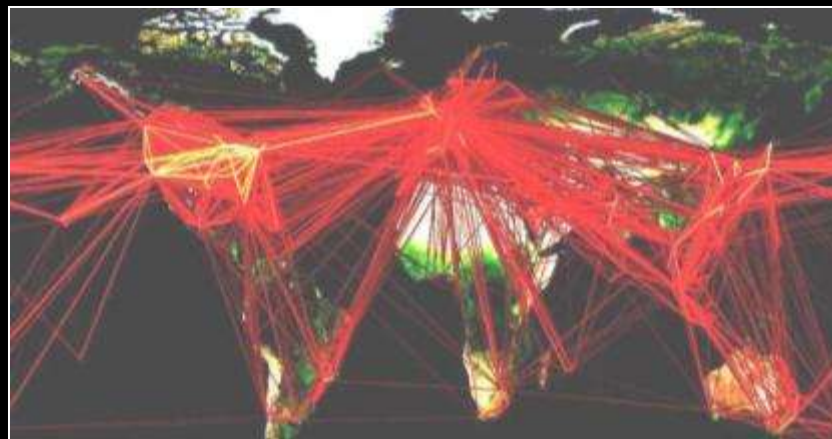
The Super Vector



**World Container
Traffic Doubled
Since 1997**



Billion Cross-Border Travelers



Global Food Networks



**The Public Health, Economic and Political Challenges
of a Major Global Bioincident**

**Preparedness for Substantial Societal Dislocations:
Systems Versus Silos**

Building Resilient Preparedness and Response Capabilities for Biosecurity

Improving the Nation's Ability to Detect and Respond to 21st Century Urgent Health Threats: First Report of the National Biosurveillance Advisory Subcommittee

Report to the Advisory Committee to the Director, CDC

April 2009



COMMISSION ON THE PREVENTION OF WEAPONS OF MASS DESTRUCTION PROLIFERATION AND TERRORISM

Prevention of WMD Proliferation and Terrorism Report Card

An Assessment of the U.S. Government's Progress in Protecting the United States from Weapons of Mass Destruction Proliferation and Terrorism

January 2010

GAO

United States Government Accountability Office
Report to Congressional Committees

June 2010

BIOSURVEILLANCE

Efforts to Develop a National Biosurveillance Capability Need a National Strategy and a Designated Leader



GAO-10-845

GAO

United States Government Accountability Office

Testimony
Before the Committee on Homeland Security, House of Representatives

For Release on Delivery Expected at 2:00 p.m. EDT Wednesday, July 29, 2009

INFLUENZA PANDEMIC

Gaps in Pandemic Planning and Preparedness Need to Be Addressed

Statement of Bernice Steinhart
Director, Strategic Issues

GAO

United States Government Accountability Office
Report to Congressional Committees

December 2009

BIOSURVEILLANCE

Developing a Collaboration Strategy Is Essential to Fostering Interagency Data and Resource Sharing



GAO-10-171

GAO

United States Government Accountability Office
Report to the Chairman, Subcommittee on Oversight of Government Management, the Federal Workforce, and the District of Columbia, Committee on Homeland Security and Governmental Affairs, U.S. Senate

February 2009

VETERINARIAN WORKFORCE

Actions Are Needed to Ensure Sufficient Capacity for Protecting Public and Animal Health

Detection of Infectious Disease Threats:

Not A Hazmat or Wide Area Sensor Network Solution



Emergency Rooms and Farms Will be the Front Line



Earlier Diagnosis and Intervention Saves Lives

Improved speed, breadth and accuracy of clinical diagnosis



- faster Rx
- accurate Rx
- prophylactic Rx for incident personnel
- robust triage
 - rationing
 - reassurance of “worried well”
 - quarantine decisions
- real time disease surveillance data
- faster ID of incident evolution
- faster incident containment and exposure controls



**The Single Most Important Leverage Point
For Rapid Mobilization of Resilient Responses
to Epi-/Pandemics, Epizootics and WMD Bioterrorism**

Surveillance Systems for the Rapid Detection and Control of Infectious and Parasitic Diseases

Signatures
of
Pathogenic
Organisms

Global
Network
of
Surveillance
and Diagnostic
Testing Systems

Rapid
Analysis
and
Response to
Diagnostic and
Surveillance
Information

Profile



Sense



Act





Global Disease Surveillance



EMERGENCY ID NET



Public Health Department's Surveillance



U.S. Influenza Sentinel Provider Surveillance Network



Quarantine Activity Reporting System (QARS).



Geodemographic Information Systems (GIS): Real-Time, Front Line, Ground Zero Data from Field Sampling and Sentinels



Sensor Networks for Remote Health Status Monitoring: Mobile Phones and Real Time Reporting



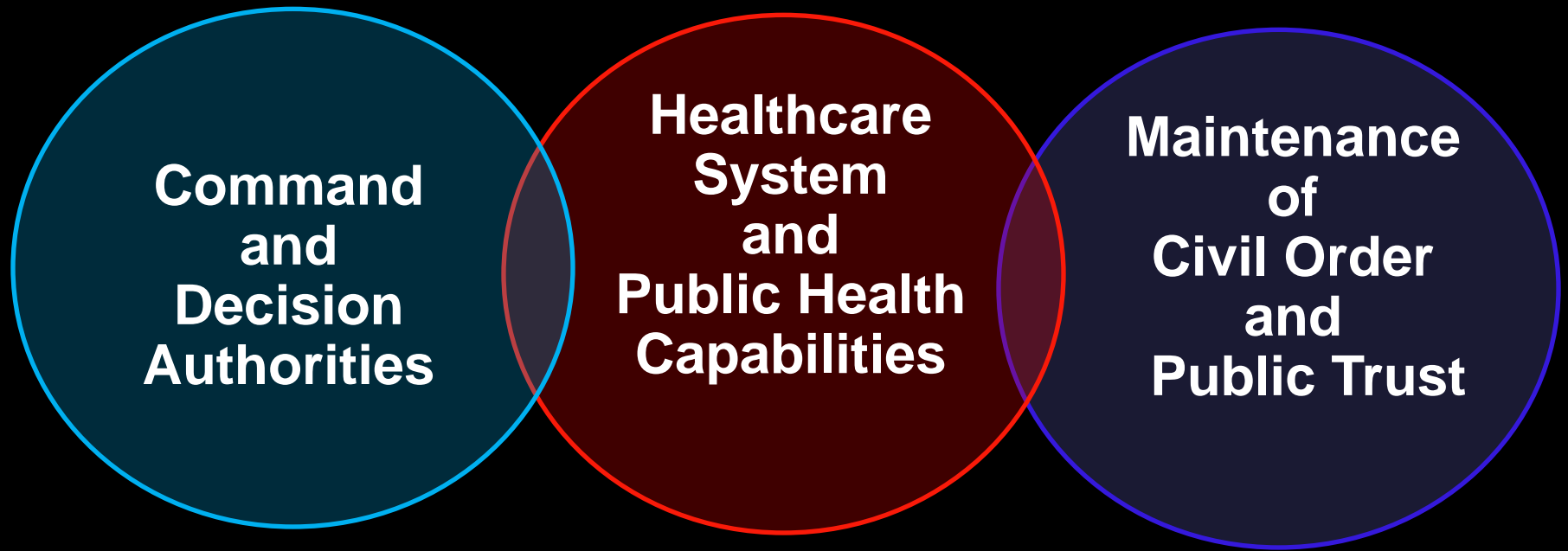
- geolocation data (where)
- temporal information (when)
- contextual information (what)
- improved decision support (action)



“For most of us design is invisible until it fails”
Bruce Mau



The Three Core Components of Bioincident Management



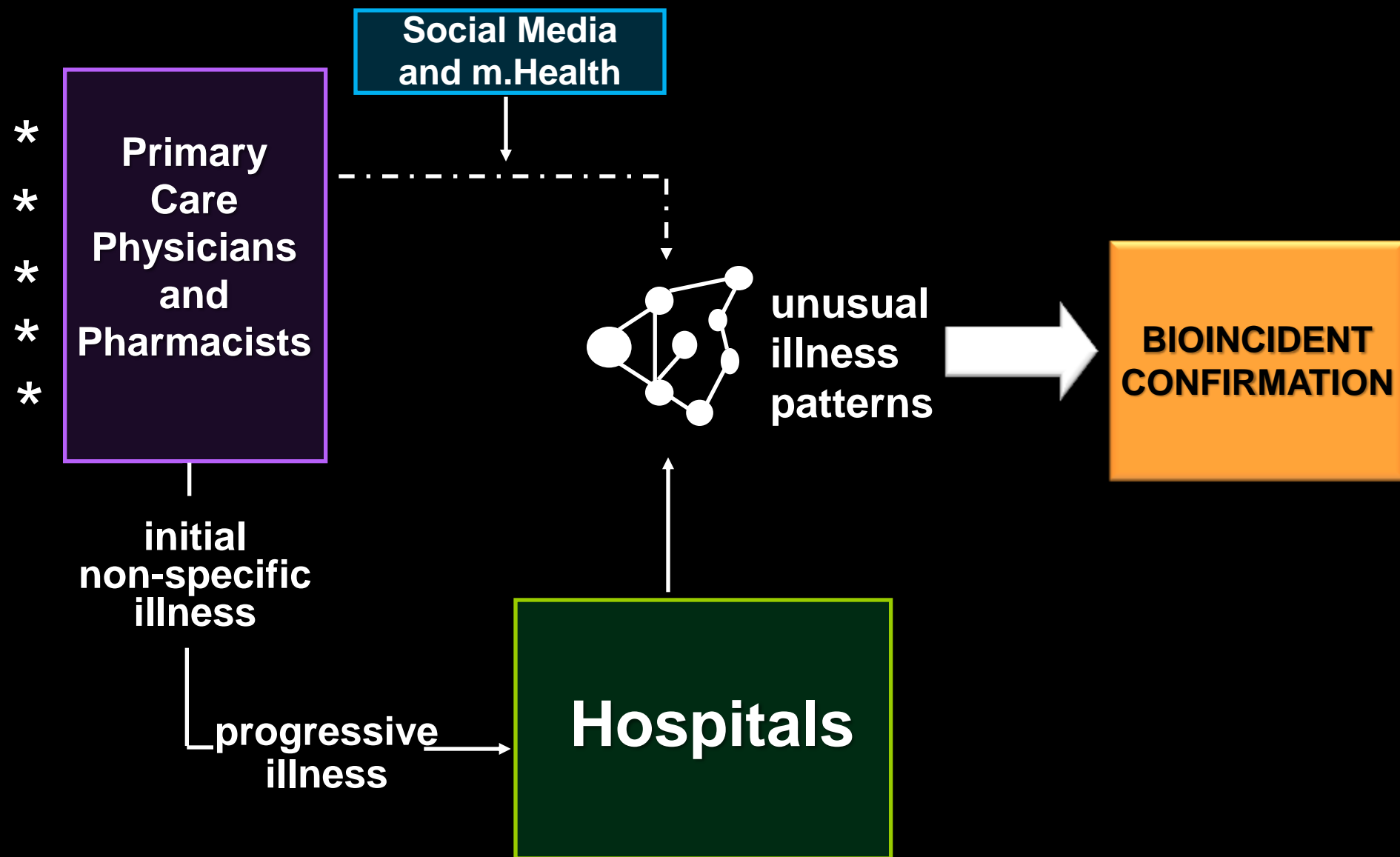
- **robust inter-operable communication networks for real-time situational awareness and rapid actions**
- **managing the media and the 'worried well'**
- **transparency, credibility and public trust**

Medical Consequence Management of Major Bioincidents

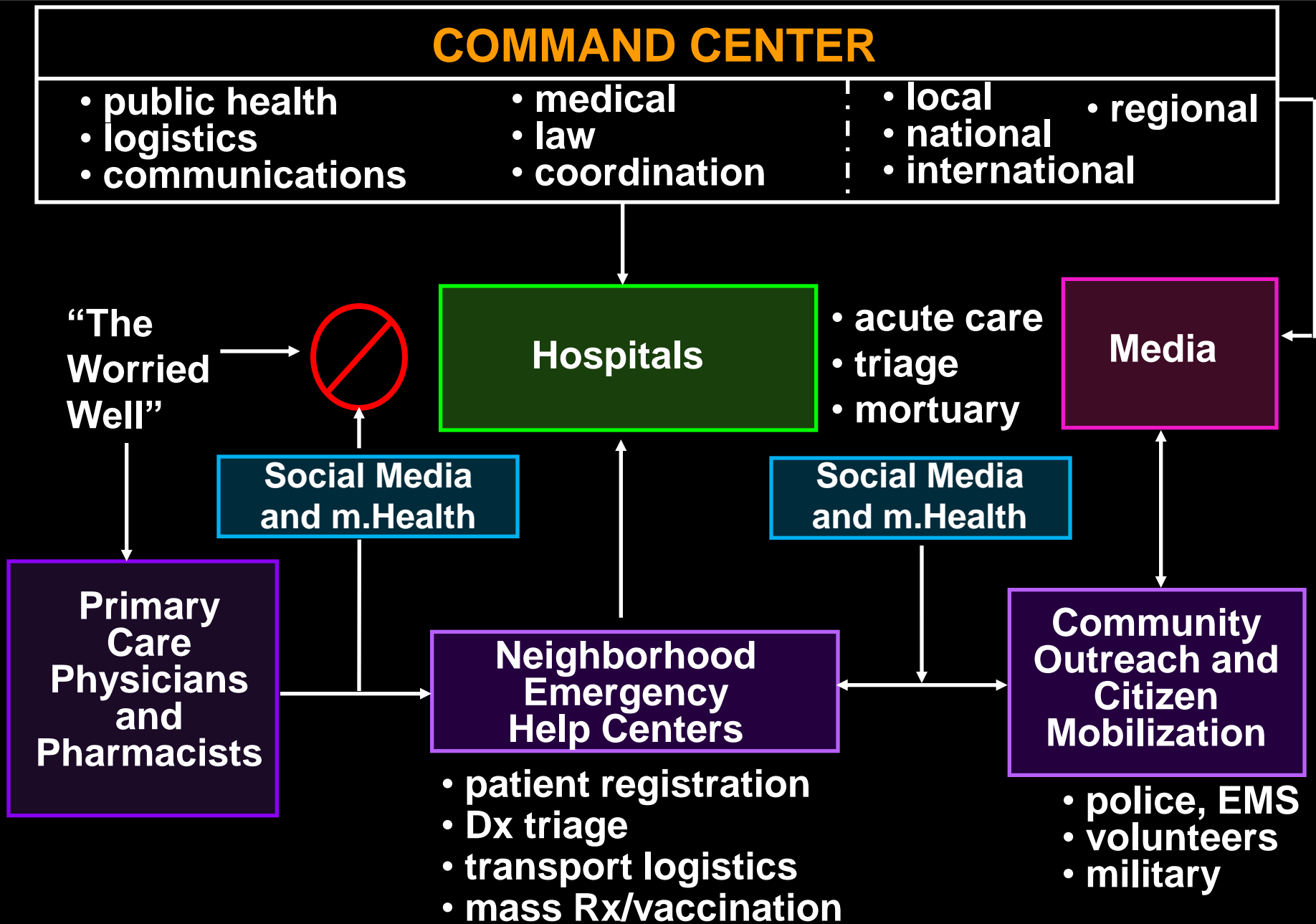
Key Success Factors

- **tested disaster management plan**
- **responder training and education**
- **command structure**
 - **demarcated roles, responsibilities, authority**
 - **robust communication channels**
- **single source POC for key interfaces**
 - **ground zero staff (multiple ground zeros in CBW)**
 - **emergency services and first responders**
 - **medical/public health**
 - **politicians and inter-agency coordination**
 - **conventional media and social media**

The Lag Phase in Bioincident Detection



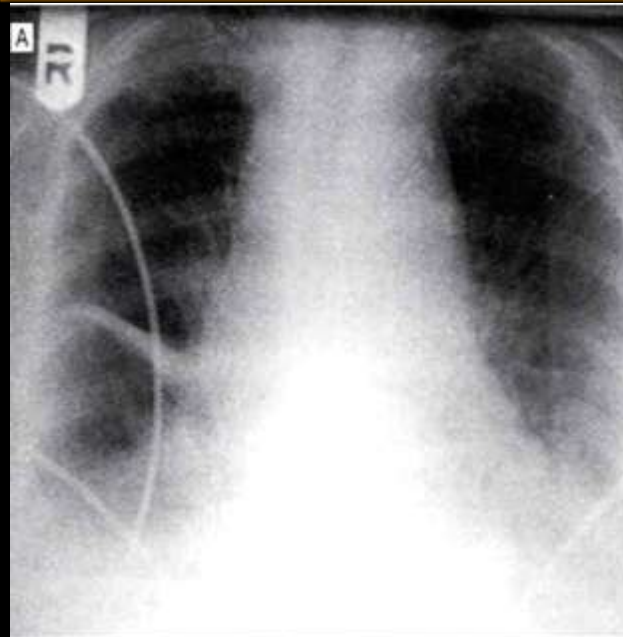
Consequence and Crisis Control in a Bioincident



Education and Training



Diagnostic Accuracy



Infection Control

Availability of Therapy

Overload and Triage

Distribution of Medical Emergency Supplies for a Major Epidemic/Pandemic



- pre-positioning for known threats: The Strategic National Stockpile
- rapid movement by commercial carriers
- managing political/public/media responses for bioincidents with limited or no Rx/vaccine options

Vulnerability of Global, National and Local Supply Chains in a Major Epidemic/Pandemic

Medicines

- “just-in-time” supply networks
 - major hospitals 2/3 deliveries per day
- out-patient prescription drugs
 - insurance company limits on prescription volume (USA)
- majority of drug intermediates, excipients and final products sourced off-shore
- 95% generic drugs used in US (64% of total Rx) are made off-shore, primarily in PRC and India
- no national stockpile for routine non-BCM prescriptions

Medical Countermeasures (MCMs) for Special Populations: Emergency Use Authorization

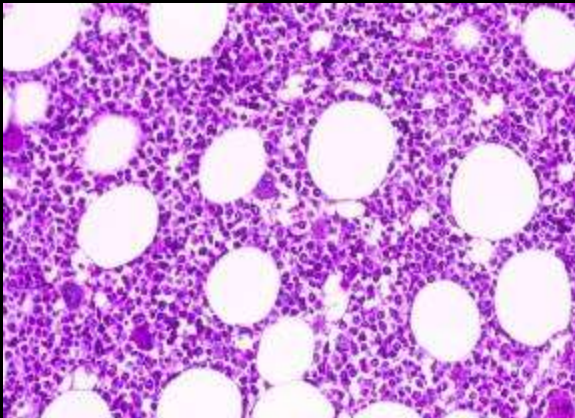
Children



Pregnant



Aged



Immunosuppressed

**Impaired Major
Organ Function**

ICU-Critical Care

Control of Population Movement and Supply Chain Networks

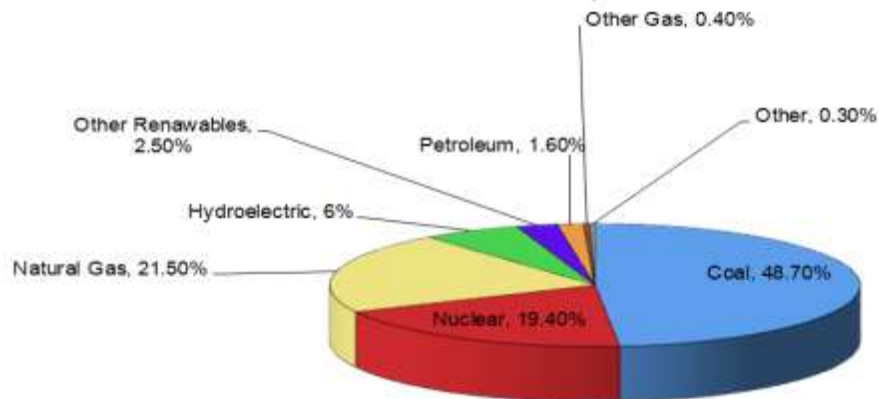


Vulnerability of Global, National and Local Supply Chains in a Major Epidemic/Pandemic

Energy



Net Power Generation in the US by Fuel Source, 2007



Source: Coal Fields of the Conterminous United States, Originator: USGS, Eastern Energy Year: 2011 July update; Publication Date: May 2, 1999; <http://pubs.usgs.gov/of/1999/of99-030/>
 Region boundaries and names are adapted from those used by the Energy Information Administration's National Energy Modeling System. Map: Congressional Cartography, Library of Congress 2007

The Crucial Role of the Media in Incident Management



Pre-recorded Modules



Familiar (Trusted?) Face(s)



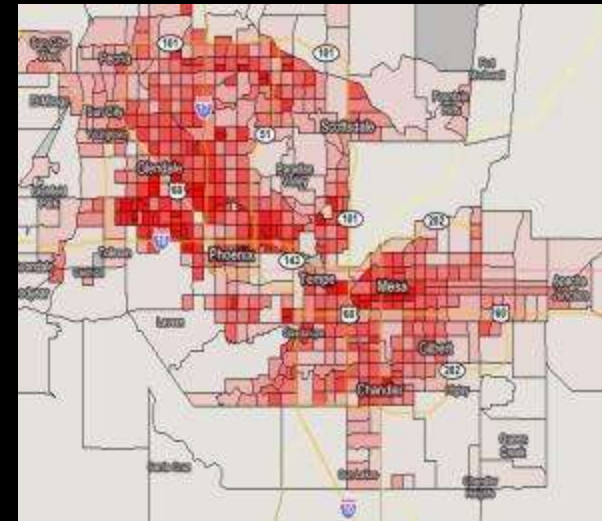
Credibility and Reality



Setting Examples to Limit Civil Disorder

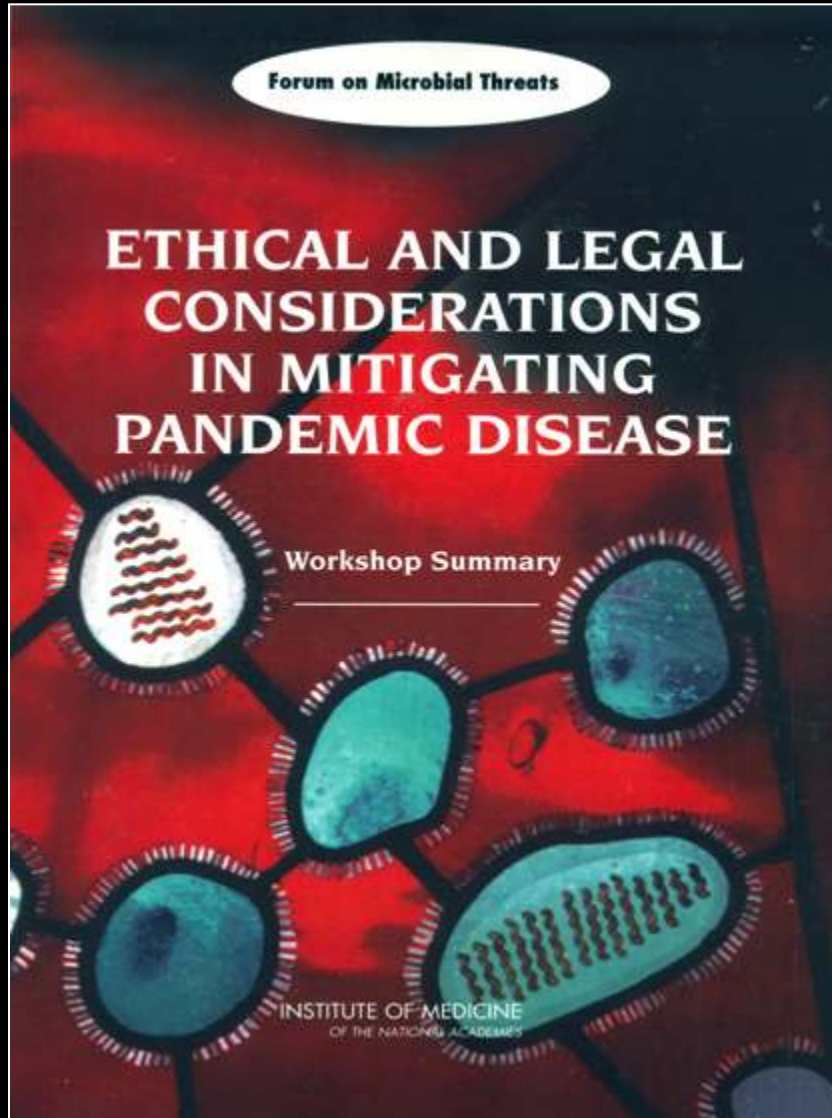


Authoritative Leadership



Community Cooperation

Legal Aspects of Public Health and Counter-Terrorism Actions to Contain Bioincidents



- suspension of civil liberties
- imposition of quarantine
- triage decisions and rationing
- mandatory medical examination and treatment
- mandatory treatment with unapproved drugs and vaccines
 - informed consent
 - indemnification
 - special populations
- DoD and Posse Comitatus

The Mass Casualty Decontamination Challenge and/or Isolation Challenge

How do you go from decontaminating a few ambulatory, protected responders...



...to hundreds or thousands of incapacitated, unprotected civilians?

Biometrics and Infectious Disease Surveillance in a World of Rapid Global Transit



MEDICINE AT THE BORDER
Disease, Globalization and Security,
1850 to the Present



Edited by Alison Bashford



The Growing Threat from Infectious Agents

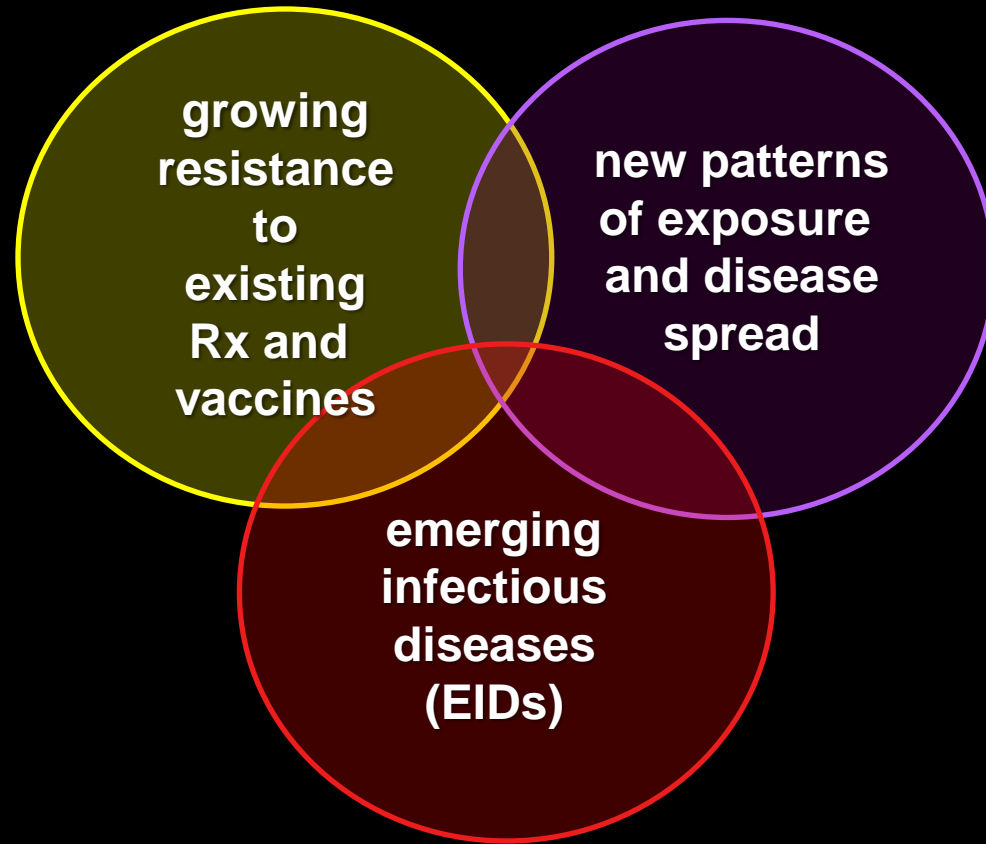
Asleep at the Switch!

Bag Bugs and Few New Drugs

Comfort and Complacency: The Enemies of Vigilance and Preparedness



Outpacing Infectious Diseases



NO ESKAPE!: Resistant Bugs and Few New Drugs



- increasing resistance in G⁺ and G⁻ pathogens in hospital and community settings

- the **ESKAPE** pathogens

Enterococcus faecium

Staphylococcus aureus

Klebsiella pneumoniae

Acinetobacter baumannii

Pseudomonas aeruginosa

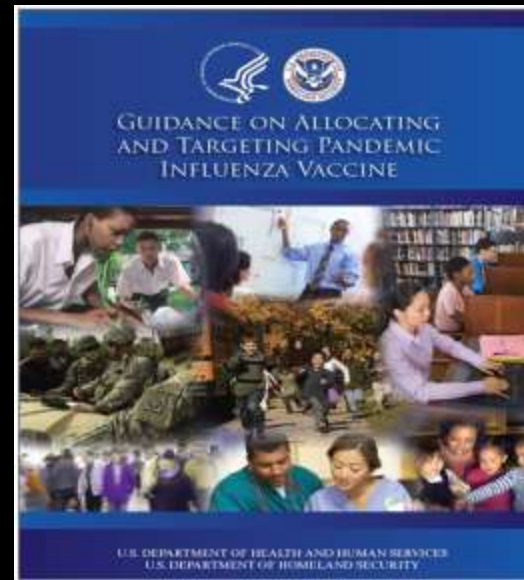
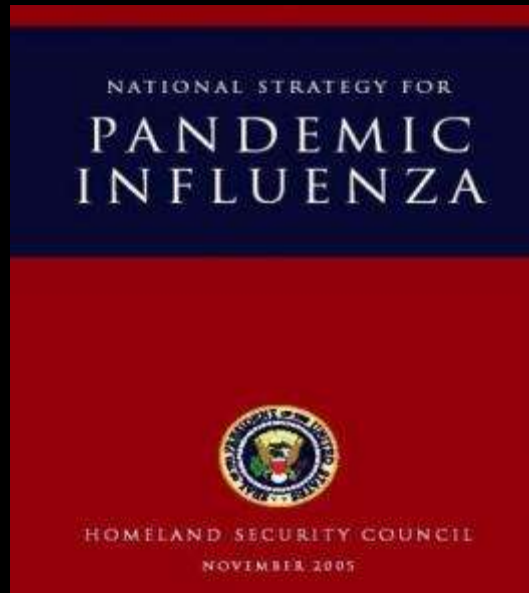
Enterobacter species



The Valley of Dearth: The Consequence of Declining R&D Investment in Antibiotic Discovery*

- **75% decrease in antibacterials approved from 1983 to 2013**
- **only 16 agents currently in Phase II / III clinical trials (versus total 1218; 820 for cancer)**
 - **only 3 as new ‘classes’ with novel mechanisms of action**
 - **absence of agents for therapy of resistance in G-bacilli and MDR-TB**
 - **lack of systemic agents in advanced development for organisms resistant to all current antibacterials**

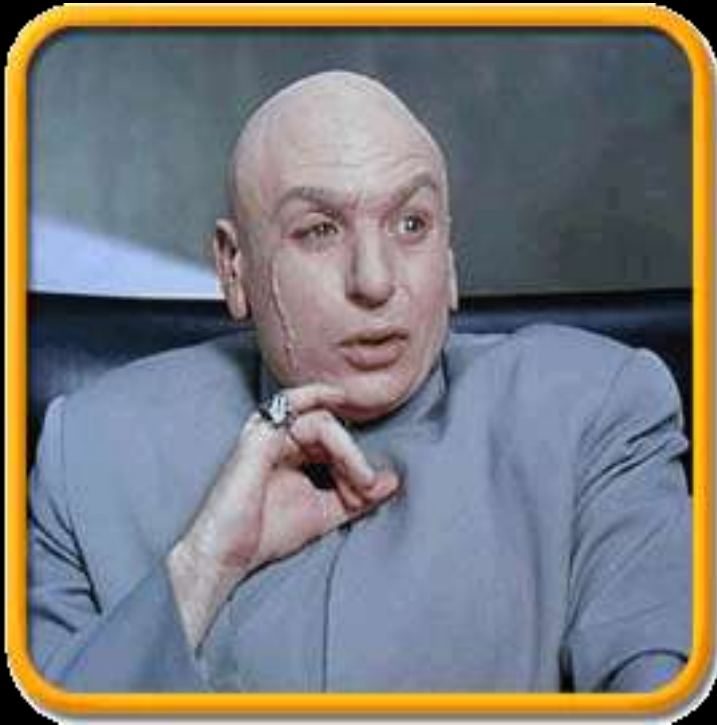
The Imperative for Innovation in Vaccine Production Technologies



“If this virus was killing more of its victims, there’d be lots of questions about whether this vaccine was produced soon enough”

**Dr. Michael Osterholm
Director, CIDRAP, Univ. Minnesota**

Future Trajectory Trends and Threat Expansion



New 'Dual-Use' Technologies

Dual-Use Technologies

Expanding the Biothreat Spectrum

Synthetic Biology: A Powerful Dual-Use Technology

Synthetic Biology



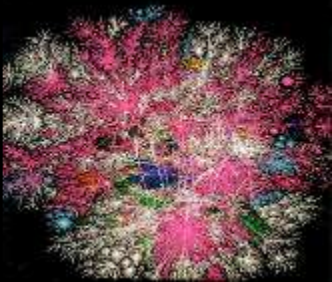
**“Creating artificial life with DNA synthesis.
That’s sort of the equivalent
of machine-language programming.
If you want to change the world in some big way,
use biological molecules.”**

**Bill Gates
Wired 2010**

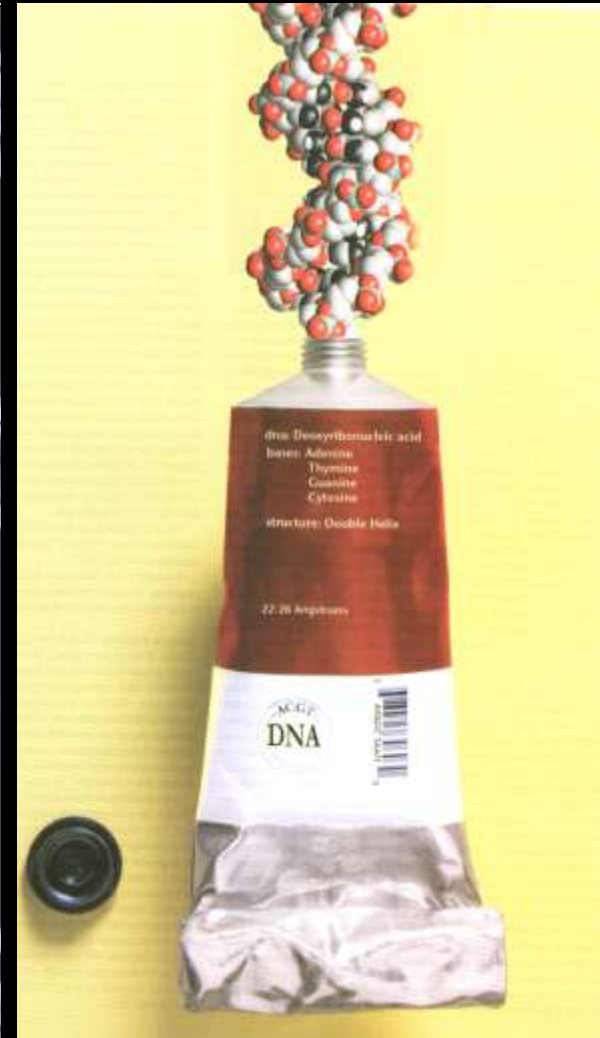
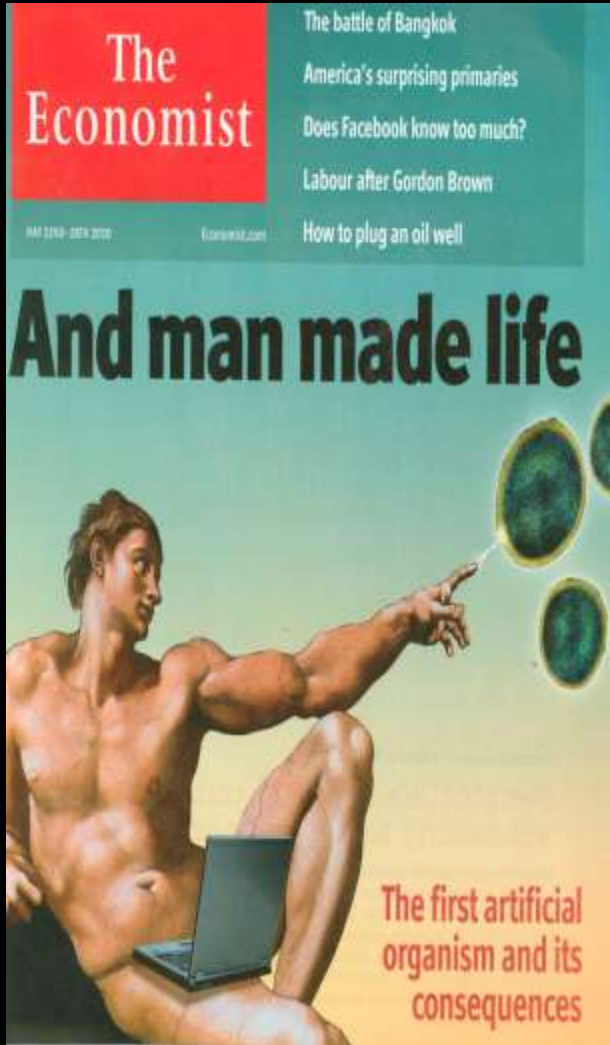
The Expanded Dimension of the 'Bio' Challenge



- **thinking beyond 'bio' as just infectious agents (bugs)**
- **systems biology**
 - **targeted disruption of ANY body function**
 - **novel C and B threats**
- **synthetic biology**
 - **exploring biospace: designing new life forms**
 - **designer organisms to attack materials/infrastructure**

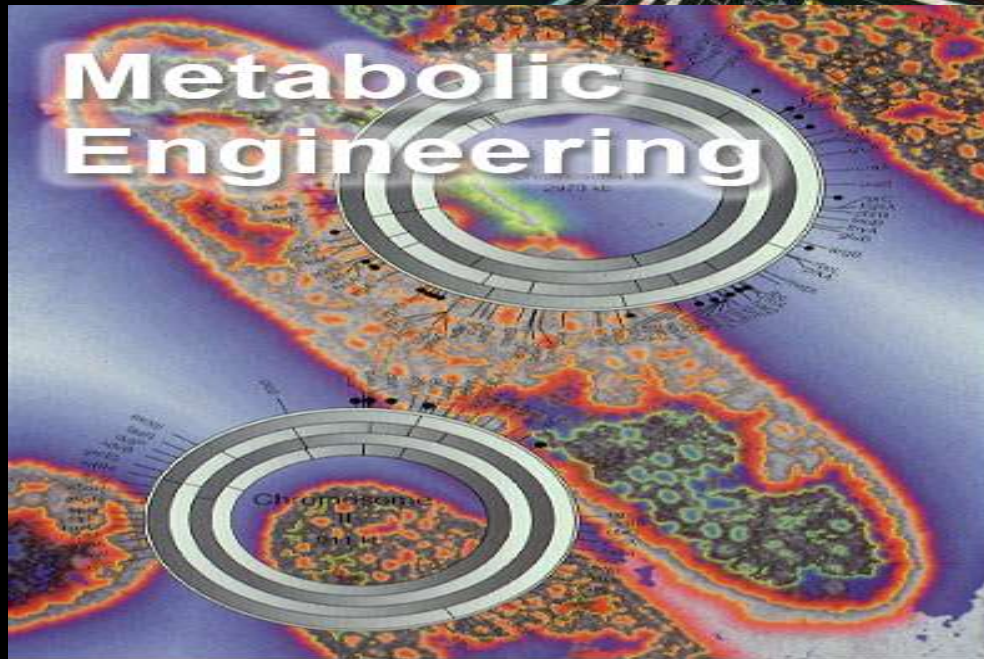


Synthetic Biology



Synthetic Biology: Engineering Novel Organisms with Novel Functions

**Programmable
Genomes**



**A New Industrial
Ecology and Novel
Biosynthesis**

GLOBALIZATION, BIOSECURITY, AND THE FUTURE OF THE LIFE SCIENCES



New approaches to biological risk assessment



Science
Policy Centre
INTERNATIONAL
WORKSHOP
web: royalsociety.org/policy

Twenty five | 350 years of
and beyond | excellence in science

Strategic Plan for Outreach and Education On Dual Use Research Issues



Report of the National Science Advisory Board for Biosecurity (NSABB)

December 10, 2008

RESPONSIBLE RESEARCH

WITH BIOLOGICAL SELECT
AGENTS AND TOXINS



NATIONAL RESEARCH COUNCIL
OF THE ROYAL SOCIETY

Synthetic biology

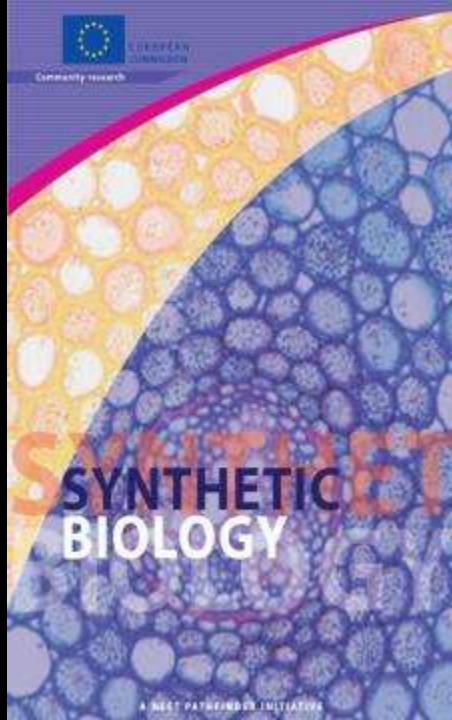
1 and 2 June 2008



scientific
DISCUSSION MEETING
SUMMARY

web: royalsociety.org

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and beyond | excellence in science



SYNTHETIC BIOLOGY

A BEST PRACTICES INITIATIVE

postnote

July 2008 Number 340

THE DUAL-USE DILEMMA



Department of Health and Human Services

SCREENING FRAMEWORK GUIDANCE FOR PROVIDERS OF SYNTHETIC DOUBLE-STRANDED DNA



Oversight of Synthetic Biology: Risk, Regulation and Responsibility

**Biosafety:
Risk from Legitimate
R&D/Industrialization**



**Biosecurity:
Deliberate Use
to Cause Harm**



**Biohackers and
Democratization
of New Technology**



**Screening of Purchases/
Supply Transactions**

**Regulation, Legislation
and
Codes of Conduct**

**International
Harmonization**

Dual-Use Research of Concern (DURC)

Nature (2012) 482, 153

COMMENT

INFLUENZA Further explanation of the NSABB recommendations p.158



PERMITS Limitation and social learning in apes p.150

HISTORY John Dee's weaving of scientific magic in the Elizabethan court p.160

CANINE WILDLIFE Trade in whale 'quotas' may be insufficient protection p.162



Pathogenic H5N1 avian influenza has led to the culling of hundreds of millions of birds. A human-transmissible form could have much worse consequences.

Adaptations of avian flu virus are a cause for concern

Members of the US National Science Advisory Board for Biosecurity explain its recommendations on the communication of experimental work on H5N1 influenza.

Prepared by the American Association for the Advancement of Science in conjunction with the Association of American Universities, Association of Public and Land-grant Universities, and the Federal Bureau of Investigation

Bridging Science and Security for Biological Research: A Discussion about Dual Use Review and Oversight at Research Institutions

Report of a Meeting September 13-14, 2012



AAAS
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ASSOCIATION OF PUBLIC AND LAND-GRANT UNIVERSITIES

Dual-Use Research of Concern (DURC)



the WHITE HOUSE PRESIDENT BARACK OBAMA

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Proposed Policy Targets Dual Use Research of Concern

Posted by Franca Jones on February 21, 2013 at 09:25 AM EST

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Public Health Emergency



Science Safety Security
Finding the Balance Together



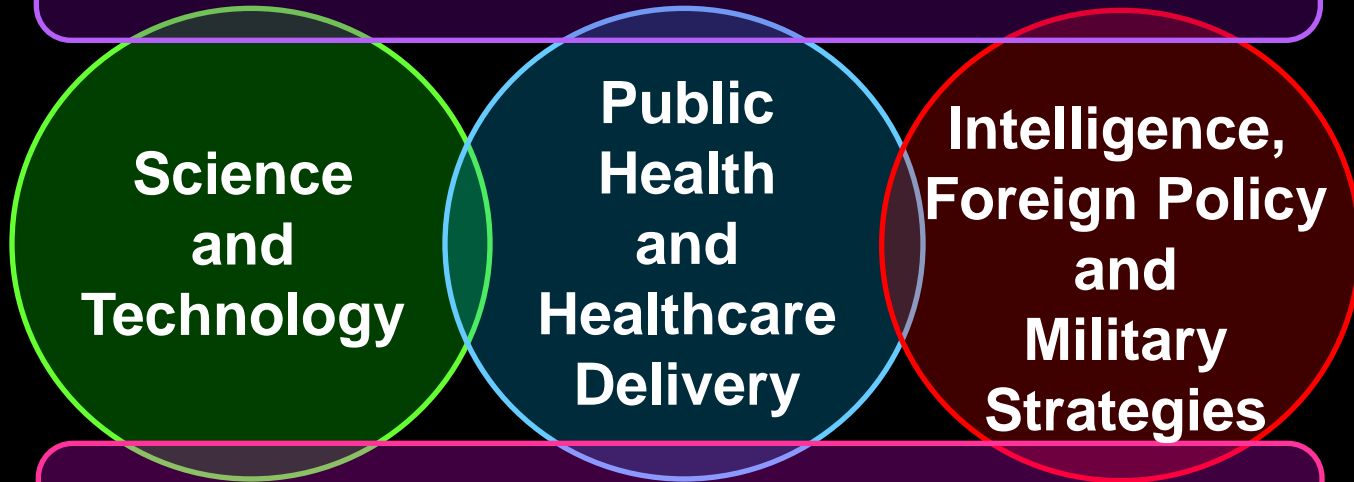
Department of Health & Human Services
USA

Framework for Guiding Funding Decisions about Research Proposals with the Potential for Generating Highly Pathogenic Avian Influenza H5N1 Viruses that are Transmissible among Mammals by Respiratory Droplets

Posted February 21, 2013

Biosecurity: A Classic Complex Systems Challenge

- global perspectives
- biological, economic, financial ecosystems

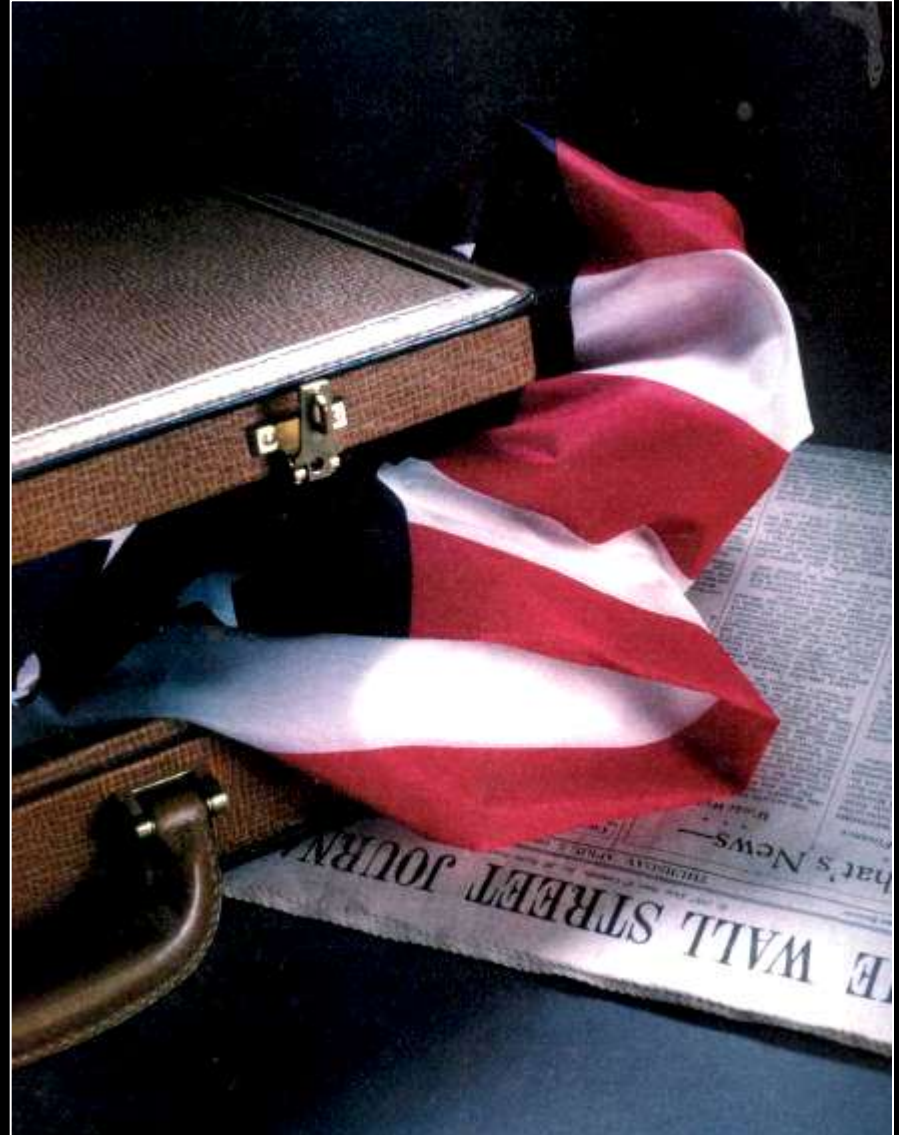


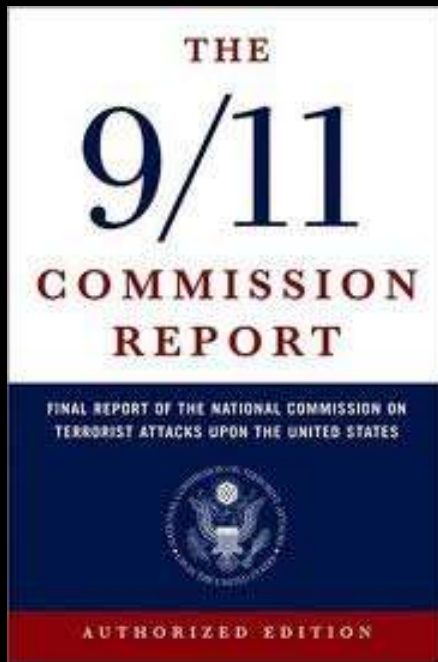
- societal priorities and cost of biosecurity
- political ideologies, intents and capabilities

Who Pays for Preparedness?



The Obligate Role of Private-Public Partnerships in Biosecurity Policy





“We believe the 9/11 attacks revealed four kinds of failures; in imagination, policy, capabilities and management.”

9/11 Commission Report 2004

Biosecurity: A Growing Void in USG Policy, Planning and Preparedness

multi-dimensional challenges demand cogent, holistic solutions

**current US capabilities are dangerously fragmented
and under-resourced**

**we are not alone: governmental neglect of biosecurity is an
omnipresent and growing global vulnerability**



The retreat from complexity: timidity trumps boldness

Is US boldness in driving advanced technologies at risk?

The Curse of Contemporary Governance: 'Quick Fixes' and the Retreat from Complexity

- **public complacency and political populism as major policy barriers**
- **unidimensional, short term policies to address multidimensional complexity with long term consequences**
- **public policy defined increasingly by length of legislative terms**
- **did not meet the street's expectations: the tyranny of quarterly earnings on industry boldness to invest in long-term R&D**
- **influence of media in shaping public policy and operational constraints**
- **the retreat from complexity**

The Retreat from Complexity



**BIG IDEAS
GO
UNEXPLORED
AND
UNFUNDED**

**TIMIDITY AND PRESERVATION
OF STATUS QUO
TRUMP BOLDNESS AND
DISRUPTIVE INNOVATION**

The Need for Greater Urgency and Adoption of Systems-Based Approaches to Biosecurity

- **current USG institutions and R&D vehicles are ill-suited to address current and projected challenges**
- **‘rapid’ and ‘translation’ are countercultural to much of the academic and USG communities**
- **the cosmetic salve of seeming to ‘do something’ is meaningless absent of results**
- **extravagant resources are/will be wasted until a forceful integrated, cross-agency ‘systemic’ approach is adopted**
- **the engagement of corporate and international agencies is a critical success factor in addressing global biosecurity challenges**

Building Robust CB Defenses

- **major vulnerabilities exist across the full spectrum of biodefense**
 - **pre-emptive detection and interdiction**
 - **early warning detection of biothreat agent release**
 - **rapid diagnosis**
 - **healthcare resources for mass casualty management**
 - **drug and vaccine coverage (quantitative and qualitative)**
 - **large scale decontamination**
 - **outdated public health laws**
 - **emergency control of media/commerce**

Addressing Global Challenges in Biosecurity

- **mobilize new expertise networks to achieve end-to-end solutions**
- **funding and assembly of requisite expertise**
 - **cross-disciplinary, cross-sector**
 - **obligate role of industrial partners**
- **sophisticated management of complex network whose composition will change constantly with new threats and new technologies**
- **financial incentives for industry for investment of market failure**
 - **antimicrobials and vaccines (public health, DDW)**
 - **biodefense medical countermeasures with no civilian markets**

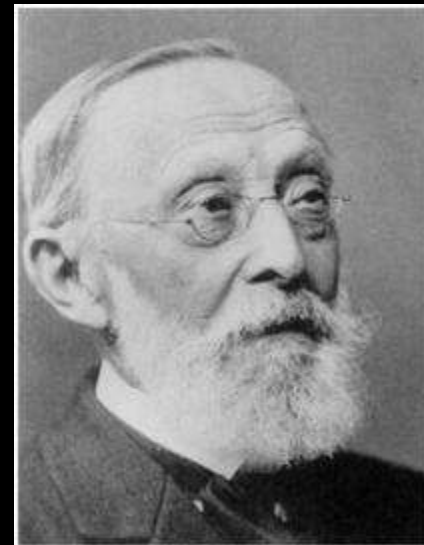
**“Politics is the art of the possible,
the calculated science of survival”**

Prince Otto von Bismarck



**“Survival owes little to the art of politics,
but everything to the calculated application
of science”.**

**Professor Rudolph Virchow
(in reply)**



Slides available @ <http://casi.asu.edu/>

