ASU COMPLEX ADAPTIVE SYSTEMS INITIATIVE
ARIZONA STATE UNIVERSITY

Biosecurity:
Enhancing Security in an Unsecure World

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Presentation to Biochem 20/20
Tempe, Arizona • 24 February 2010

"Every age has its own kind of war,
its own limiting conditions
and its own peculiar preconceptions."

Claus von Clausewitz

- security policy is determined by the threats and their deployment
- there is no single security policy that serves all needs equally well

Terrorism and The New Calculus of National Security and Foreign Affairs

Asymmetric Warfare: Terrorism and Insurgency

- radical shift in the size/capability/cost of adversarial power
- power of individuals/small groups to cause catastrophic havoc
- ‘trojan horse everything’
- ‘miniaturize, disperse and merge everything’

- low cost offense
- high cost defense

  \+

  persistent major vulnerabilities
- new strategies for new threats

- strategic primacy of

  methods for identification (ID), tagging, tracking and locating (TTL)
  - people
  - materials
  - activities

- ubiquitous embedded sensor networks
- everything is a potential sensor
- smart IT systems for proactive threat detection and interdiction

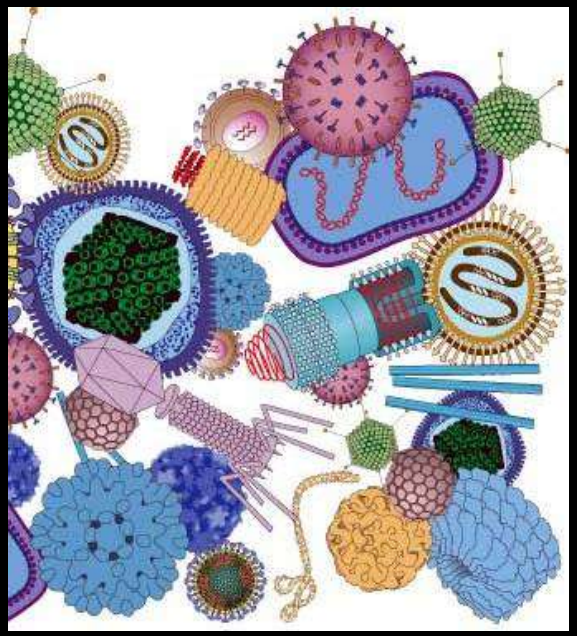
Key Questions

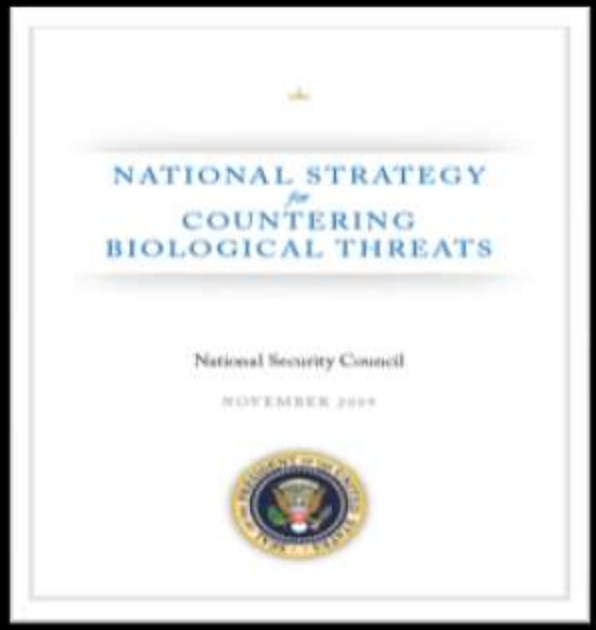
- are we maintaining our capabilities to detect, pre-empt and defeat a diversified threat spectrum?
  - peer, near-peer, non-state actors
  - conventional and unconventional threats
  - attacks on CONUS
- are we evolving fast enough to combat new adversarial strategies and tactics?
  - divide our forces between combat abroad and homeland operations
  - disrupt military deployment and supply
  - exploit deficits in USG inter-agency communication/coordination
  - skillfully use media to limit USG options

Fundamental Questions

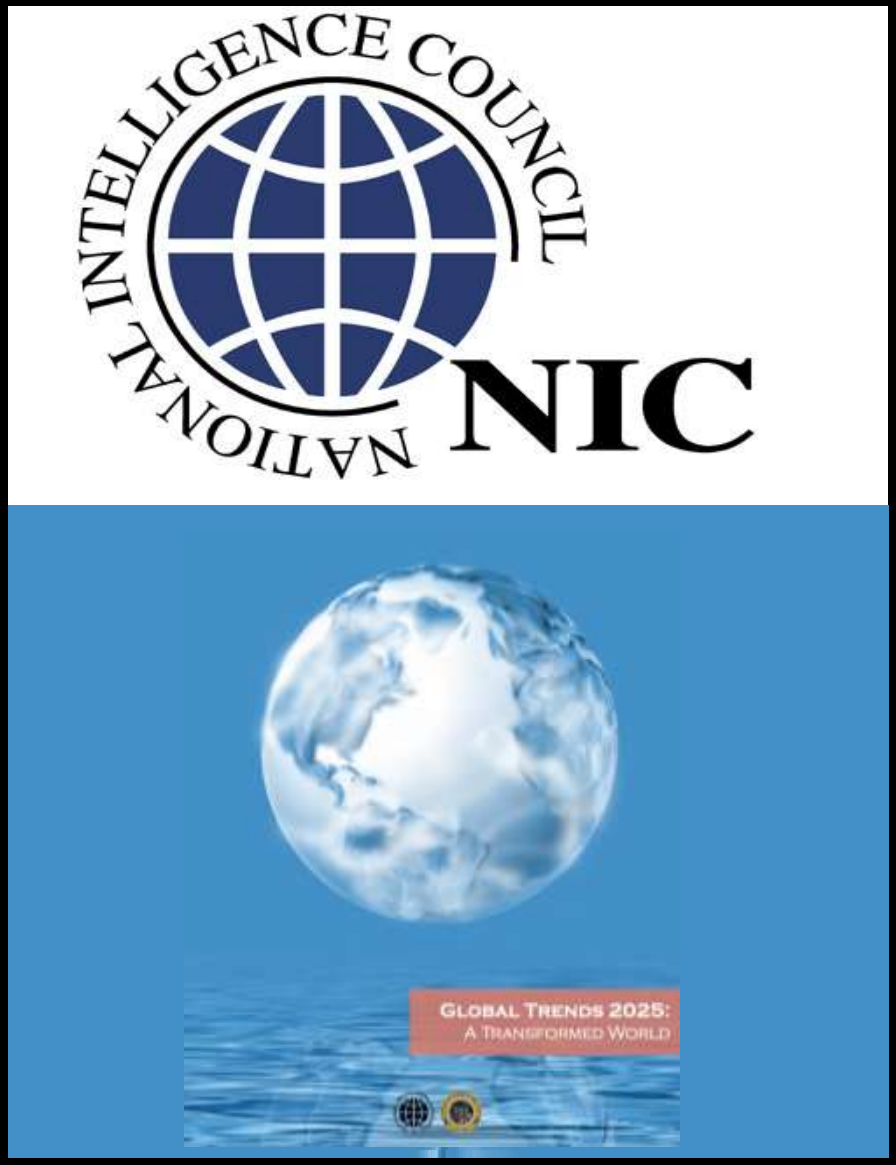
- can we define explicitly how secure we are?
- do we understand the strategic/doctrinal implications of:
  - technology convergence?
  - evolution of new peer/near-peer adversaries?
  - the ‘bandwidth’ of potential technological surprise(s)?
  - our myopia/blind spots?
- how would dramatic shortening of the cycle time from laboratory to military use of disruptive new technology alter the strategic balance?
- are we leveraging S&T as a vital (stealth) element of US foreign policy?

“Security is always excessive …..until it’s not enough”





Framing Future Security Issues
Demands a Broadened Conceptualization of National Security

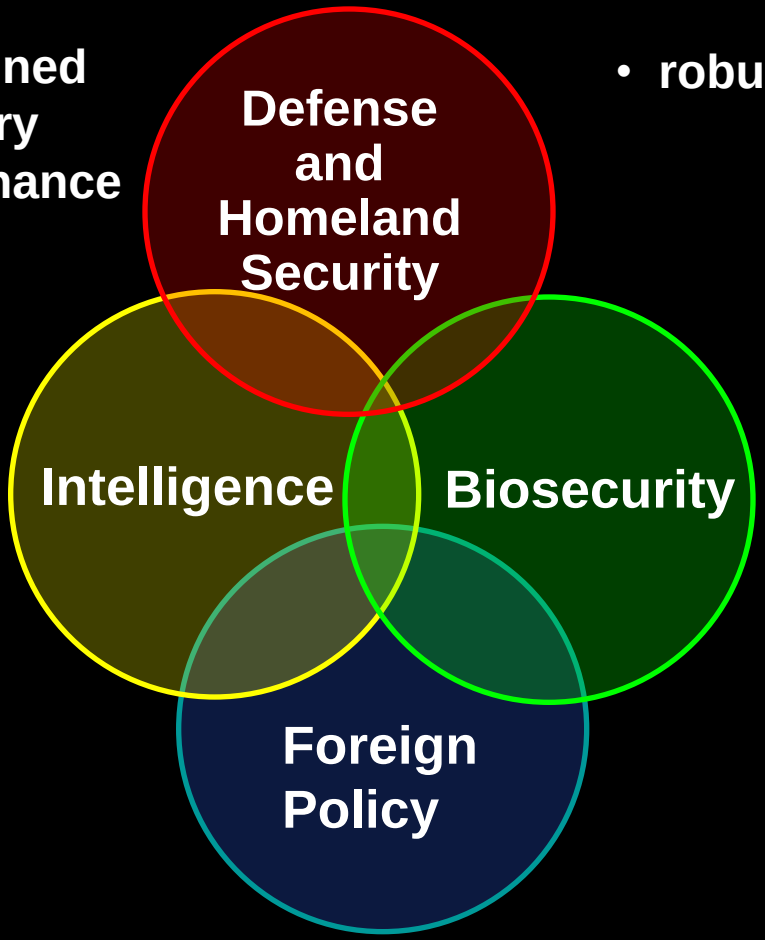


- population, food and water
- infectious/parasitic diseases
- urbanization and resources footprint
- energy
- climate and environmental sustainability
- depletion of non-renewable resources
- global trade and finance

The Multidimensional Roles of Science and Technology in National Security

- sustained military dominance

- robust homeland defense



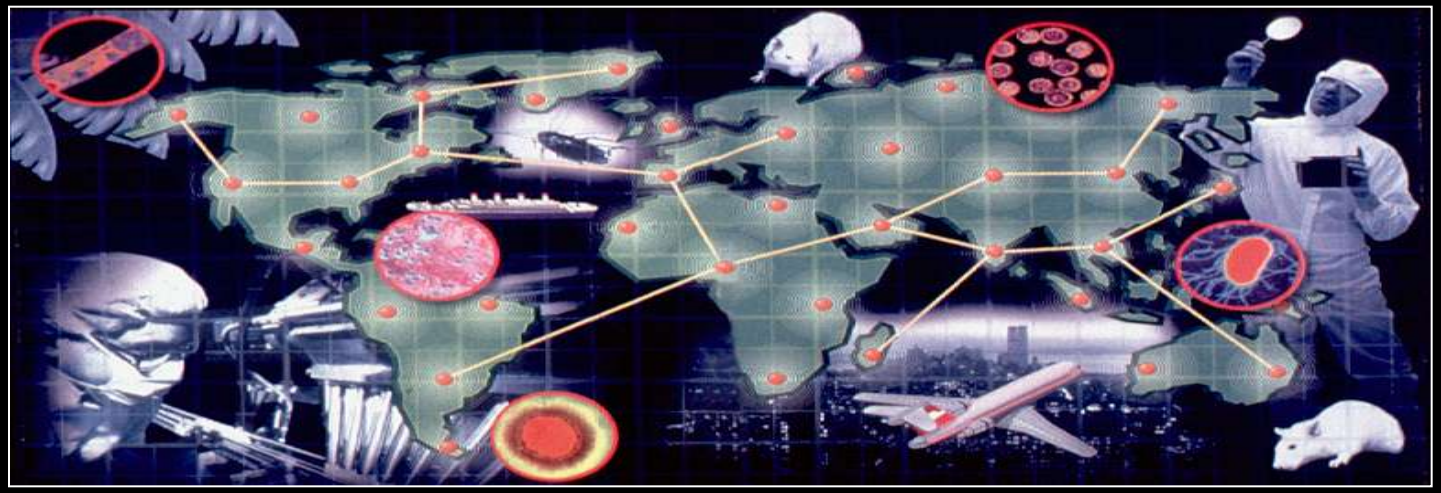
- new capabilities for threat ID and pre-emption

- managing 'the global commons'

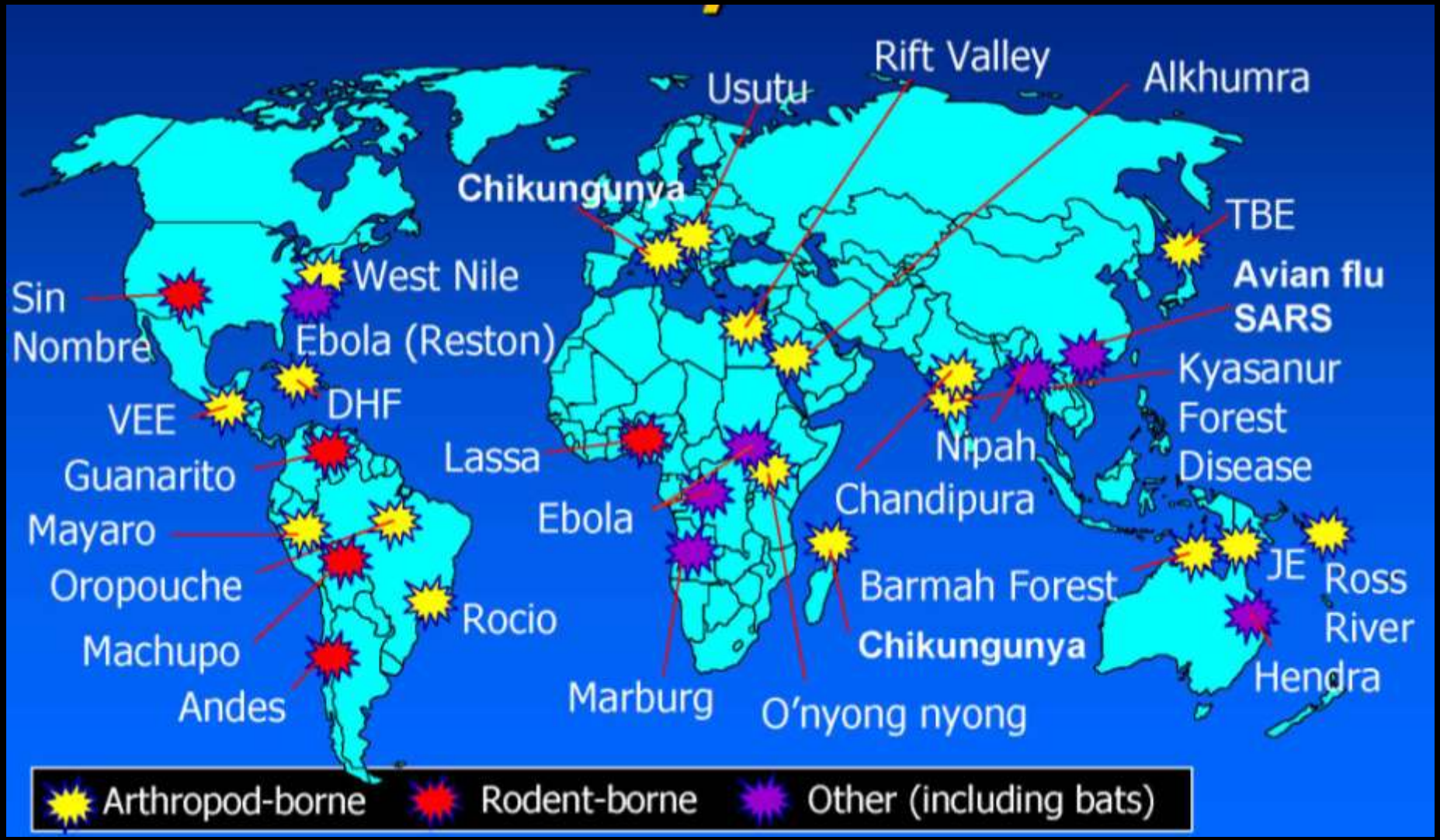
- science and technology as key (but neglected) elements of foreign affairs

A Shared Global Risk:

The Omnipresent Threat Posed By Microorganisms and Parasites



Emerging Infections:



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

High Disease Transmission

Lack of Safe Water

Toxic Waste

Major Deficits in Health Infrastructure

Expanded Eco-niches and Increased Zoonotic Risks

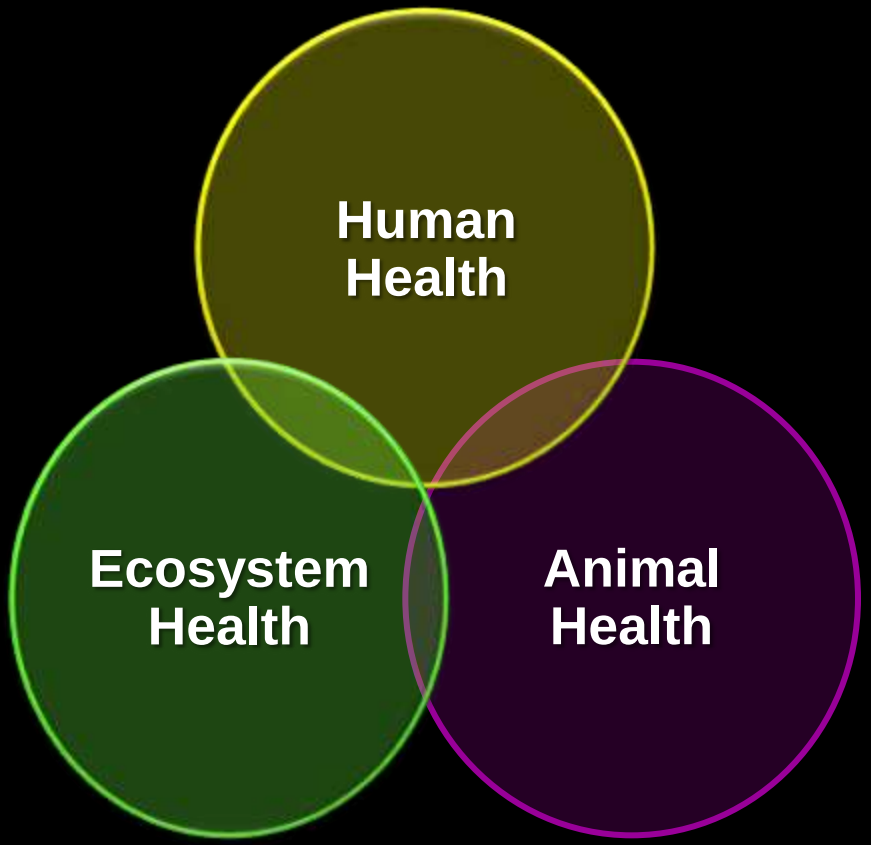
The Evolving Nature of Human Infectious and Parasitic Diseases

Mark Woolhouse Univ. Edinburgh
- **Trends Ecol. Evol. (2005) 20, 238**
- **Emerg. Infec. Dis. (2005) 11, 1842**

1407 species of human pathogens

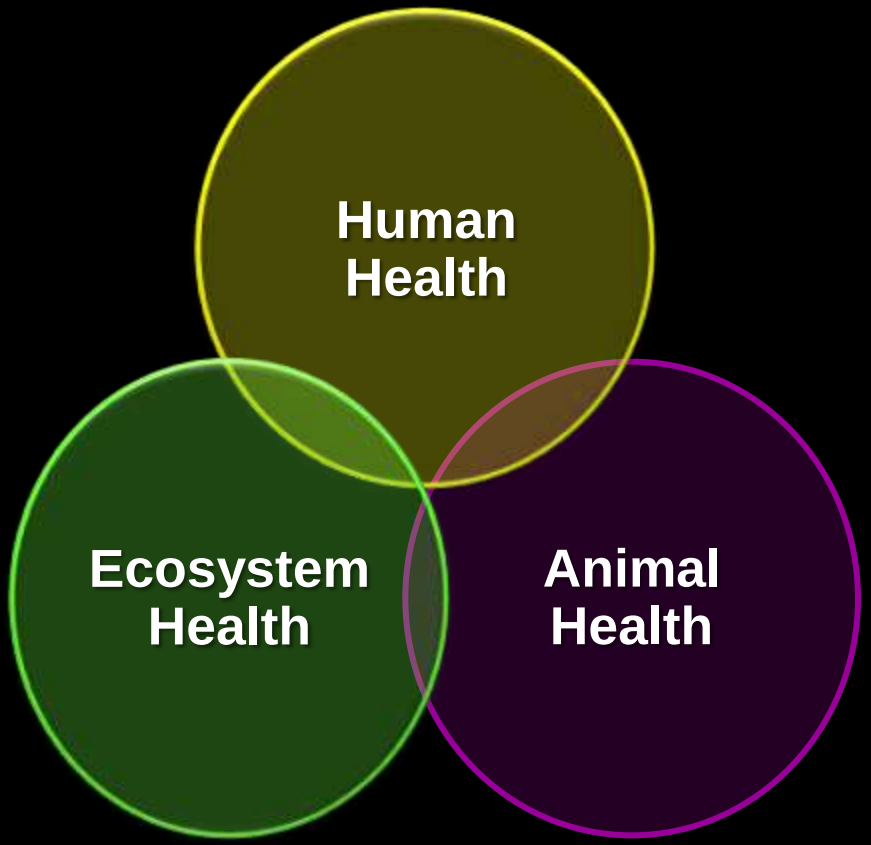
- 538 bacteria ● 208 viruses ● 317 fungi
- 57 protozoa ● 287 helminths
- 60% are zoonoses
- over 70% zoonoses arise from interactions with wildlife
- 90% IUCN listed wild mammals threatened by disease share these diseases with domestic species
- EIDs
  - 39 in last 25 years (now 46)
  - viruses are significantly over-represented
  - helminths are under-represented

"One Health": The Rationale for Integration of Historically Separate Domains and Responsibilities



- urbanization of DCs and emergence of new zoonotic threats
- food chain as increasing source of disease risks
- enhanced agricultural productivity to support global population growth
- economic impact of agricultural disease on trade, development and resources/production footprints

The Rationale for Integration of Historically Separate Domains and Responsibilities

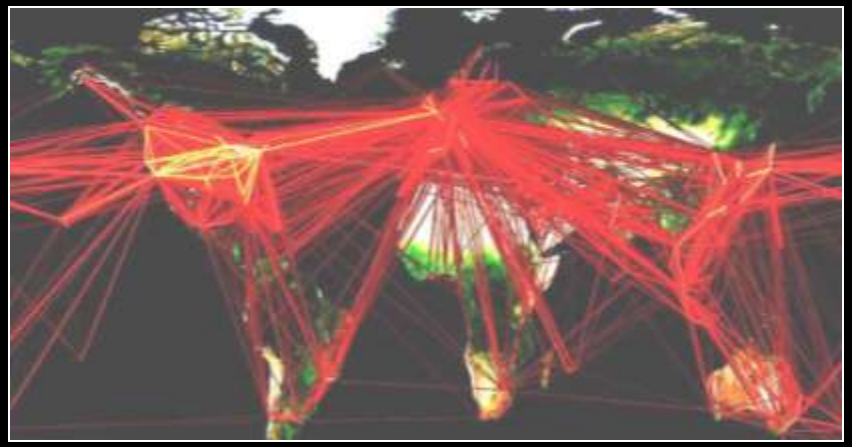


- most effective control route for zoonotic threats to humans is via the relevant animal population(s)
- knowledge of the potential impact of ecosystem perturbations on emergence of novel zoonoses must be accorded higher priority
- disparity in animal and human public health capacity undermines global disease control
- failure to optimize disease control in food production wastes limited resources and increases global food production footprint

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

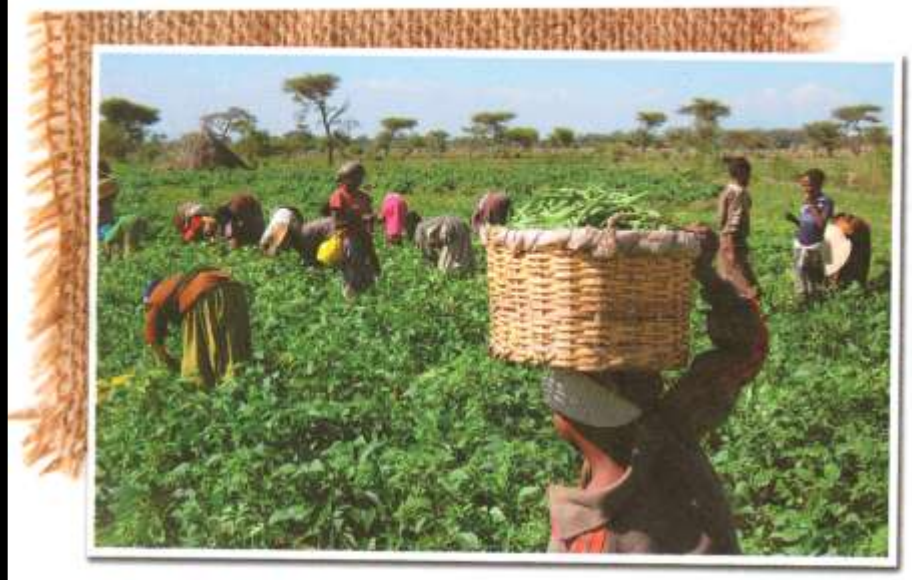
The Super Vector

Billion Cross-Border Travelers



World Container Traffic Doubled Since 1997

Global Food Networks



INTRODUCTION

Feeding the Future

FEEDING THE 9 BILLION PEOPLE EXPECTED TO INHABIT OUR PLANET BY 2050 WILL BE an unprecedented challenge. This special issue examines the obstacles to achieving global food security and some promising solutions. News articles take us into the fields, introducing farmers and researchers who are finding ways to boost harvests, especially in the developing world. Reviews, Perspectives, and an audio interview done by a high school intern provide a broader context for the causes and effects of food insecurity and point to paths to ending hunger.

SPECIAL SECTION

Science (2010)
327, 797-836

Food Security

CONTENTS

News

The Global Food Supply and Food Borne Pathogens

- food chain increasingly complex, international and inter-dependent
- food production over next 25 years Ξ total for 10,000 years
- expanding middle class (1-2 billion) in NICs and some DCs and increased demand for grain and meat projected to increase by 160% by 2020
- famines, shortages and food riots in DCs
- least expensive sourcing also least safe
- the impact of climate change

Ensuring The Safety of Food Imports

- 15% US food imported from over 150 countries
- 300 ports over 200,000 registered importers
- China 3rd largest food exporter to the U.S.
- China is in the top five in imported Fish/Crustaceans (#2), Vegetables (#3), Meat/Fish Preps (#3), Cereal/Starch (#4) & Vegetable/Fruit Preps (#2)
- full extent of imports from China unknown due to ingredients & trans-shipments

EUROSURVEI L LANCE Vol . 14 · Issue 27 · 9 July 2009 ·www.eurosurveillance.org

Foresight Infectious Diseases China Project - A novel approach to anticipating future trends in risk of infectious diseases in China: methodology and results from an initial application

A Nicoll (Angus.Nicoll@ecdc.europa.eu)[1,2,3], J Huang[4], Z Xie[4], the Foresight China Project Group[5]

1. Health Protection Agency, London, United Kingdom
2. European Centre for Disease Prevention and Control, Stockholm, Sweden
3. London School of Hygiene and Tropical Medicine, London, United Kingdom
4. Chinese Academy of Medical Sciences, Peking Union Medical College, Beijing, China

Addressing The Biosecurity Challenge:

Key Principles

- global problems require global solutions
- complex multifunctional problems will not be solved by simple, unitary approaches
- the cosmetic salve of ‘doing something’ is meaningless if it achieves nothing
- extravagant resources have been/will be wasted unless linked to a pragmatic agenda
  - tractable, actionable, measurable
- dependence on corporate – and national – resources will fail unless the relevant corporate -, political – and military – decision makers are engaged

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

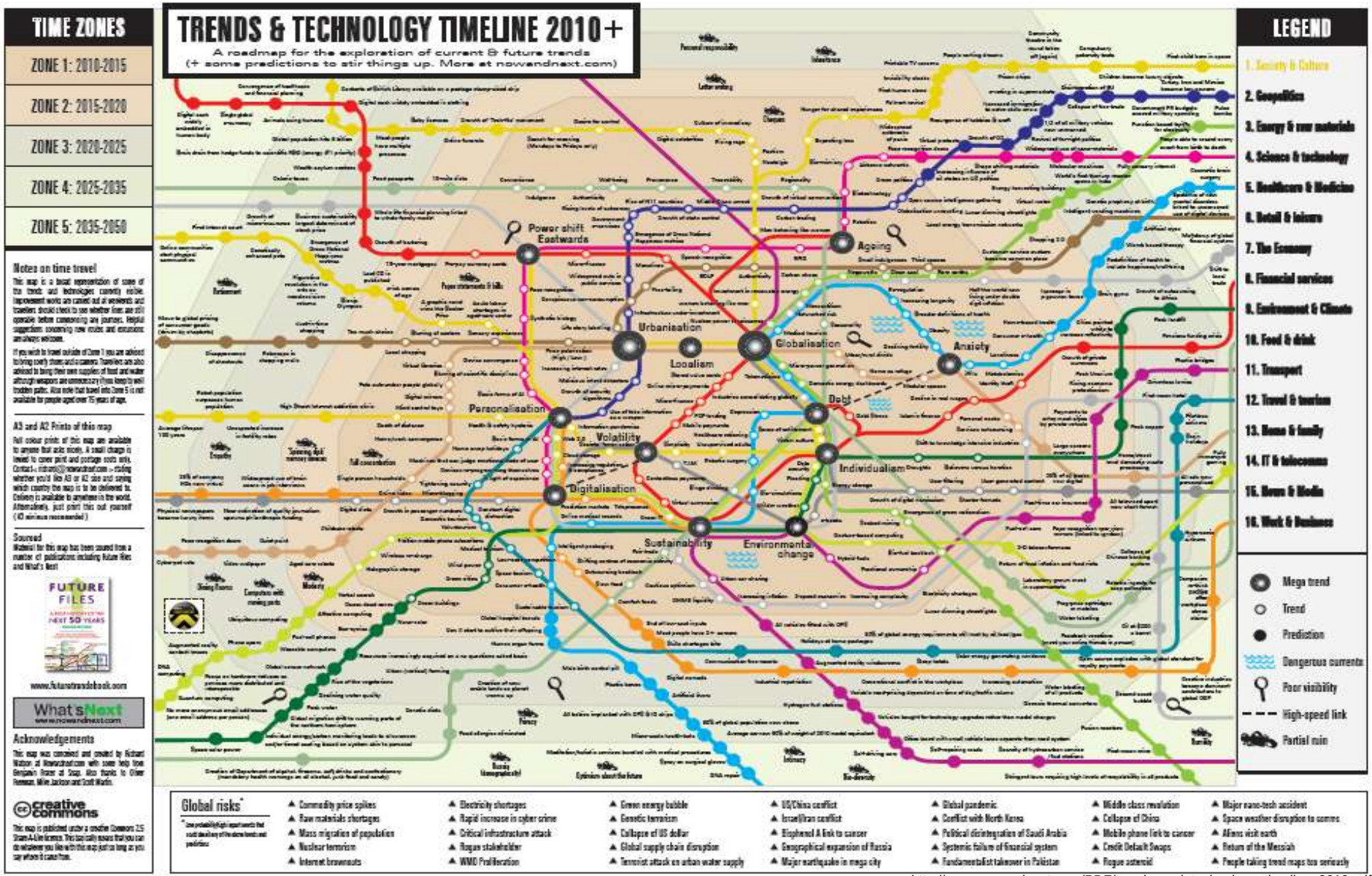
January 2010

"Each of the three last Administrations have been slow to recognize and respond to the biothreat"

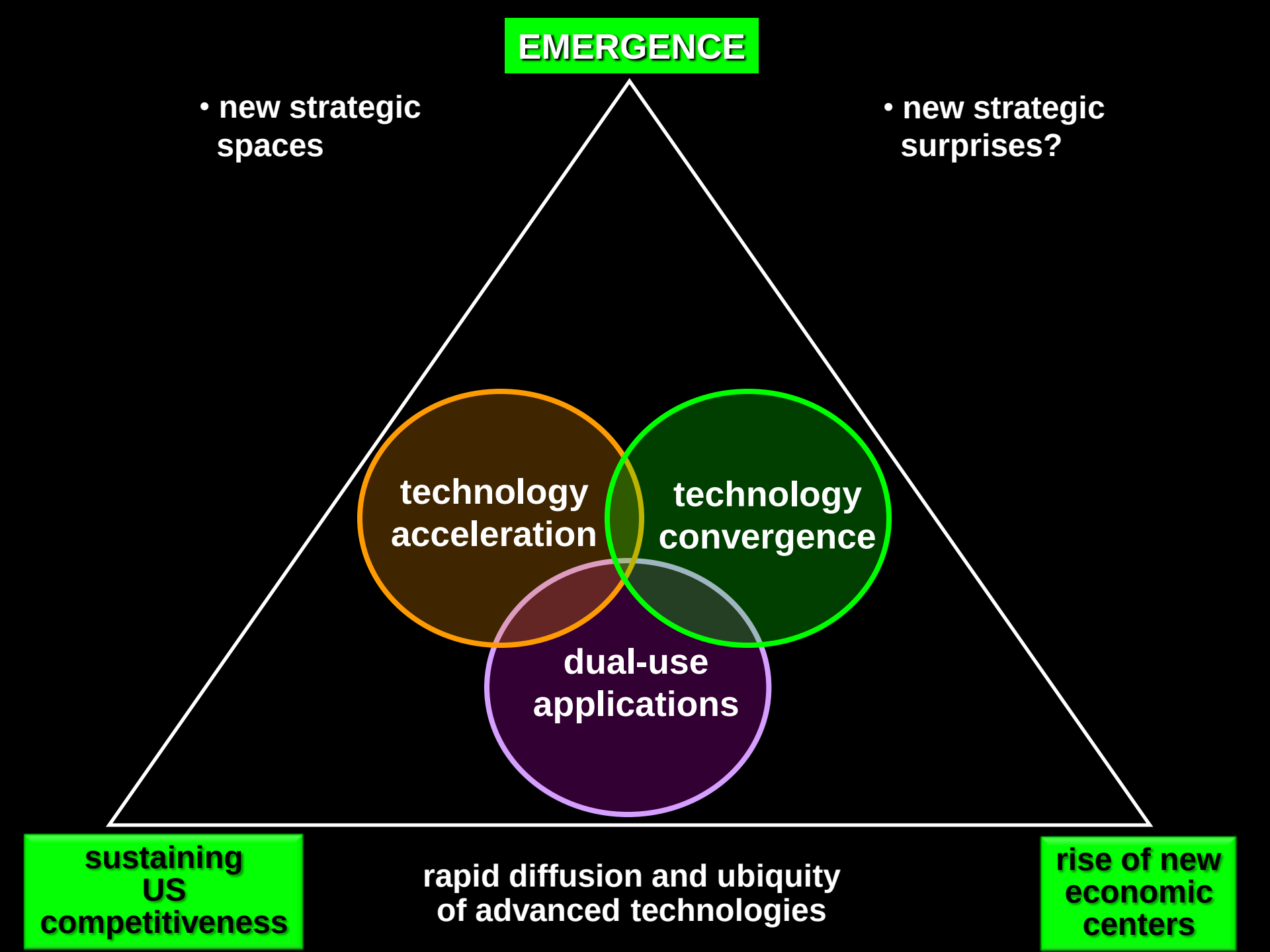
The Retreat from Complexity: The Insularity and Risk-Aversion of USG Analytical and Decision Frameworks

- ‘too hard’ problems
- denial, avoidance, paralysis
- sustained focus/funding on ‘the familiar’ and the ‘usual suspects’
- growing and dangerous deficits in USG expertise in next generation “disruptive technologies”

Technology Convergence and the Changing Calculus of Warfare and National Security



http://www.nowandnext.com/PDF/trends_and_technology_timeline_2010.pdf

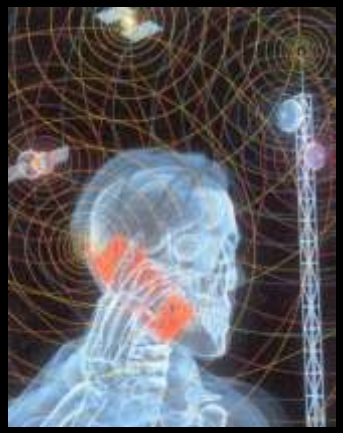

EMERGENCE
• new strategic spaces
• new strategic surprises?
technology acceleration
technology convergence
dual-use applications
sustaining US competitiveness
rapid diffusion and ubiquity of advanced technologies
rise of new economic centers

The New Strategic "Spaces" in Military Affairs and National Security

Systems and Synthetic Biology

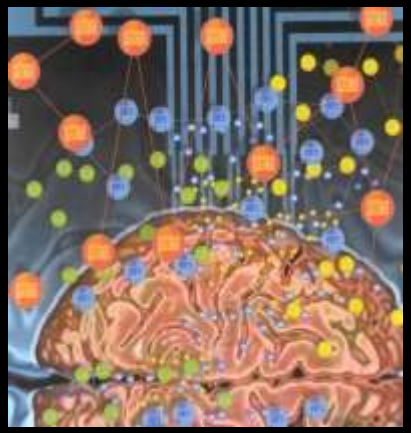
"Biospace"

Ubiquitous Sensing



"Connected Space"

Brain: Machine Interactions



"Smart Space"

Infocosm and the Metaverse

"Cyberspace"

Militarization of Space

"Outer Space"

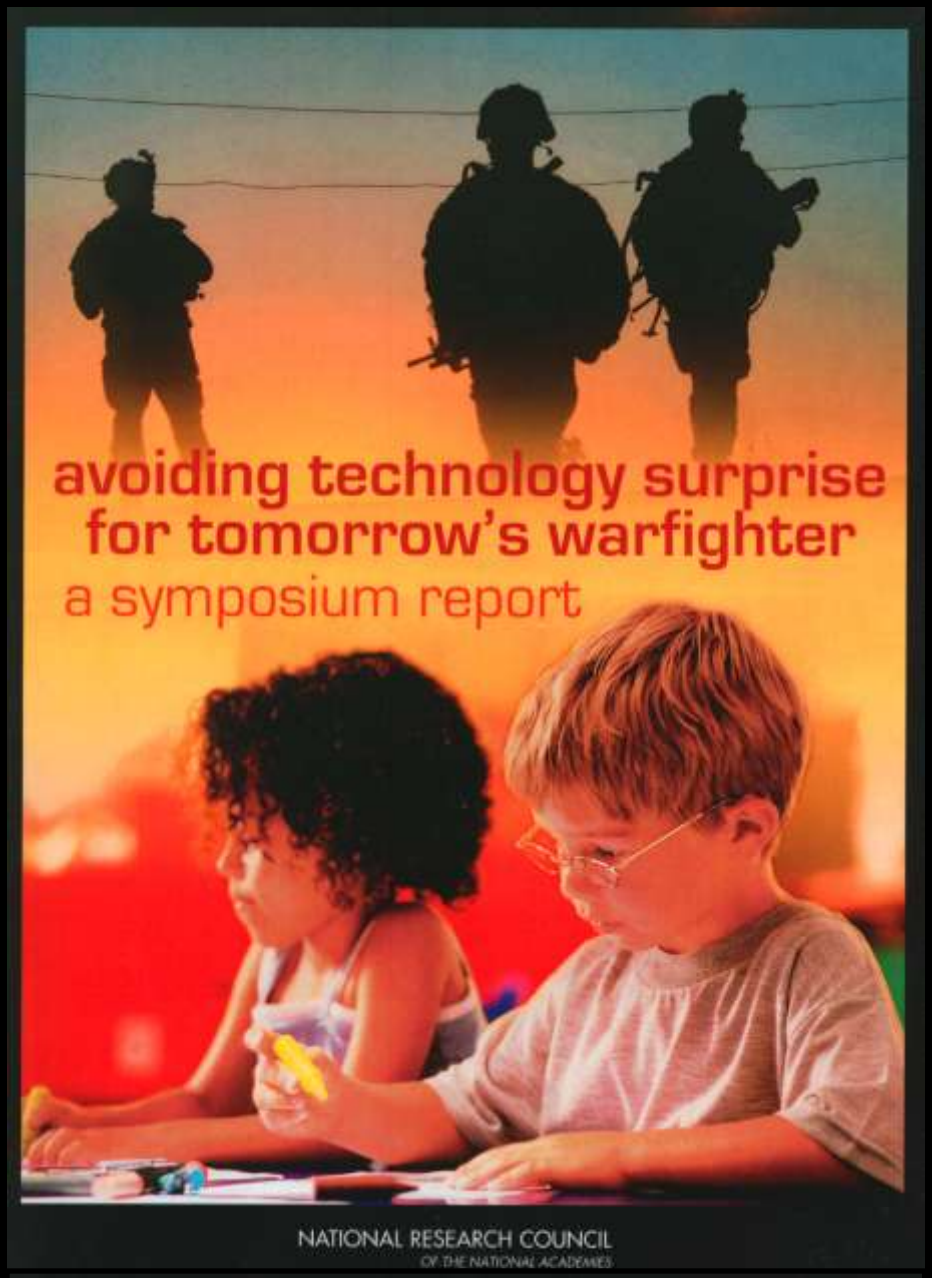
Constantly Emerging and Evolving Multi-Dimensional Matrices of Knowledge Ecologies

Global Challenges

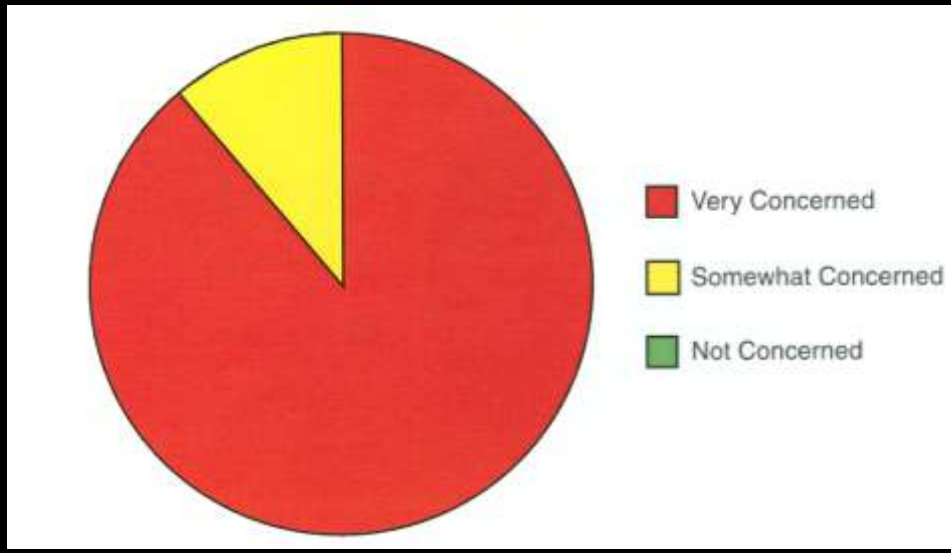
Systems of Innovation

Evaluation of New Technologies, Risks and Implications for National Security

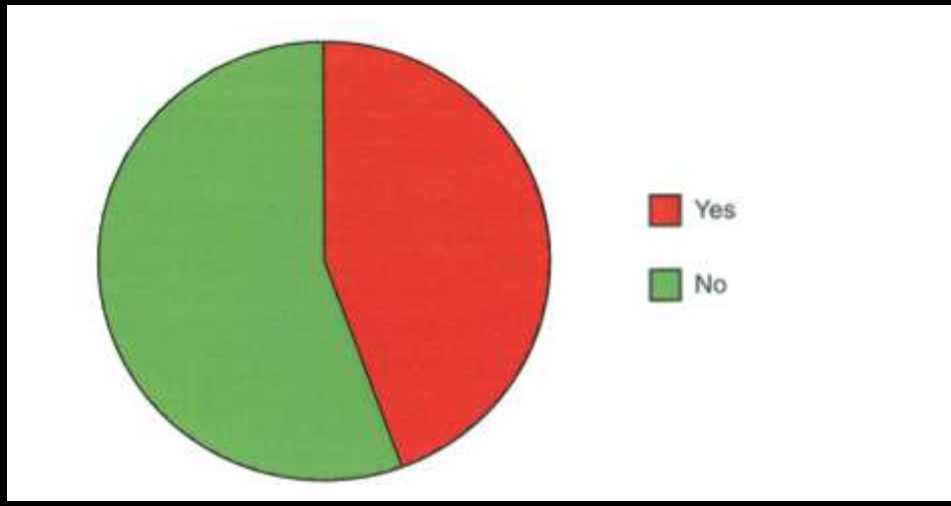
- the possible
- the probable
- the time to field
- the cost to field
- the options for defense
- the options for offense



NRC Symposium
29 April 2009

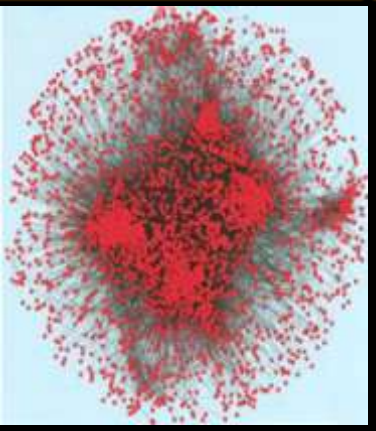
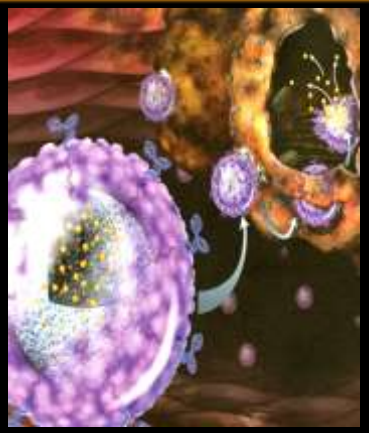


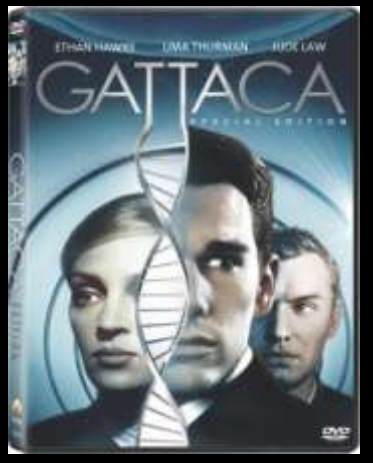
How concerned are you about the potential for technology surprise?

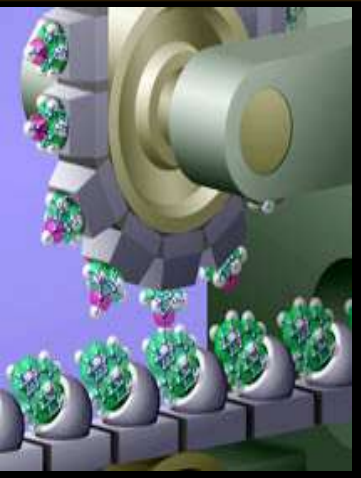
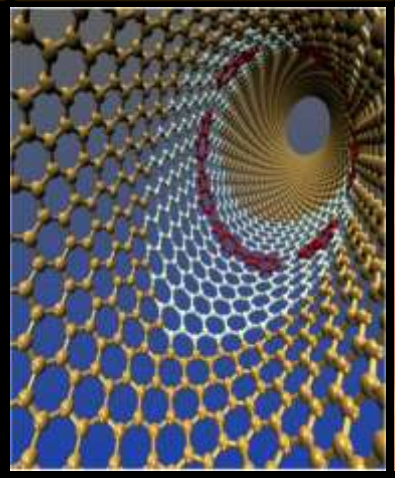


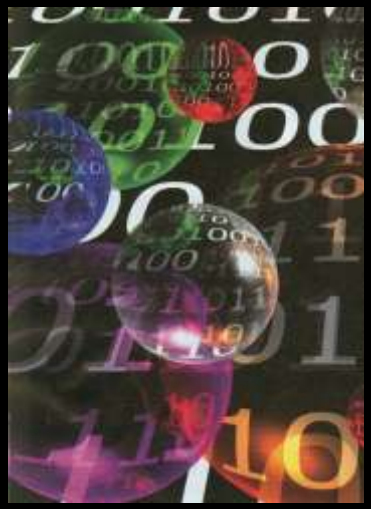
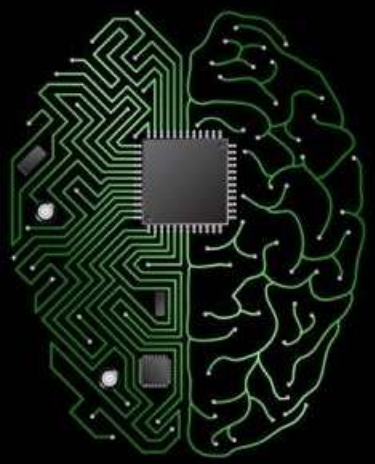
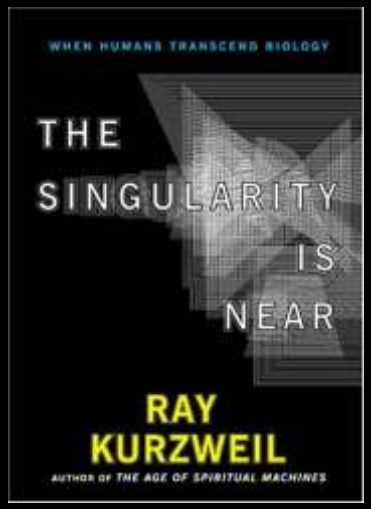
Have you ever experienced surprise?

Transcending Boundaries: Emergent Domains Arising from Technology Convergence

Systems Biology	Targeted Rx	Regenerative Medicine	HPO	Genetic Identity
				

Bio-Enhancement	Bionic-Enhancement	Cognitive Enhancement	Genetic Enhancement	Bio-Stratified Population
				

Molecular Foundries	Novel Materials	Micro-Devices	Ubiquitous Sensing	Robotics
				

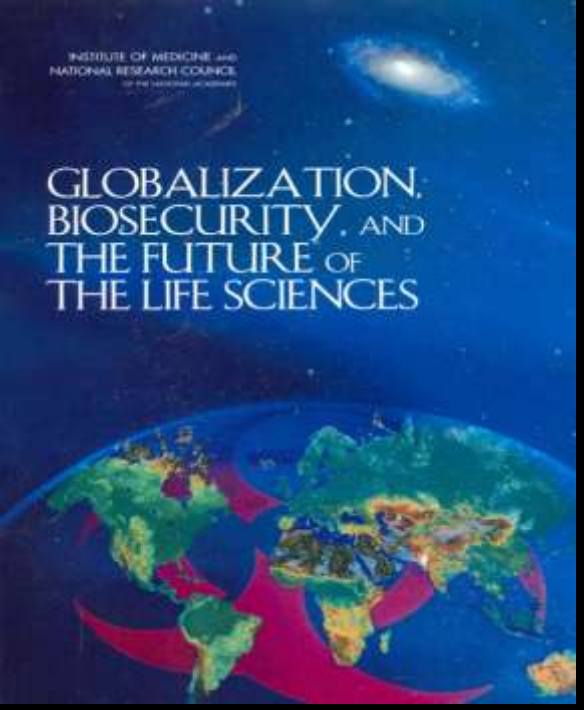
Ambient Intelligence	Digital Anthropology	Cogint	Intelligent Machines	Singularity
				

Massive Computing Power and Analytical Parsing

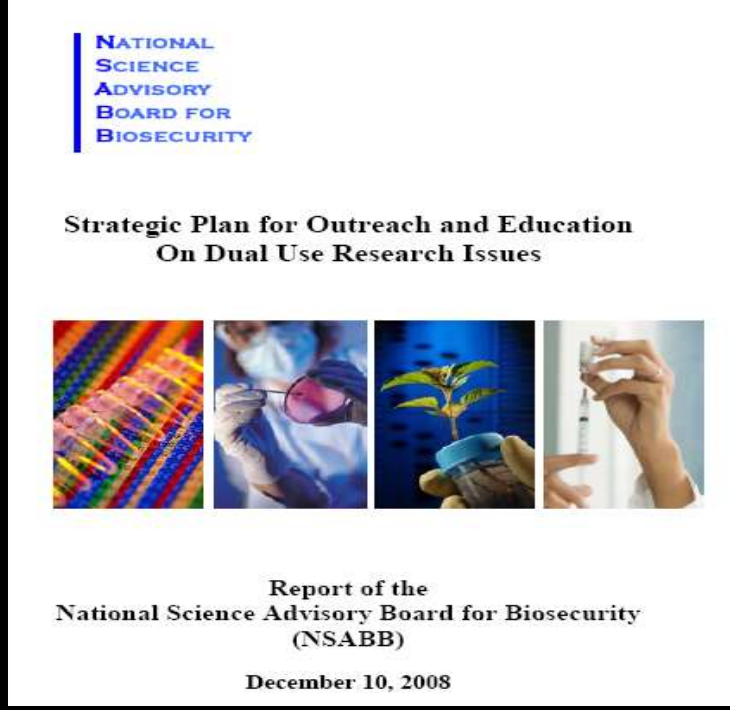
RESPONSIBLE RESEARCH

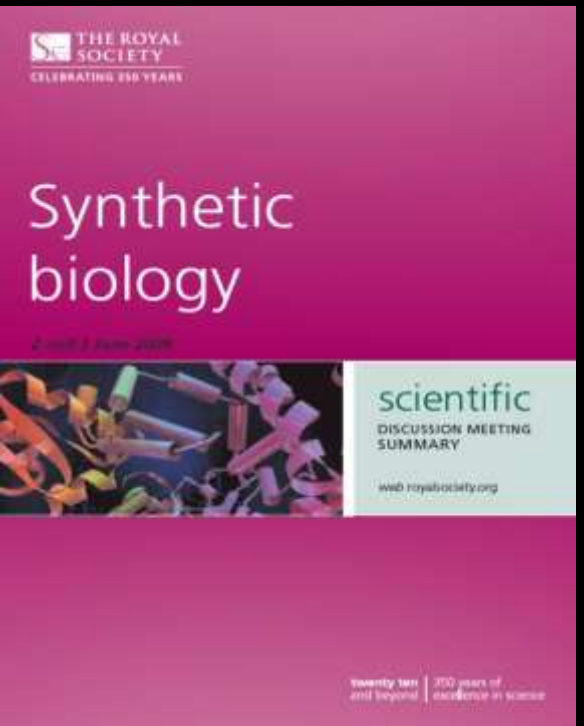
WITH BIOLOGICAL SELECT AGENTS AND TOXINS

NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES


INSTITUTE OF MEDICINE AND
NATIONAL RESEARCH COUNCIL
GLOBALIZATION, BIOSECURITY, AND THE FUTURE OF THE LIFE SCIENCES


THE ROYAL SOCIETY
CELEBRATING 350 YEARS
New approaches to biological risk assessment
Science Policy Centre
INTERNATIONAL WORKSHOP
web.royalsociety.org/policy
twenty ten and beyond | 350 years of excellence in science


NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY
Strategic Plan for Outreach and Education On Dual Use Research Issues
Report of the National Science Advisory Board for Biosecurity (NSABB)
December 10, 2008


THE ROYAL SOCIETY
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Synthetic biology
scientific
DISCUSSION MEETING SUMMARY
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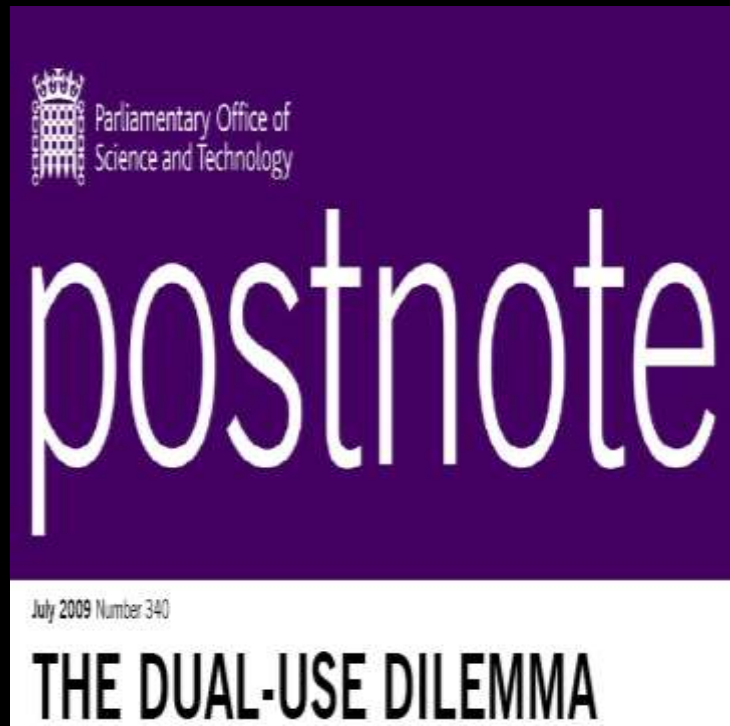
twenty ten and beyond | 350 years of excellence in science


Community research
SYNTHETIC BIOLOGY


Parliamentary Office of Science and Technology
postnote
July 2009 Number 340
THE DUAL-USE DILEMMA

Preparedness:
Building Resilient Systems

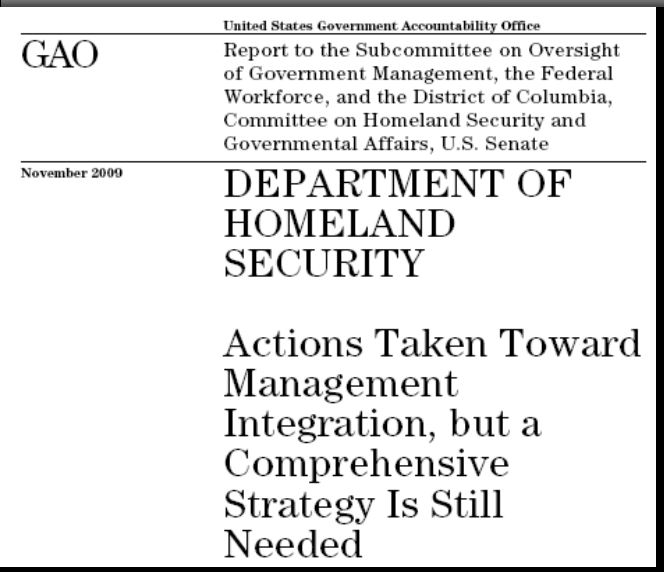
“For most of us design is invisible Until it fails”: Bruce Mau. Massive Change. 2004

Building Resilient Systems for Outpacing Infectious Diseases

- effective control demands an integrated, "systems-based" approach
  - global surveillance and rapid detection of EIDs
  - constant innovation in new medical countermeasures
  - coherent and sustained R&D incentives
  - transparent and reliable regulatory and reimbursement policies
  - sophisticated public health infrastructure and agile responsiveness
  - knowledgeable healthcare professionals
  - harmonization of global policies and political will

The Fragmented Silos of USG: A Dangerous Vulnerability

The Challenge to Integrate National Security Capabilities


United States Government Accountability Office

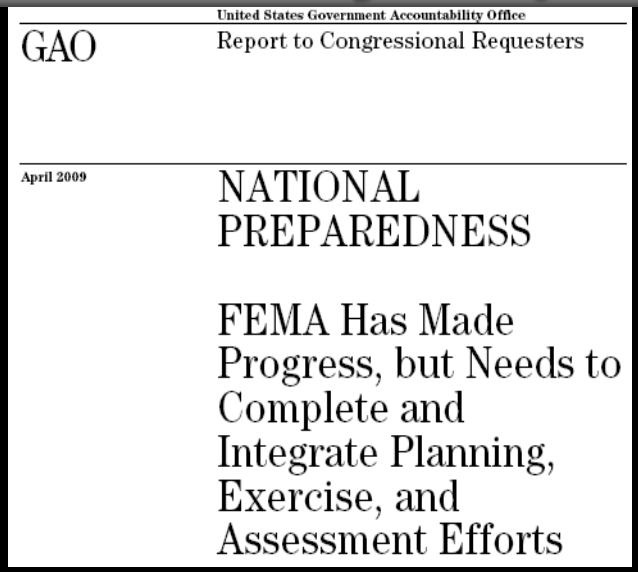
GAO

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

November 2009

DEPARTMENT OF HOMELAND SECURITY

Actions Taken Toward Management Integration, but a Comprehensive Strategy Is Still Needed


United States Government Accountability Office

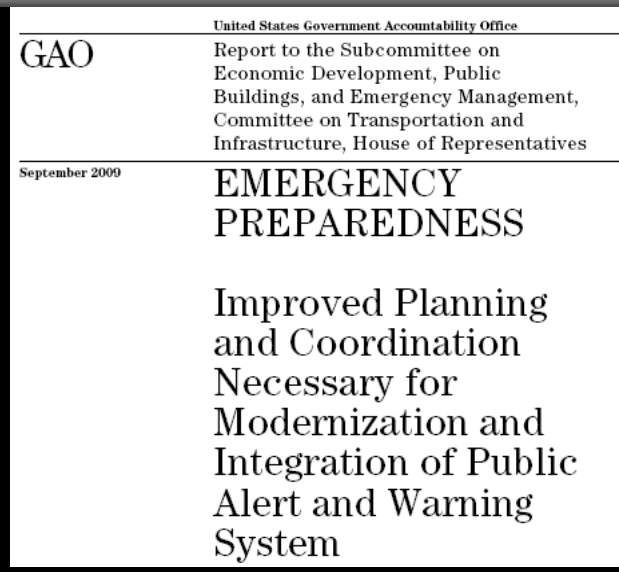
GAO

Report to Congressional Requesters

April 2009

NATIONAL PREPAREDNESS

FEMA Has Made Progress, but Needs to Complete and Integrate Planning, Exercise, and Assessment Efforts


United States Government Accountability Office

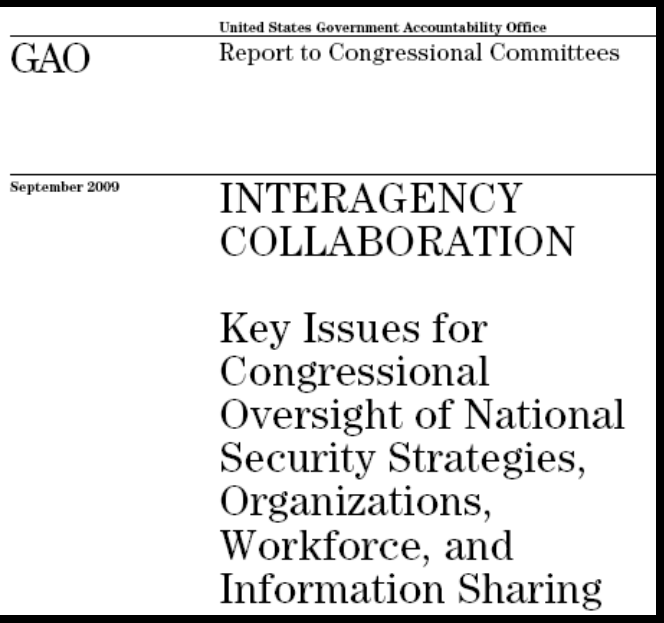
GAO

Report to the Subcommittee on Economic Development, Public Buildings, and Emergency Management, Committee on Transportation and Infrastructure, House of Representatives

September 2009

EMERGENCY PREPAREDNESS

Improved Planning and Coordination Necessary for Modernization and Integration of Public Alert and Warning System


United States Government Accountability Office

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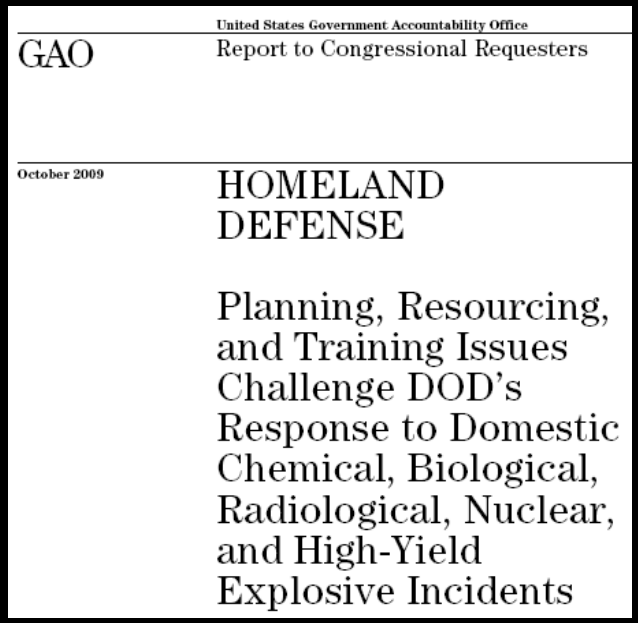
Report to Congressional Committees

September 2009

INTERAGENCY COLLABORATION

Key Issues for Congressional Oversight of National Security Strategies, Organizations, Workforce, and Information Sharing


United States Government Accountability Office

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Report to Congressional Requesters

October 2009

HOMELAND DEFENSE

Planning, Resourcing, and Training Issues Challenge DOD's Response to Domestic Chemical, Biological, Radiological, Nuclear, and High-Yield Explosive Incidents


United States Government Accountability Office

GAO

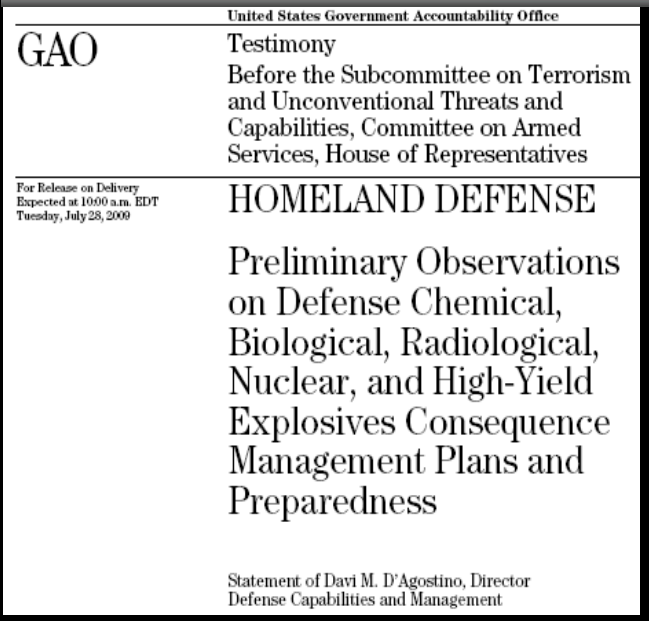
Report to Congressional Requesters

September 2009

HOMELAND DEFENSE

U.S. Northern Command Has a Strong Exercise Program, but Involvement of Interagency Partners and States Can Be Improved

Building Resilient Preparedness and Response Capabilities for Biosecurity


United States Government Accountability Office

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Testimony

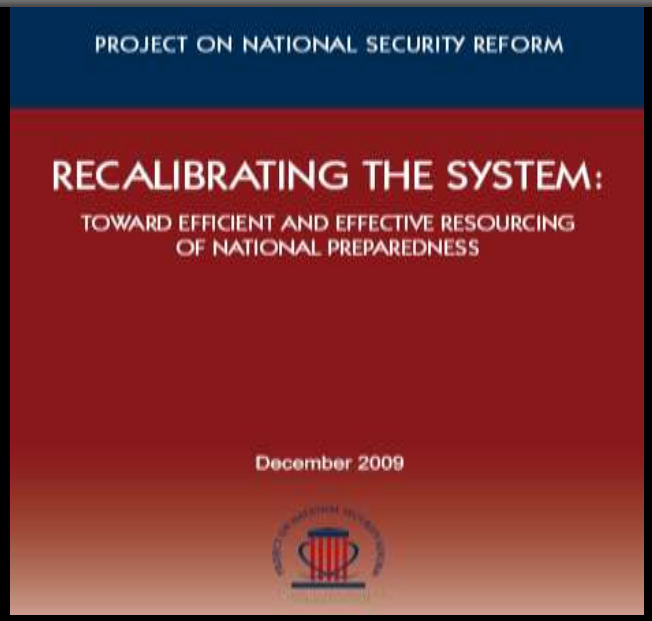
Before the Subcommittee on Terrorism and Unconventional Threats and Capabilities, Committee on Armed Services, House of Representatives

For Release on Delivery
Expected at 10:00 a.m. EDT
Tuesday, July 28, 2009

HOMELAND DEFENSE

Preliminary Observations on Defense Chemical, Biological, Radiological, Nuclear, and High-Yield Explosives Consequence Management Plans and Preparedness

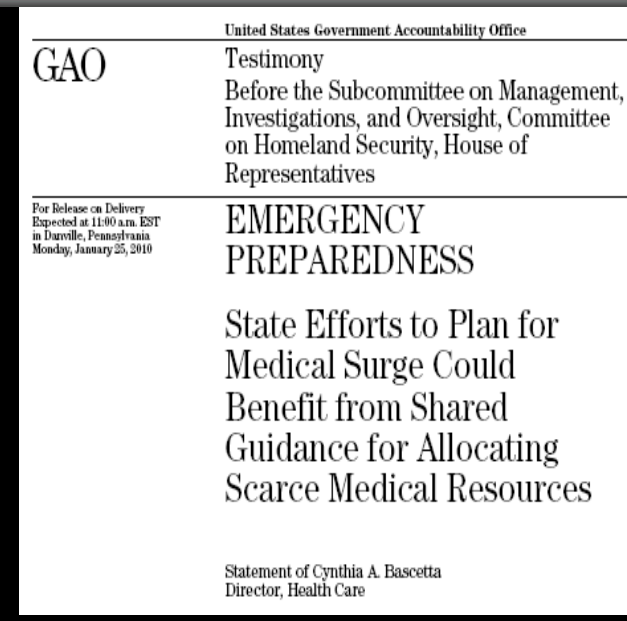
Statement of Davi M. D'Agostino, Director
Defense Capabilities and Management


PROJECT ON NATIONAL SECURITY REFORM

RECALIBRATING THE SYSTEM:

TOWARD EFFICIENT AND EFFECTIVE RESOURCING OF NATIONAL PREPAREDNESS

December 2009


United States Government Accountability Office

GAO

Testimony

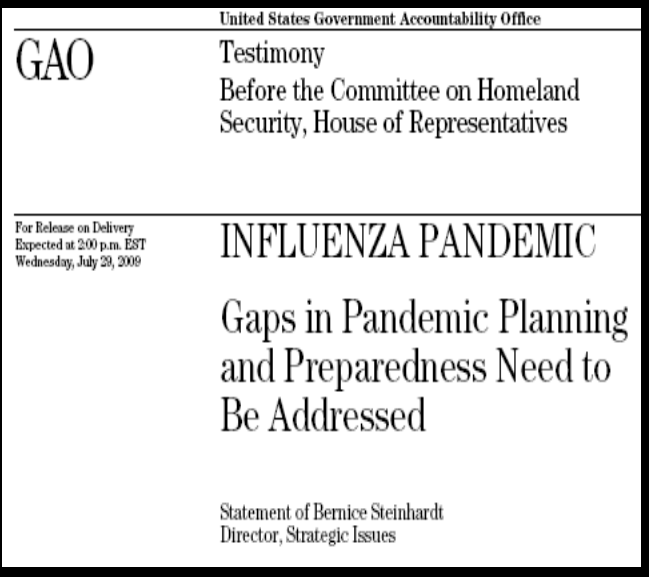
Before the Subcommittee on Management, Investigations, and Oversight, Committee on Homeland Security, House of Representatives

For Release on Delivery
Expected at 11:00 a.m. EST
in Danville, Pennsylvania
Monday, January 25, 2010

EMERGENCY PREPAREDNESS

State Efforts to Plan for Medical Surge Could Benefit from Shared Guidance for Allocating Scarce Medical Resources

Statement of Cynthia A. Bascetta
Director, Health Care


United States Government Accountability Office

GAO

Testimony

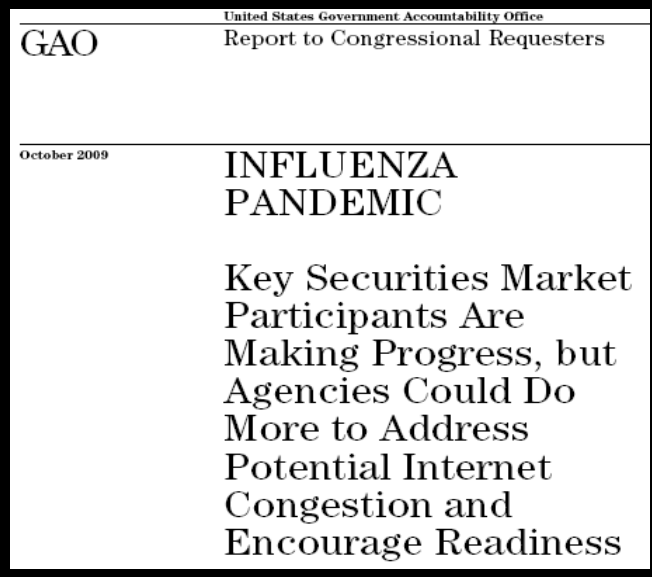
Before the Committee on Homeland Security, House of Representatives

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

INFLUENZA PANDEMIC

Gaps in Pandemic Planning and Preparedness Need to Be Addressed

Statement of Bernice Steinhardt
Director, Strategic Issues


United States Government Accountability Office

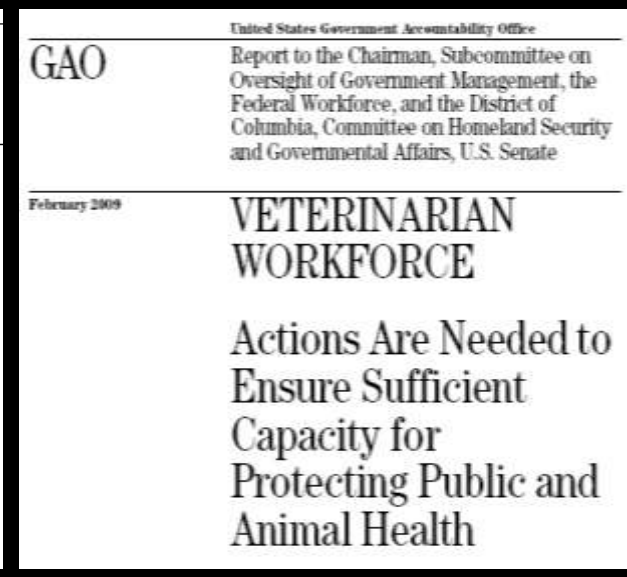
GAO

Report to Congressional Requesters

October 2009

INFLUENZA PANDEMIC

Key Securities Market Participants Are Making Progress, but Agencies Could Do More to Address Potential Internet Congestion and Encourage Readiness


United States Government Accountability Office

GAO

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

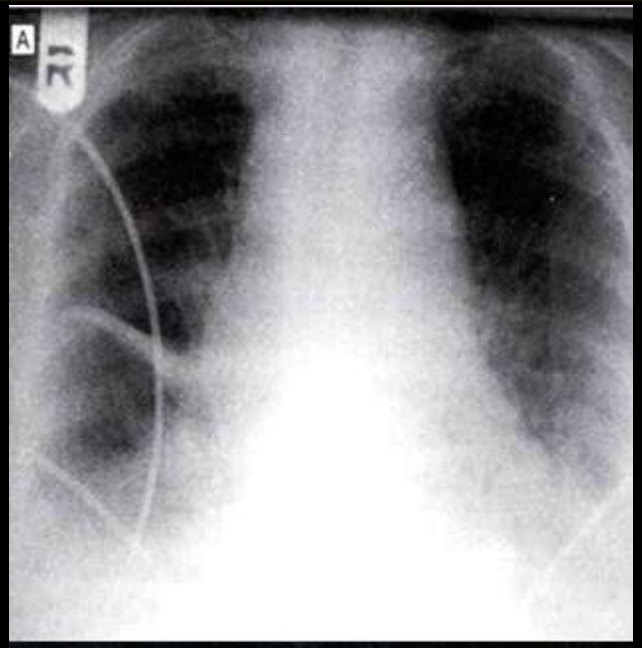
February 2009

VETERINARIAN WORKFORCE

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

Education and Training

Diagnostic Accuracy

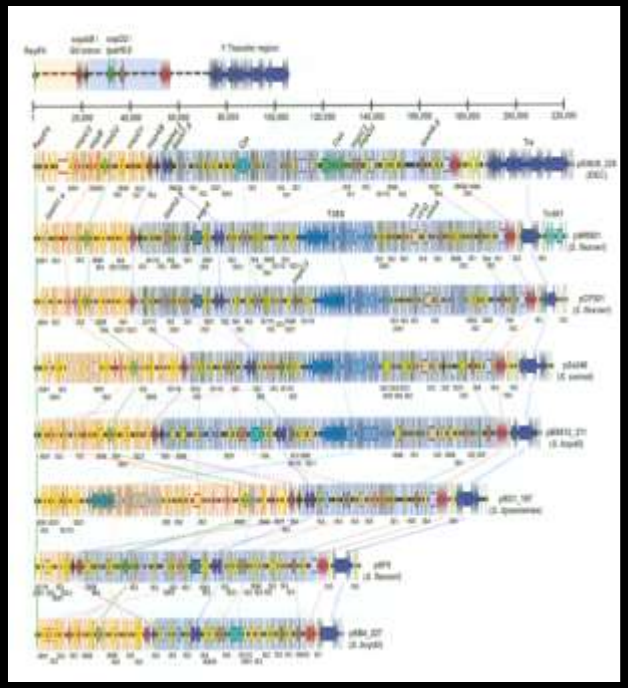


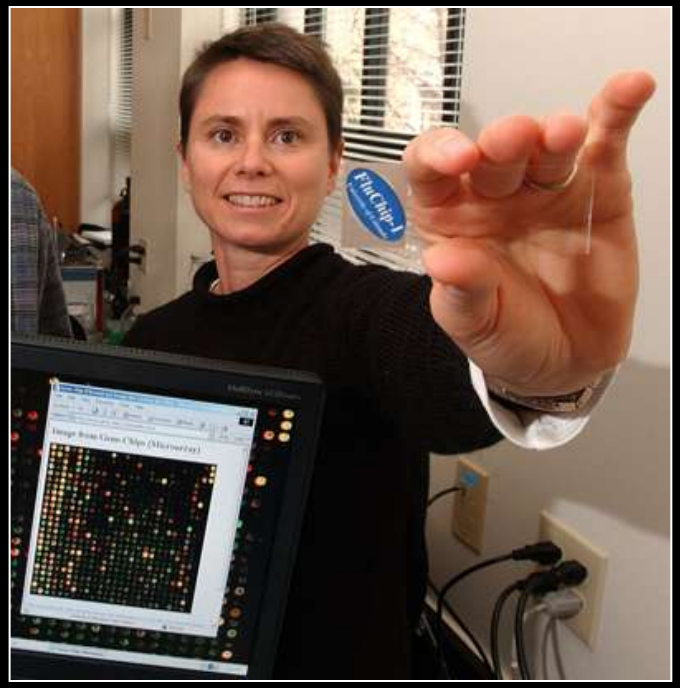
Infection Control

Availability of Therapy

Overload and Triage

Improved Diagnostic Tests for Infectious Diseases





Earlier Diagnosis and Intervention Saves Lives

Improved speed, breadth and accuracy of clinical diagnosis

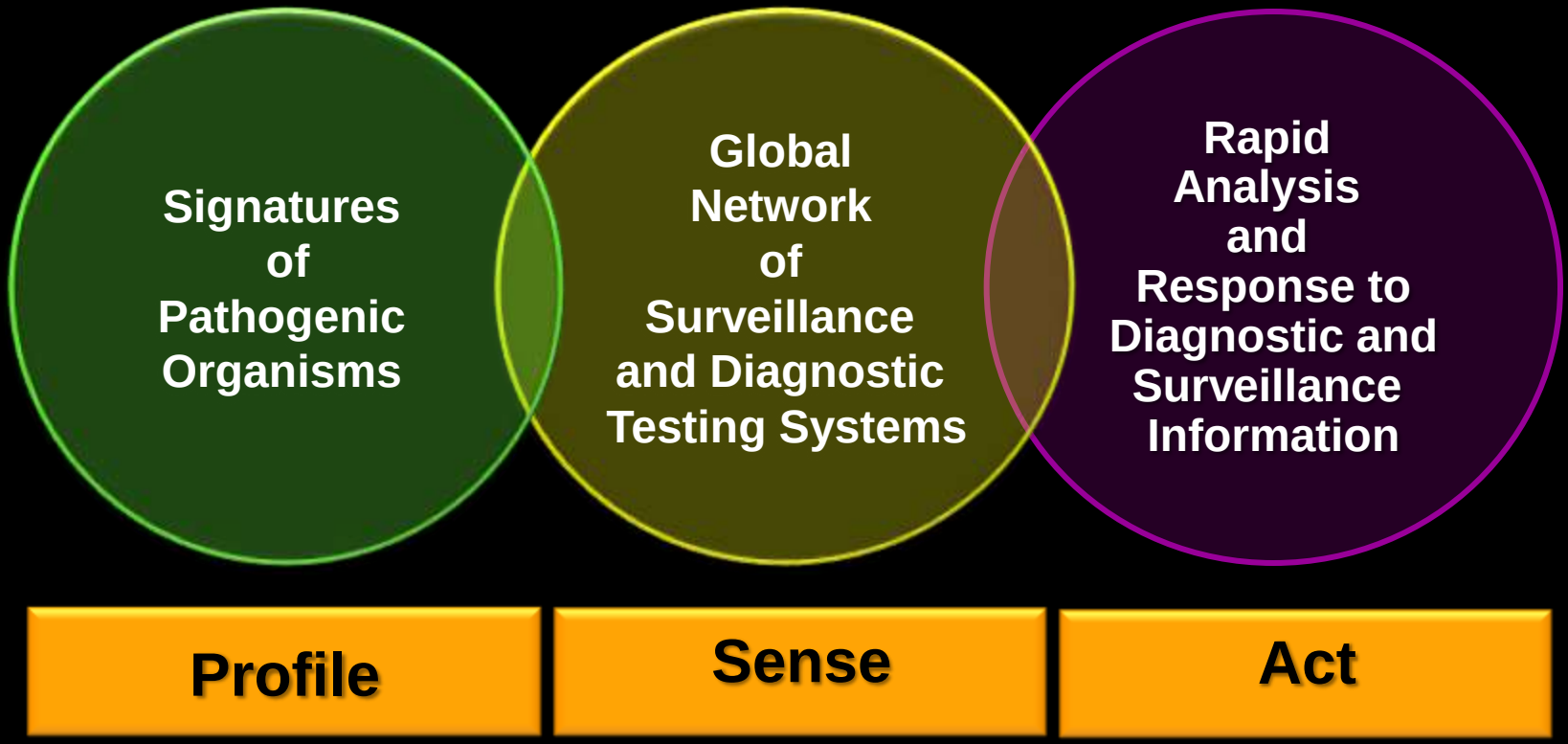
- faster Rx
- accurate Rx
- prophylactic Rx for incident personnel

- 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-/Pan-demics and WMD Bioterrorism

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



Global Disease Surveillance

Eurosurveillance

World Health Organization

CDC
Centers for Disease Control and Prevention

EMERGEncy ID NET

HealthMap
Global Disease Alert Map

IDSA
Infectious Diseases Society of America

Public Health Department's Surveillance

OIE

ProMED-mail

GPHIN
RMISP

biocaster

U.S. Influenza Sentinel Provider Surveillance Network

DoD - GEISWeb
Global Emerging Infections System

BioPortal

AROC
Argus Research Operations Center

TropNet Europ

GIDEON

Quarantine Activity Reporting System (QARS).

GeoSentinel
The Global Surveillance Network of the ISTM and CDC
a worldwide communications & data collection network of travel/tropical medicine clinics

google.org

RABNET
Human and Animal Rabies

EUNID
European Network of Infectious Diseases

EMPRES WATCH
emergency prevention systems

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

HealthMap

Global Disease Alert Map

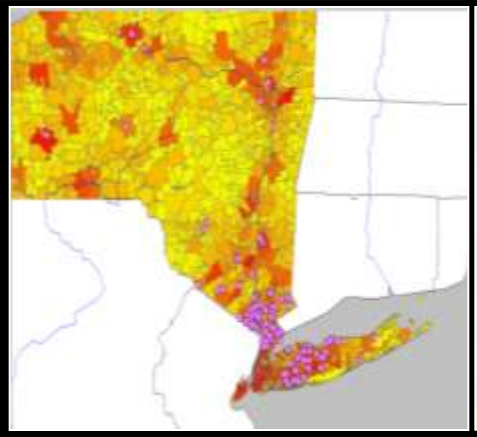
English | Español | Français | Português | Русский | 中文 | عربية

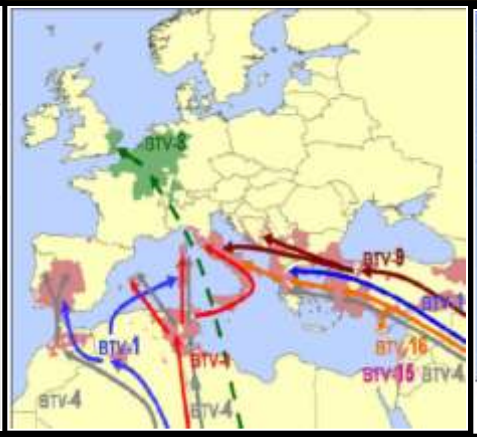
NEJM H1N1 Case Reports | About | Twitter | Blog | Donate | Store | Feedba

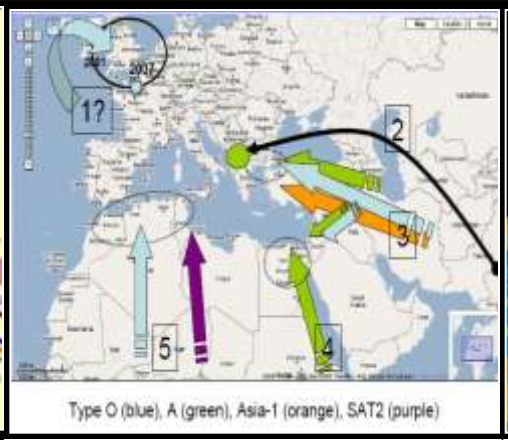
Geodemographic Information Systems: Mapping Disease Patterns and Modeling Trends

Anomaly Detection and Early Alert

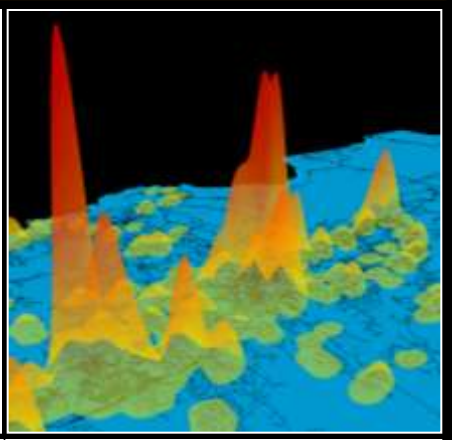
Disease Progression

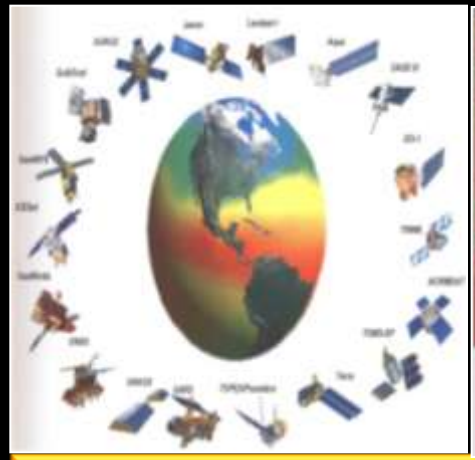


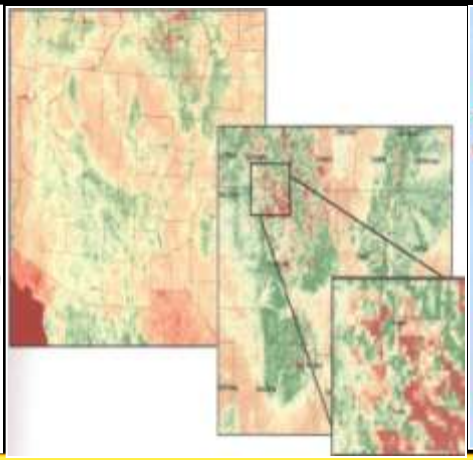


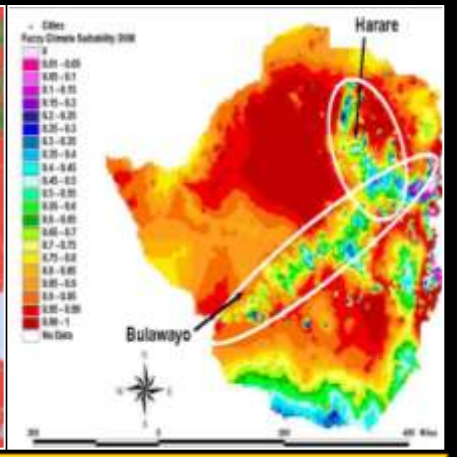


Type O (blue), A (green), Asia-1 (orange), SAT2 (purple)



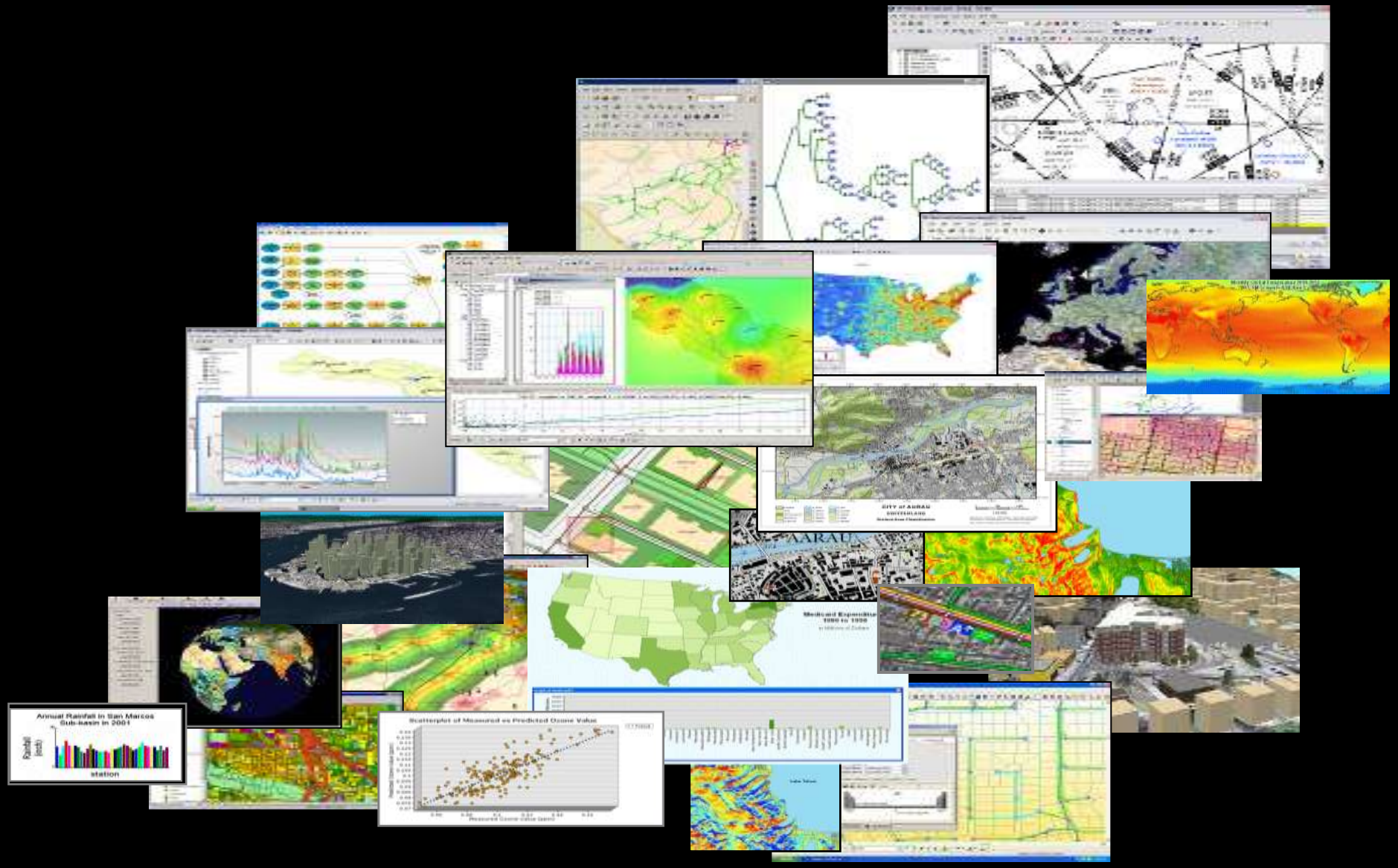




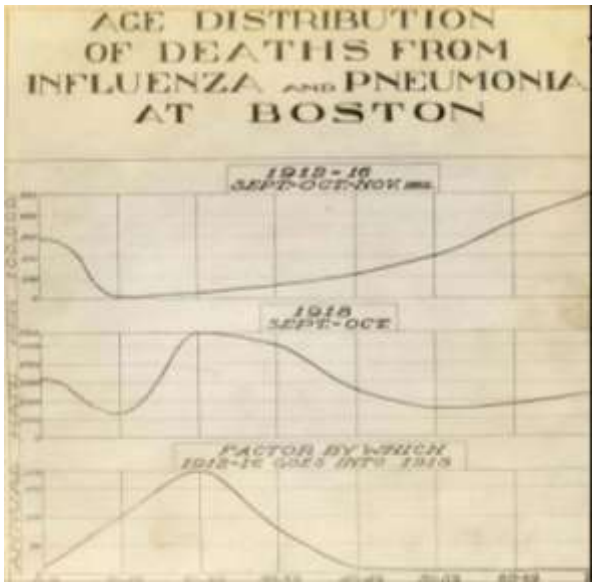


Satellite Surveillance and Predictive Modeling of Disease Trends

The Increasing Importance of Geodemographic Information Systems (GIS) in Global Public Health



Modeling the Likely Evolution of Pandemic Influenza



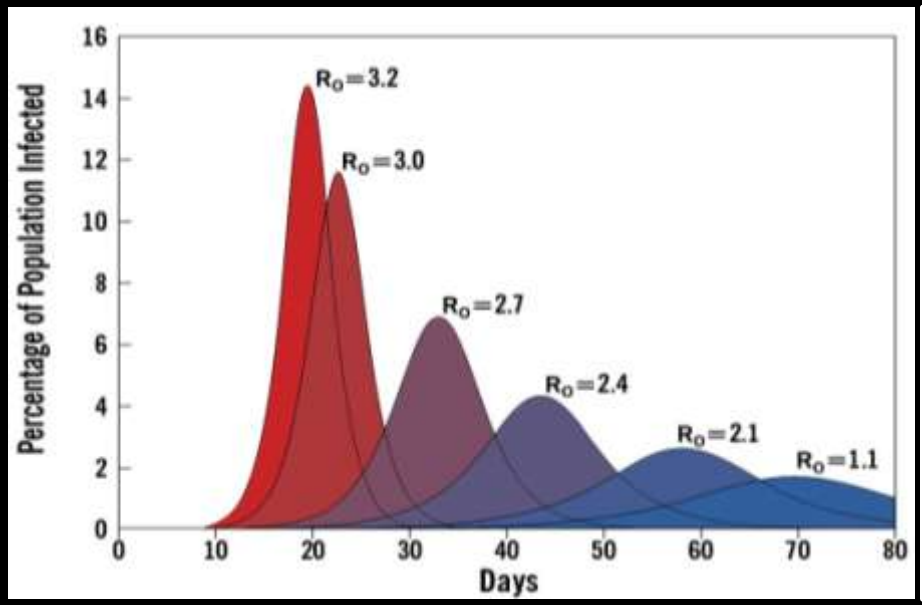
$$\frac{dX(t)}{dt} = \mu - X(t)\left[\sum_{i=1}^{4}\beta_i\left(Y_i(t) + \phi_i\sum_{i\neq j}Y_j(t)\right)\right] - \mu X(t)$$

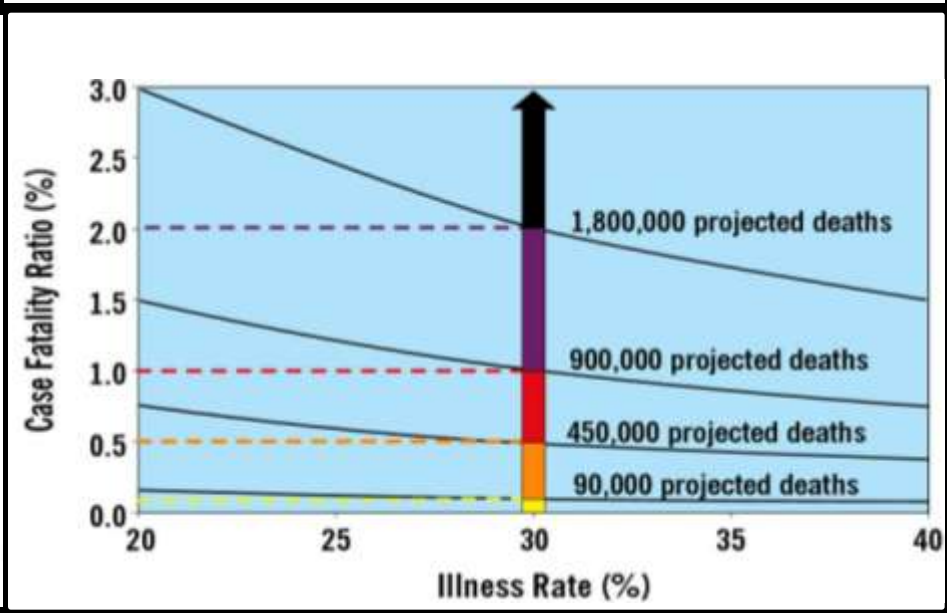
$$\frac{dY_i(t)}{dt} = X(t)\left[\beta_i\left(Y_i(t) + \phi_i\sum_{i\neq j}Y_j(t)\right)\right] - \sigma Y_i(t) - \mu Y_i(t)$$

$$\frac{dZ_i(t)}{dt} = \sigma Y_i(t) - Z_i(t)\sum_{j=1,j\neq i}^{4}\left[\beta_j\left(Y_j(t) + \phi_j\sum_{k\neq j,k=1}^{4}Y_{kj}(t)\right)\right] - \mu Z_i(t)$$

$$\frac{dY_{ij}(t)}{dt} = Z_i(t)\left[\beta_j\left(Y_j(t) + \phi_j\sum_{k\neq j,k=1}^{4}Y_{kj}(t)\right)\right] - \sigma Y_{ij}(t) - \mu Y_{ij}(t)$$

$$1 = X(t) + \sum_{i=1}^{4}Y_i(t) + \sum_{i=1}^{4}Z(t) + \sum_{i,j=1,i\neq j}^{4}Yij(t) + Z\text{-}(t)$$



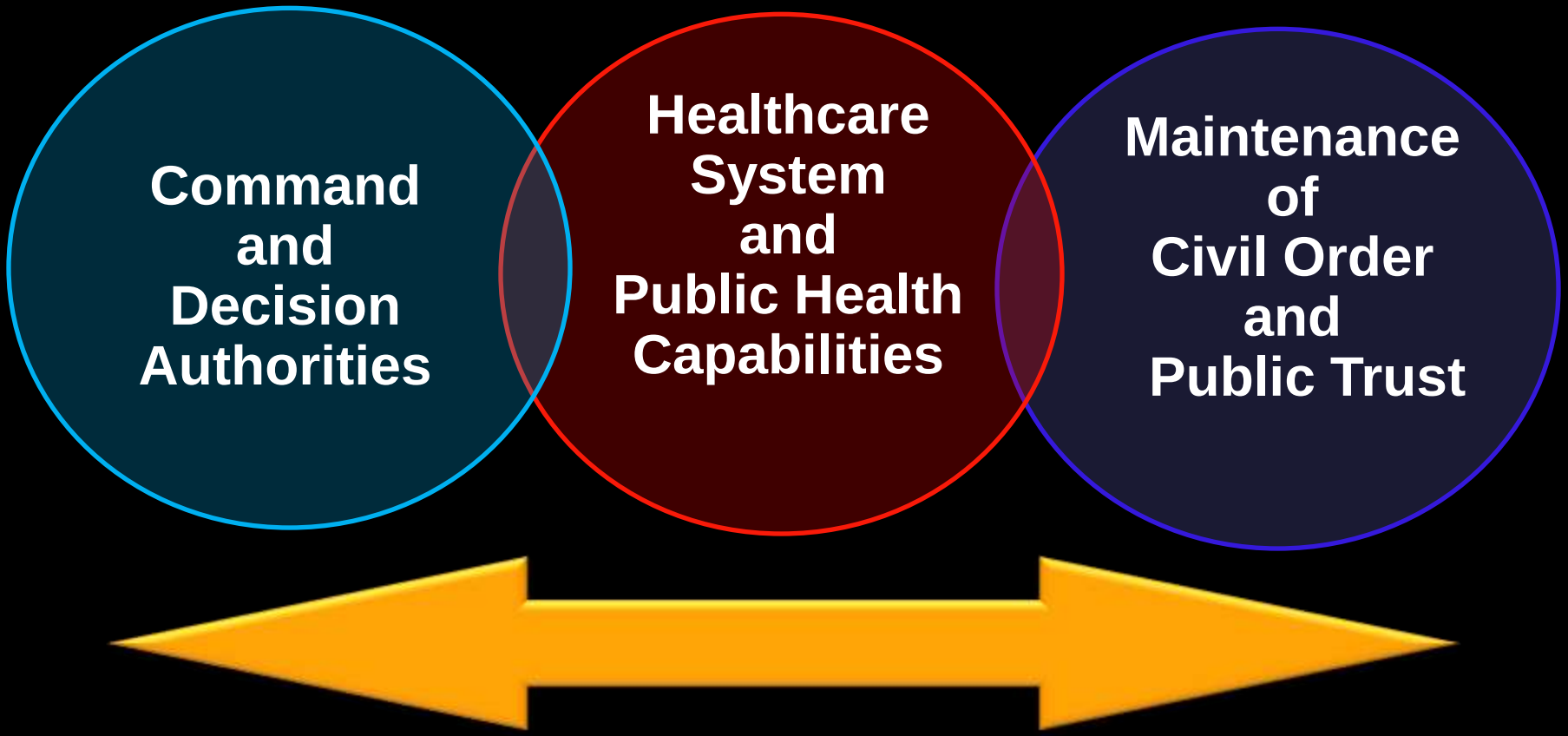


Medical Consequence Management of a Major Epidemic/Pandemic

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
  - emergency services and front line personnel
  - medical/public health
  - politicians and inter-agency coordination
  - media

The Three Major Components of Bioincident Management



- robust networks for situational awareness, decision authorities and rapid actions
- managing the media
- transparency, credibility and public trust

Medical Supply Chain Risks in a Major Epidemic/Pandemic: People and Products

Walgreens
The Pharmacy America Trusts

CVS/pharmacy®
for all the ways you care℠

Boots

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

- global “just-in-time”/”friction-free” economy creates a unique set of vulnerabilities
- limited contingency planning
- the ostrich/denial school still predominates in disaster planning
- international governments will have limited resources to respond to “everywhere and everything” for 12-18 months
- erosion of public distrust, business failures and threat to economic and civil order

Hope is Not a Strategy!

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 prescriptions

Non-Medical But Critical Domestic Supply Chains for Societal Health, Safety and Civil Order

- power
- water and sewage
- transportation to maintain critical supply chains
- fuel
- mortuary services
- hazardous materials
- law enforcement
- telecommunications
- critical infrastructure emergency management
- banking
- overall business continuity

Governmental and Authoritative Leadership

- **Transparency, Timing, Trust**

The first question President Obama received during his press conference on April 29, 2009 was: "Why aren't you closing the Mexico-US border to prevent the entry of swine flu?"

Media Sensationalism and Public Response to H1N1 Threat

Maintaining Global Preparedness for a High Virulence Pandemic

- H1N1: high transmissibility - low virulence/mortality
- H5N1: low transmissibility – high virulence/mortality
- H5N1 x (H1N1) or (X): potential for devastating pandemic

Global Avian Influenza Network for Surveillance (GAINS)

H5N1 Prepandemic Influenza Vaccines

Omnivest Pharmaceuticals

Public Response to H1N1 Vaccine for Pandemic Protection

“Millions demand it,
millions refuse it,
and millions don’t know what to think”

John Carroll
Editor, FierceBiotech (23 Oct. 2009)

The Politics of Pandemic Preparedness

Manufacturer Recalls 800,000 Doses of H1N1 Vaccine; Flu Experts Not Worried

Massive Recall Is No Reason for Concern, Infectious Disease Experts Say

By TODD NEALE and DAN CHILDS

ABC News Medical Unit in Collaboration with MedPage Today

Dec. 15, 2009

High Risk Patients Await Flu Vaccines

Published 12/25/2009 by Infectious Diseases Society of America

MedImmune Monovalent 2009 (H1N1) Influenza Nasal Spray Vaccine – Shortened Shelf Life of Certain Lots

CDC Health Update

Distributed via Health Alert Network

CDCHAN-00304-09-12-23-ADV-NÂ

MedImmune announces limited, voluntary, non-safety-related recall

Summary

On December 18 and 21,

FT.com FINANCIAL TIMES

Europe

FT Home > World > Europe

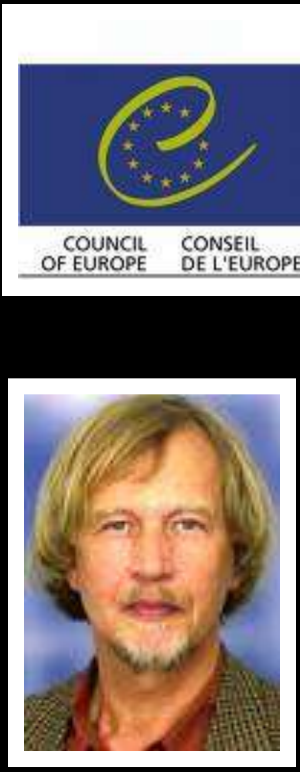
Sarkozy under fire on flu vaccine 'fiasco'

By Scheherazade Daneshkhu and Andrew Jack in Paris

Published: January 4 2010 22:23 | Last updated: January 5 2010 11:01

Nicolas Sarkozy, the French president, was at the centre of a political storm after health authorities admitted they had a huge oversupply of vaccines for the H1N1 swine flu virus and were trying to sell them on to other countries.

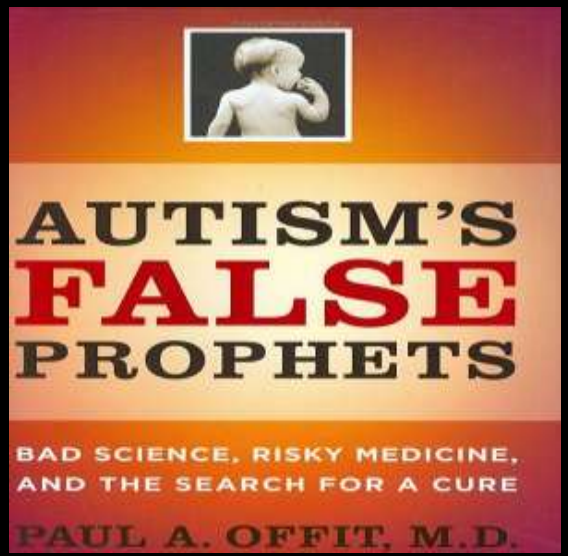
“Faked Pandemics- a Threat for Health”



- Motion to COE by Wolfgang Wodarg, Chair, Healthcare Committee, January 2010
- “WHO in cooperation with some big pharmaceutical companies and their scientists re-defined pandemics and lowered the alarm threshold”
- “Those standards forced politicians…… to sign marketing commitments for vaccines against swine flu and spend billions to catch up with the alarming scenario that big pharma, media and WHO are spreading”

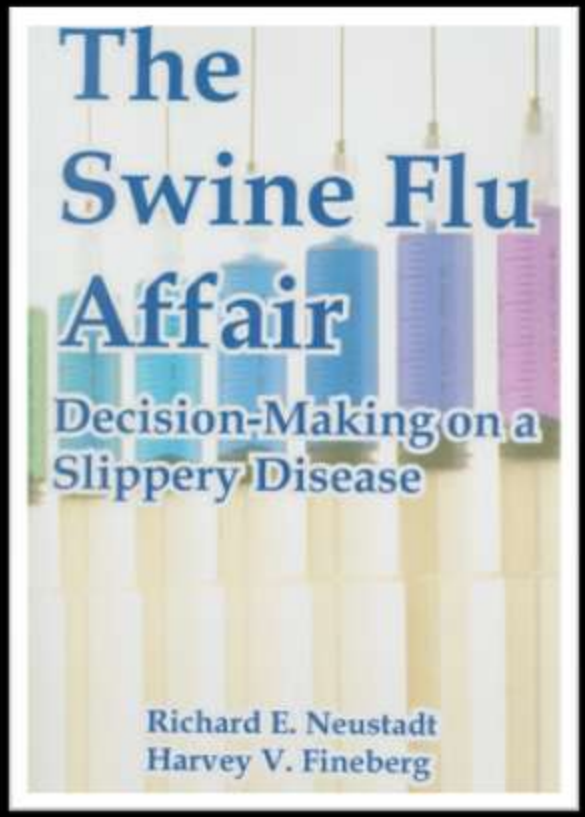
Source: Scrip News 6 Jan. 2010

Vaccine Safety:
Media Sensationalism and Celebrity Quackery



“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
USA Today 8 Oct. 2009



New Incentives for R&D Investment in Diagnostics, Drugs and Vaccines to Outpace Infectious Diseases

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

- 75% decrease in antibacterials approved from 1983 to 2009
- only 16 agents currently in Phase II / III clinical trials
  - only 3 as new ‘classes’ with novel mechanisms of action
  - absence of agents for therapy of AMR in G^-bacilli
  - lack of systemic agents in advanced development for organisms resistant to all current antibacterials

* source: H.W. Boucher et. al. (2009) Clin. Inf. Dis. 48, 1

Incentives for R&D Investment in Antibiotics

Equal Relevance to Stimulating R&D innovation in diagnostics, anti-virals and vaccines

The I0 X ’20 Initiative (20 Nov. 2009)

- grand challenge to develop 10 new antibiotics by 2020

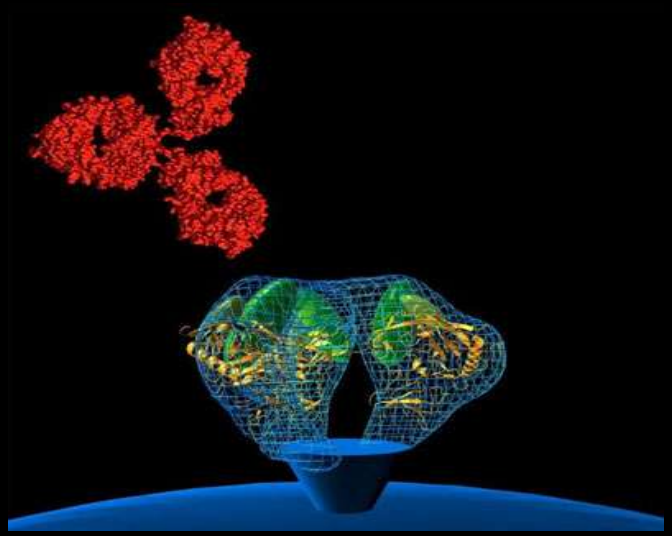
New US-EU Task Force (2 Nov. 2009)

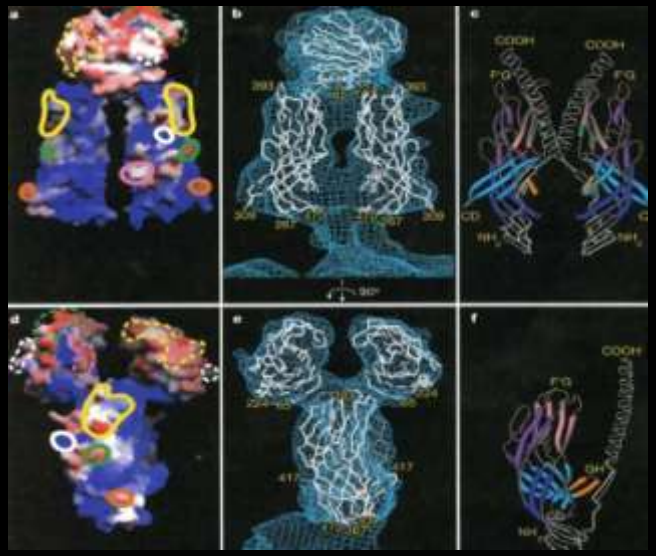
- encourage R&D on new antimicrobial drugs
- yet to be defined strategy/funding

Incentives for R&D Investment in Novel Anti-Infectives and Vaccines

- ‘orphan-drug’-type incentives for ‘prioritized’ diseases
- R&D tax credit
- extension of patient life or market exclusivity
- transferable priority review vouchers for expedited review of another product
- transferable patent extensions
- advanced purchase commitments
- ‘non-use’ market compensation for next-generation agents held ‘in reserve’ to combat pan-resistant infections
- ‘call options for antibiotics’

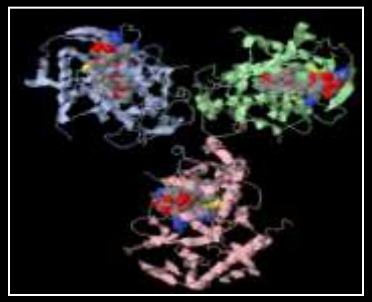
Combating ‘Agent X”: Transforming Vaccine Development





- convert vaccine production from a ‘biologics’ process to a ‘chemical’ manufacturing process
- reduce R&D cycle from 10-25 years to less than 1 year
- shorten production cycles run-time from 6-12 months to days/weeks

Combating ‘Agent-X’



- production of the relevant epitopes by chemical synthesis versus traditional ‘biological’ production methods
- dramatic reduction in vaccine production time
- rapid scaleability and production plant flexibility versus ‘biological’ methods
- compositional uniformity of chemically synthesized antigens eliminates need for regulatory approval of individual lots (unlike biological products)

USG Investment in Medical Countermeasures

United States Government Accountability Office

GAO

Report to Congressional Committees

July 2009

PROJECT BIOSHIELD

HHS Can Improve Agency Internal Controls for Its New Contracting Authorities

OPTIMIZING INDUSTRIAL INVOLVEMENT
WITH MEDICAL COUNTERMEASURE DEVELOPMENT:

A REPORT OF THE NATIONAL BIODEFENSE SCIENCE BOARD

February 2010

Congressional Research Service

Project BioShield: Authorities, Appropriations, Acquisitions, and Issues for Congress

Frank Gottron
Specialist in Science and Technology Policy

January 22, 2010

"Only industry can give us a clear answer
to these questions (on Bioshield)
This would require a process of
government listening and industry speaking."

Sen. J. Lieberman (I-CT)
2006

Bioshield and Medical Countermeasures (MCMs)

- failure to understand economics and logistics of MCM industry
- failure to attract large companies with proven track record
- NIH and MCMs
  - productivity, accountability, COI
- lack of political support and leadership void
  - appropriations versus stable budgets and planning
  - diversion of funds
  - elimination of biosecurity leadership at NSC
- GOCO
  - the concept that refuses to die
- regulatory transparency/consistency
  - ‘animal rule’ and HGS anthrax antitoxin, raxibacumab (11/09)

Bioshield and Medical Countermeasures (MCMs): Incentives to Engage Industry

- guaranteed markets
  - all R&D investment is comparative (ROI as obligate criterion)
  - back-loaded incentives and competitive ROI versus upfront pay-as-you-go payments
  - defense contractor model inappropriate
- need for MCM incentives to address both natural and bioterror pathogens
- investment in research (and development) tools
  - truncate R&D cycle
  - broader spectrum ‘pan-agent’ Rx/vaccines

- COMFORT
- COMPLACENCY
- COMMITMENT

**“But I must go and meet the danger there,
or it will seek me in another place,
and find me worse provided.”**

- William Shakespeare, Henry IV

Biosecurity

environmental sustainability and non-renewable resources

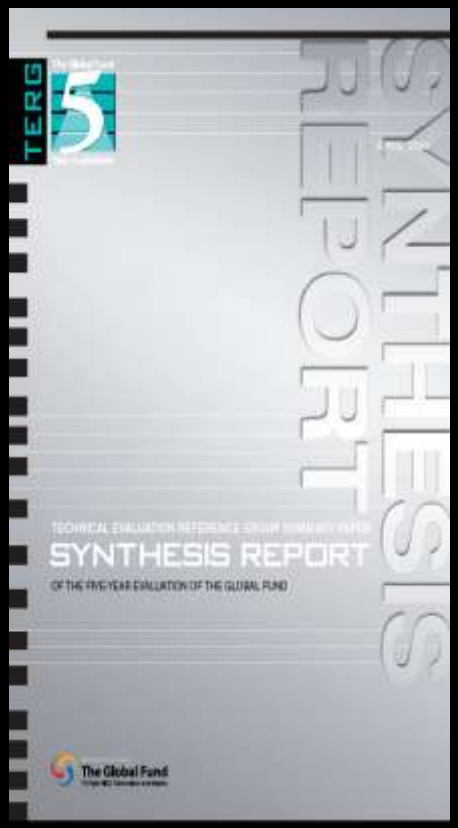
global public health

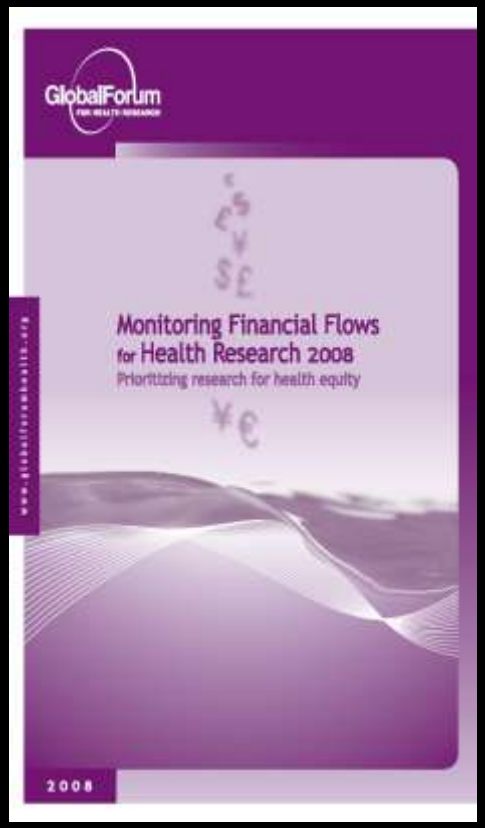
political instability and escalating conflict

terrorism and international security

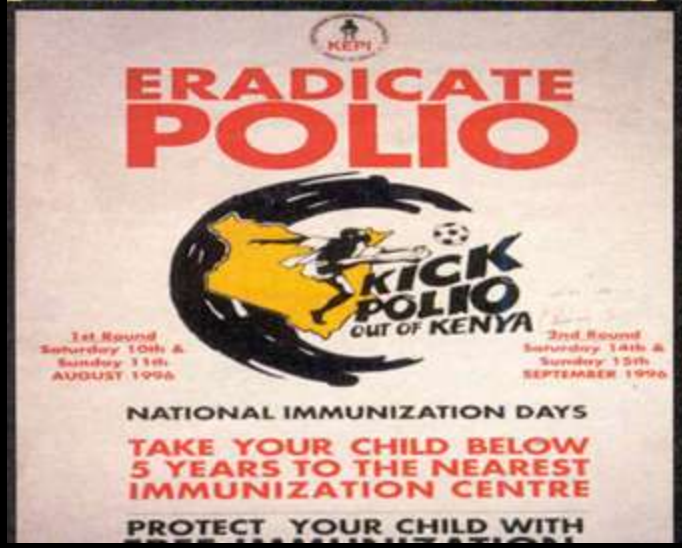
International Engagement, Commitment and Political Resolve

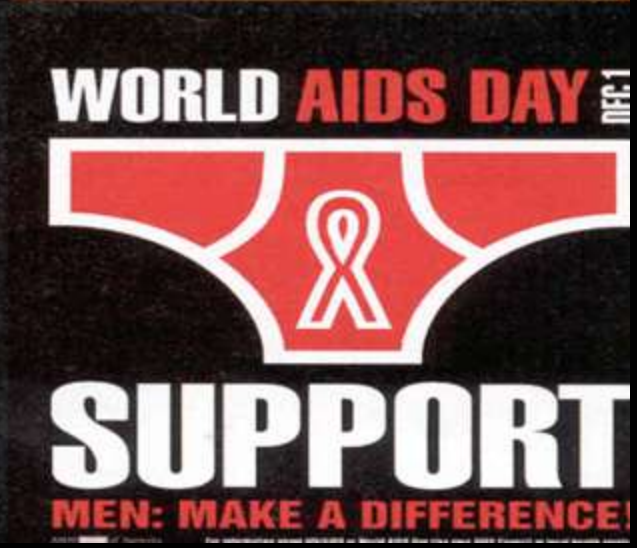
Millennium Development Goals (MDGs): Combating the Burdens of Poverty, Illiteracy and Infectious Diseases





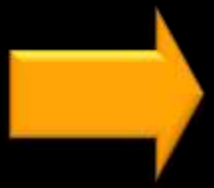
Re) Building an International Public Health Infrastructure





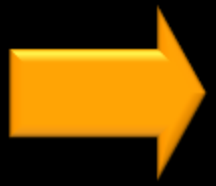
From Nibbling at the Edges to Engagement in the Root Causes

- ill-defined performance metrics and technology transfer processes



- tractable, actionable, measurable policies
- accountability

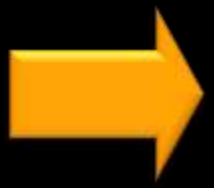
- political correctness (PC)



- purposeful commitment (the real PC)
- denunciation of corruption, ineptitude and activist extremism

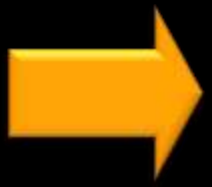
From Nibbling at the Edges to Engagement in the Root Causes

- public health marginalized in foreign policy and international security policies



- prioritizing global health as a key component in investment, trade, diplomacy and military policies

- vulnerabilities created by highly variable national and global preparedness capabilities

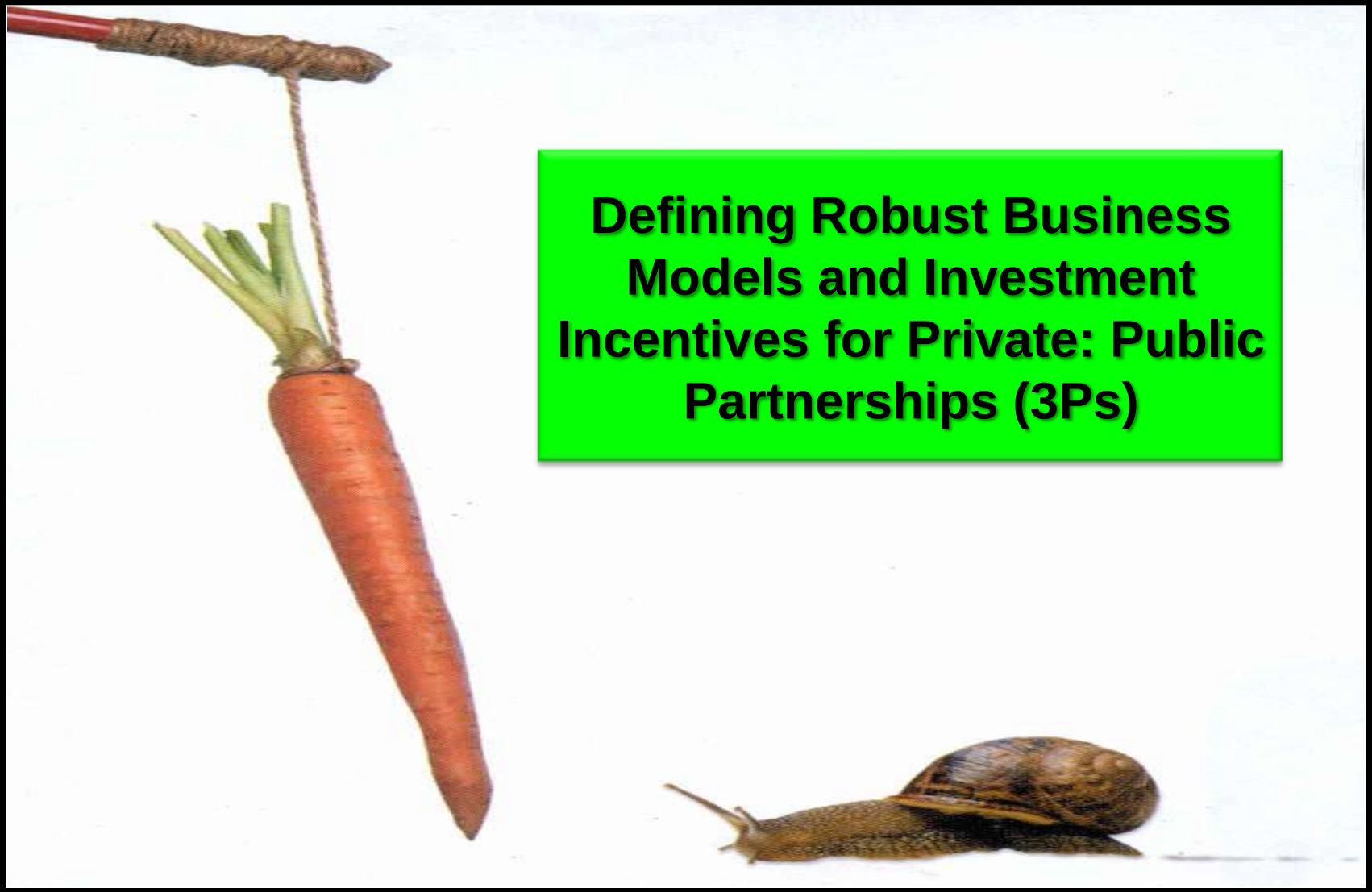


- political will, investment and trans-generational commitment to build resilient systems

Priorities

- encourage nations to make infectious disease control an urgent priority
  - link to debt relief, aid, corporate investment
- build global capacity for disease surveillance and outbreak response
- support education, research and training as key to prevention and control
- promote public : private partnerships to increase the availablity of diagnostics, drugs and vaccines
- promote research on factors that favor disease emergence

To Build Resiliency?



Defining Robust Business Models and Investment Incentives for Private: Public Partnerships (3Ps)


icddr,b
KNOWLEDGE FOR GLOBAL LIFESAVING SOLUTIONS


Global Polio
Eradication Initiative


PMI
Saving Lives in Africa
PRESIDENT'S MALARIA INITIATIVE


DFID
Department for
International
Development


The United States President's
Emergency Plan for AIDS Relief


2
Medicines for Malaria Venture


TB ALLIANCE
GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT


USAID
FROM THE AMERICAN PEOPLE


BILL & MELINDA
GATES foundation


bvgh
BIO Ventures
for Global Health


GAVI
ALLIANCE


Investing in our future
The Global Fund
To Fight AIDS, Tuberculosis and Malaria


UNDP


IFFIm
SUPPORTING
GAVI


THE
ROCKEFELLER
FOUNDATION


unicef


PATH
A catalyst for global health


iavi
International AIDS
Vaccine Initiative


INTERNATIONAL
PARTNERSHIP for
MICROBICIDES


AERAS
GLOBAL TB VACCINE FOUNDATION


DNDi
Drugs for Neglected Diseases initiative

Free Swim: UNITAID Request for 19 Drugs for Patent Pool for AIDS Medicines

Norvir (ritonavir)

Viramune (nevirapine)

Reyataz (atazanavir)

Viread (tenfovir disoproxil fumarate)
Emtriva (emtricitabine)
GS-9350
Elvitegravir

Epivir (famivudine) (GSK)
Ziogen (abacavir) (GSK)
Lexiva, Telzir (fosamprenavir) (GSK)
Selzentry (maraviroc) (Pfizer)

Stocrin, Sustiva (efavirenz)

Invirase (saquinavir)

Prezistae (duranavir)
Intelence (etravirine)
Rilpivirine

Bridging the Gulf of Distrust and Ignorance

Public Sector

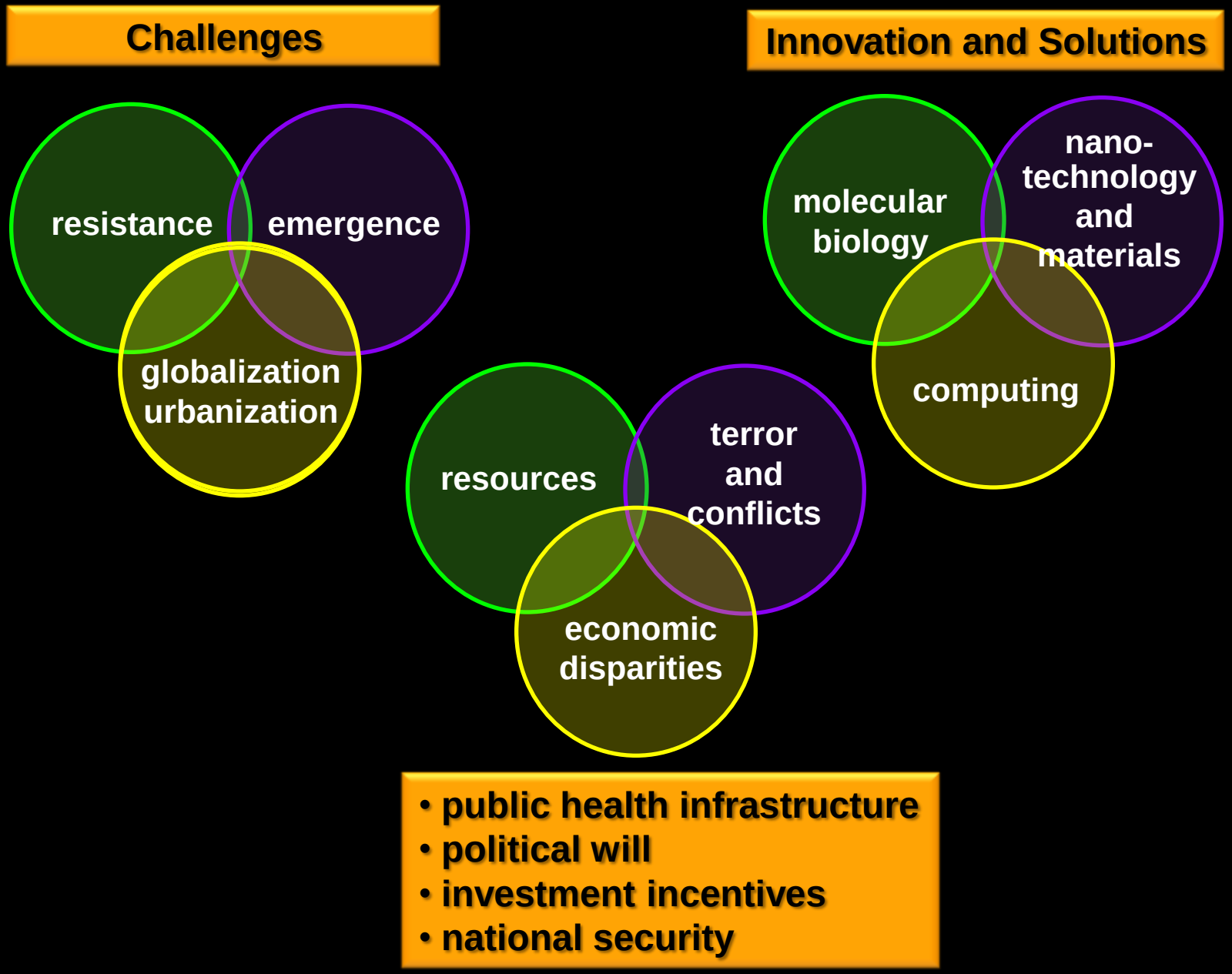
- minimal understanding of the industrial base
  - technical complexity of development
  - time, cost, risk and lead times
  - unrealistic expectations
  - inconsistent regulatory policies
- distrust/resentment of profit motive/IP
- persistence of GOCO idealism : public production for public good
  - consistent record of inefficiency and failure
  - facilities obsolescence
  - inconsistent funding

Bridging the Gulf of Distrust and Ignorance

Private Sector

- bureaucratic, inefficient and wasteful public sector
- arrogant academic community with no knowledge or concession of intellectual/logistical challenges of development/manufacturing
- unrealistic and unreliable public tender markets
- taxation, price and profit controls
- resentment of NGO slanders/tactics
- the ‘slippery slope’ of tiered-pricing/compulsory licensing

Convergence and Connectivity



A Powerful Fifth Column

The Retreat from Complexity:
The Curse of Contemporary Governance

The Poverty of Imagination:
The Discomfort and Denial of Radical Change(s)

Hubris:
Divisiveness, Delusion and Dangers Ignored

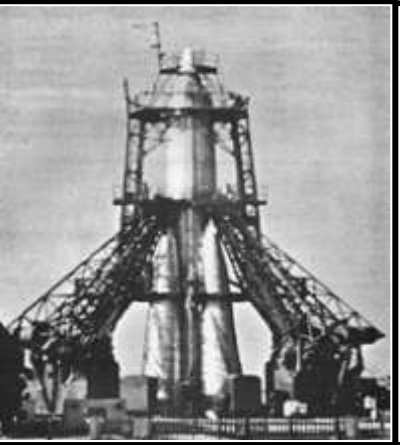
Meeting the Challenge(s) Posed by Global Infectious Diseases

- growing threat awareness as catalyst for action
- availability of new genetic and biotechnology capabilities for discovery of diagnostics (Dx), drugs (Rx) and vaccines (Vax)
- rebuilding global surveillance networks using advances in sensor technologies, computing and telecommunications
- strengthening national public health and epidemic/pandemic management capabilities
- increased involvement of private: public partnerships
- new financial incentives for R&D
- regulatory and reimbursement reforms
- global political engagement and commitment

Meeting Previous Grand Challenges














“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)