

# **The Increasing Importance of the Life Sciences in National Security**

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**[www.casi.asu.edu](http://www.casi.asu.edu)**

**Presentation at: Food and Drug Administration's  
Medical Countermeasures Initiative (MCMI) Lecture Series,  
White Oak Facility, Silver Spring, MD.  
October 6, 2011**

**Slides available @ <http://casi.asu.edu/>  
and will also be posted to FDA intranet**



### **Declared Interests:**

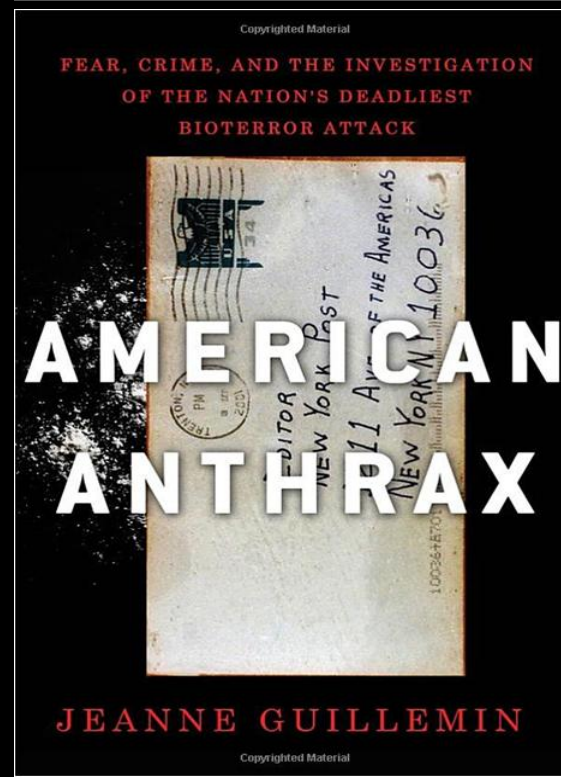
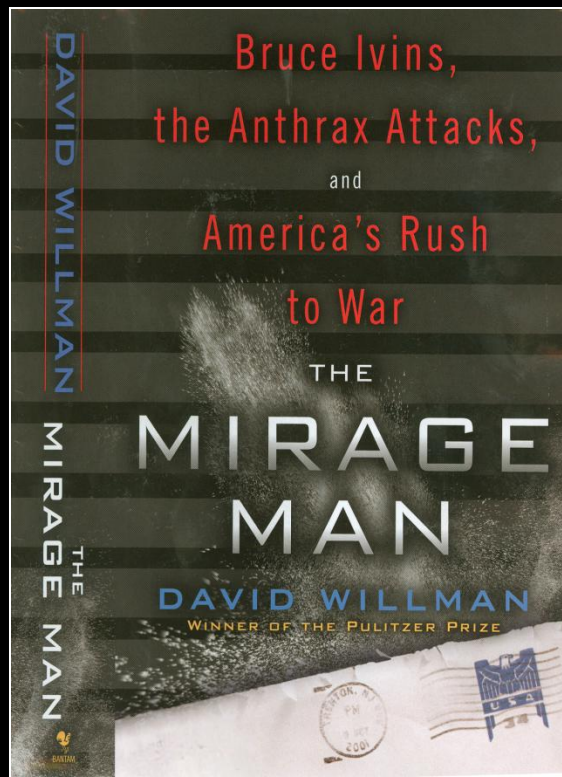
- **Board of Directors: Monsanto, Exelixis, Caris Life Sciences**
- **Scientific Advisory Board: Burrill and Co., Synthetic Genomics, Anacor**
- **IOM Forum on Global Infectious Diseases**
- **USG Activities: DoD, DHS**



# Terrorism, Asymmetric Warfare and The New Calculus of National Security and Foreign Affairs









# Seeking Security in an Insecure World

## Terrorism



## WMD Proliferation



## New Power Centers



## Natural Disasters



## Environmental Deterioration



## Depletion of Non-Renewable Resources

# Framing Future Security Issues Demands a Broadened Conceptualization of National Security



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



GLOBAL TRENDS 2025:  
A TRANSFORMED WORLD





# Feeding The Future



- food chain increasingly complex, international and inter-dependent
- food production over next 25 years  $\equiv$  total for 10,000 years
- expanding middle class (1-2 billion) in NICs and some DCs projected to increase demand for grain and meat 160% by 2020
- famines, shortages and food riots in DCs
- the impact of climate change on growing conditions and harvest losses (drought, pests)

# Ensuring The Safety of Food Imports

- 15% US food imported from over 150 countries
- 300 ports over 200,000 registered importers
- China 3<sup>rd</sup> largest food exporter to the U.S.
- 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

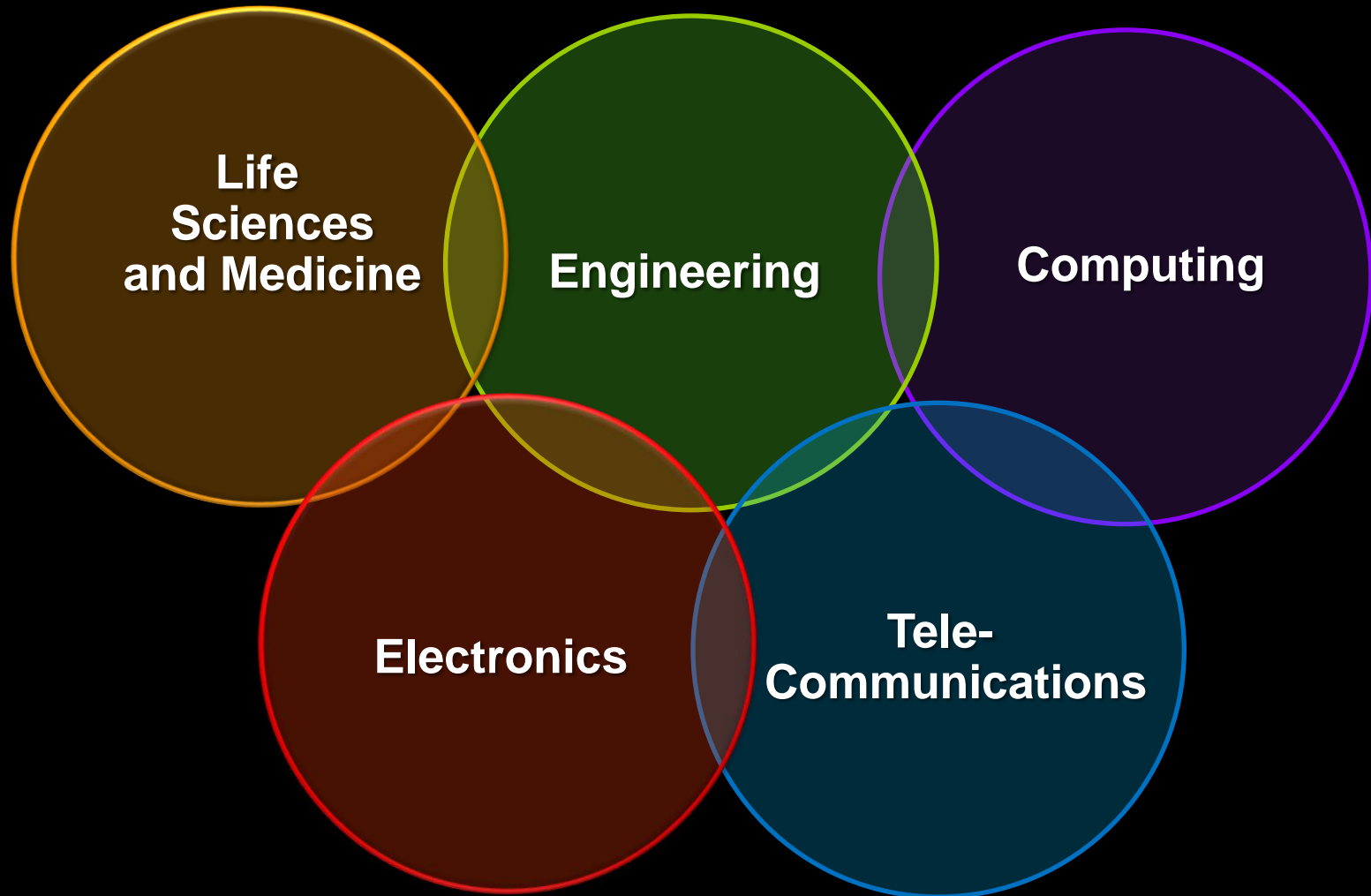




# Technology Acceleration and Convergence

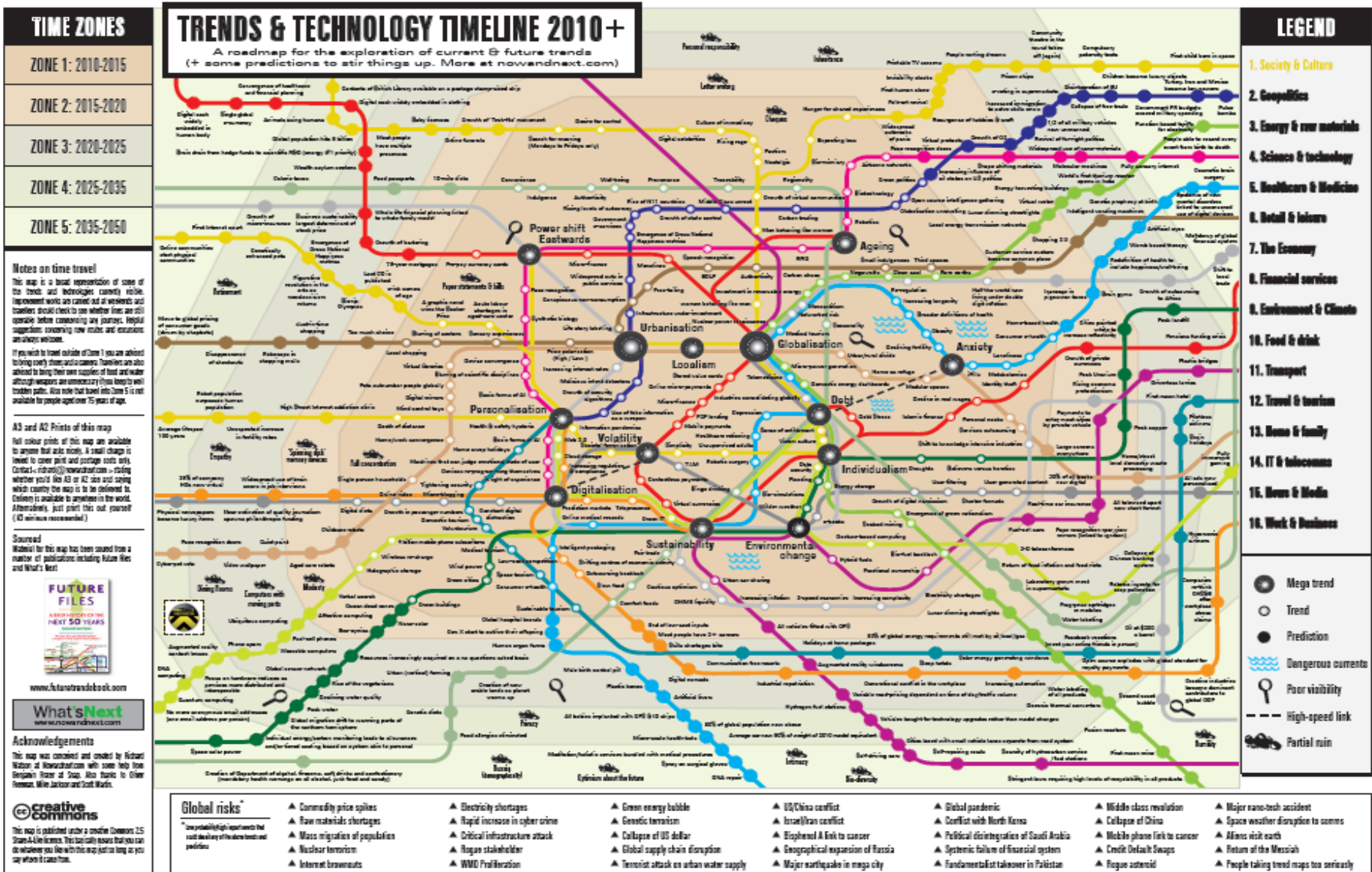


# Technology Convergence





# Technology Convergence and the Changing Calculus of Warfare and National Security



# EMERGENCE

- new strategic spaces
- new hazards

- new strategic surprises?

technology  
acceleration

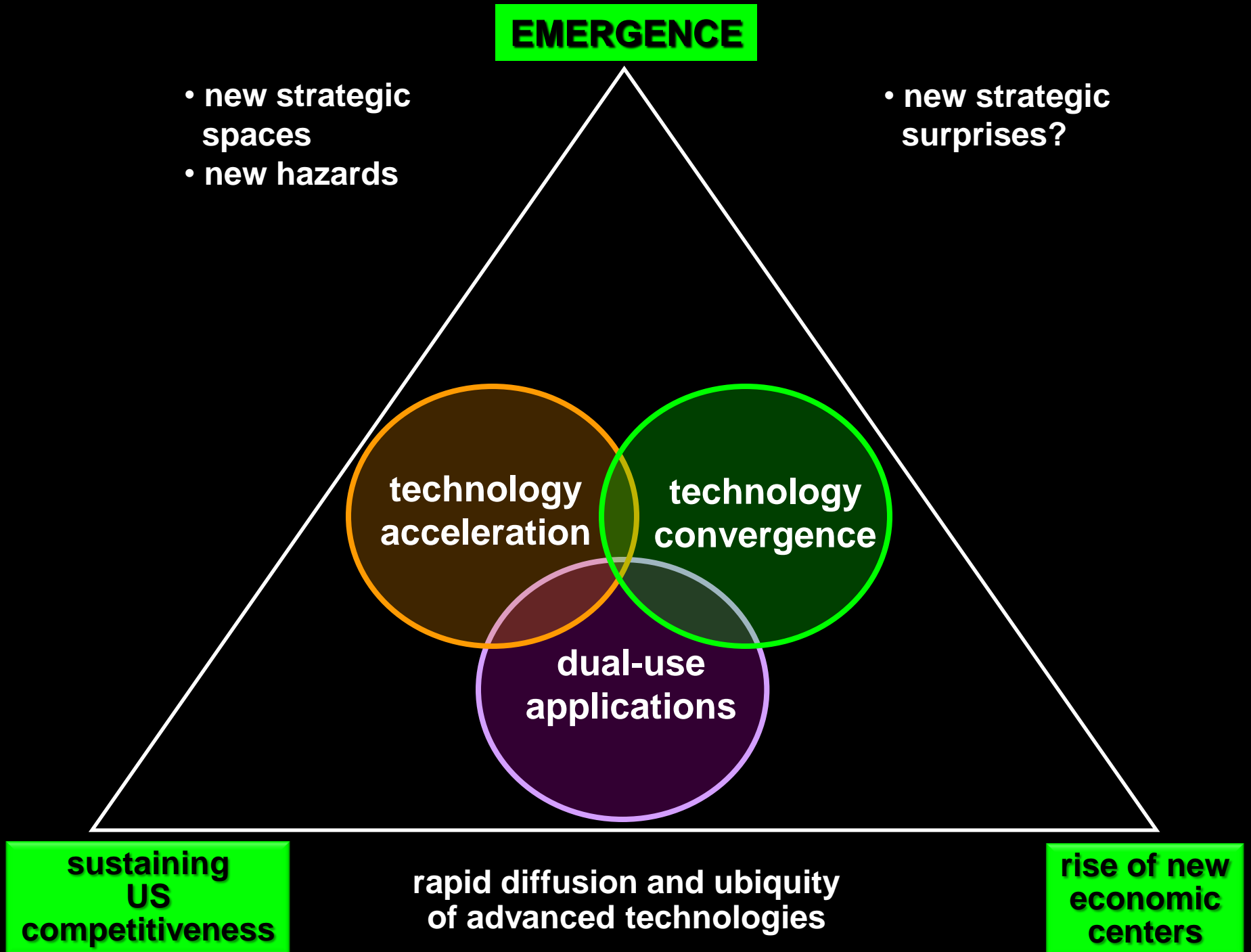
technology  
convergence

dual-use  
applications

sustaining  
US  
competitiveness

rapid diffusion and ubiquity  
of advanced technologies

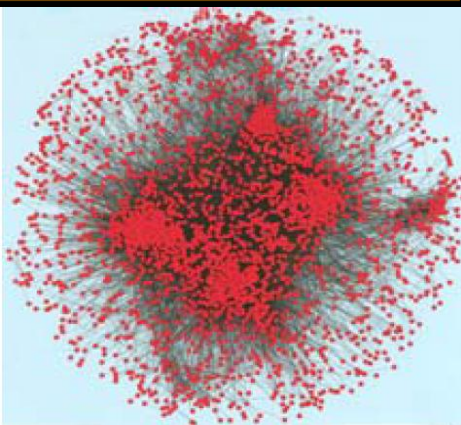
rise of new  
economic  
centers



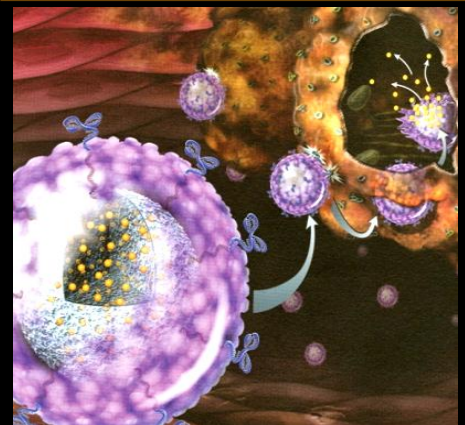


# Transcending Boundaries: Emergent Domains Arising from Technology Convergence In the Life Sciences

**Systems Biology  
and Synthetic Biology**



**Targeted  
Rx**



**Regenerative  
Medicine**



**HPO**



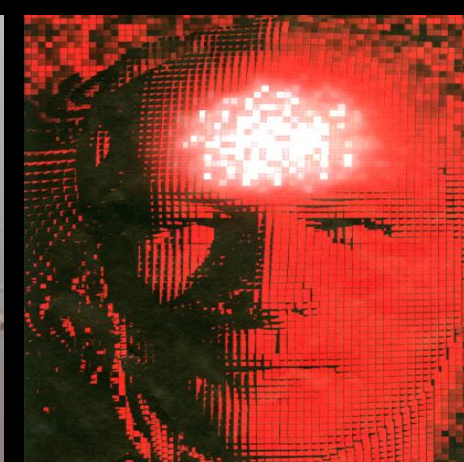
**Bio-  
Enhancement**



**Bionic-  
Enhancement**



**Cognitive  
Enhancement**

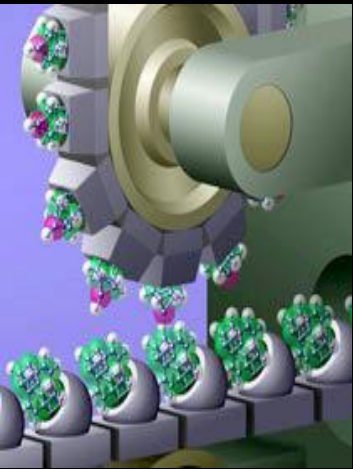


**Genetic  
Enhancement**

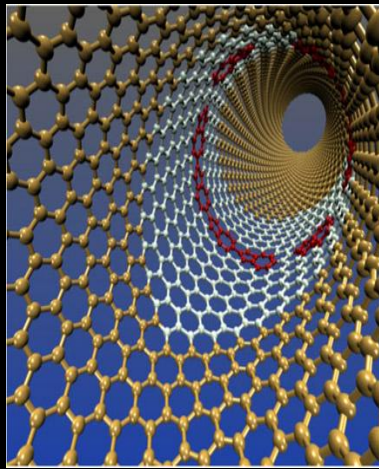




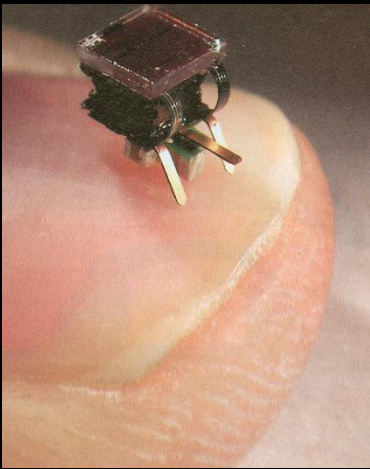
**Molecular  
Foundries**



**Novel  
Materials**



**Micro-  
Devices**



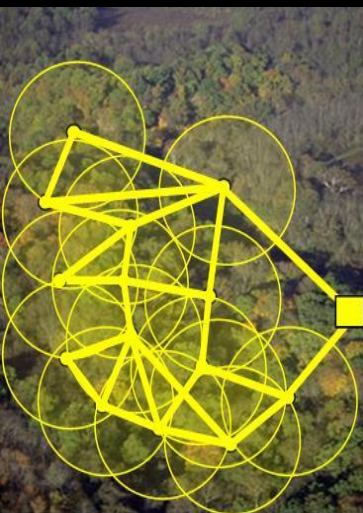
**Ubiquitous  
Sensing**



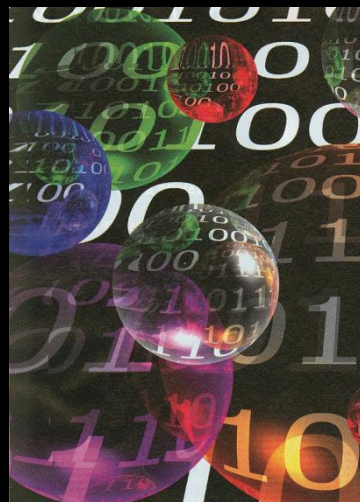
**Robotics**



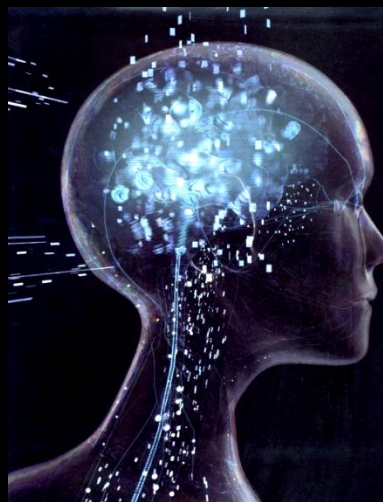
**Ambient  
Intelligence**



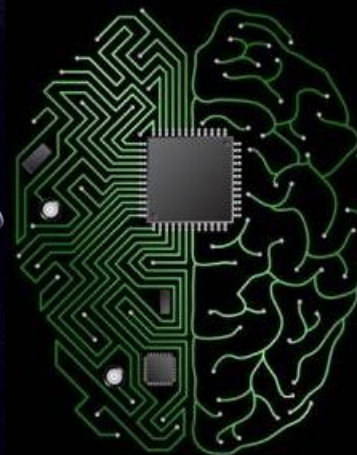
**Digital  
Anthropology**



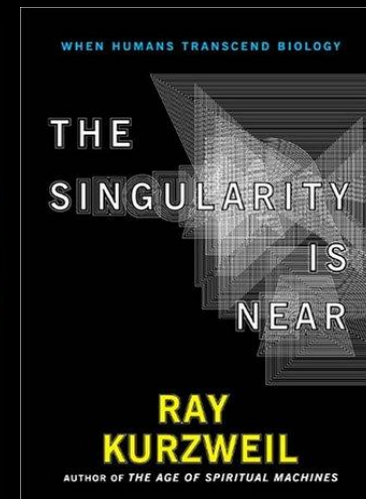
**Cogint**



**Intelligent  
Machines**



**Singularity**



**Massive Computing Power and Analytical Parsing**





HOW DO YOU STAY  
ONE STEP AHEAD OF



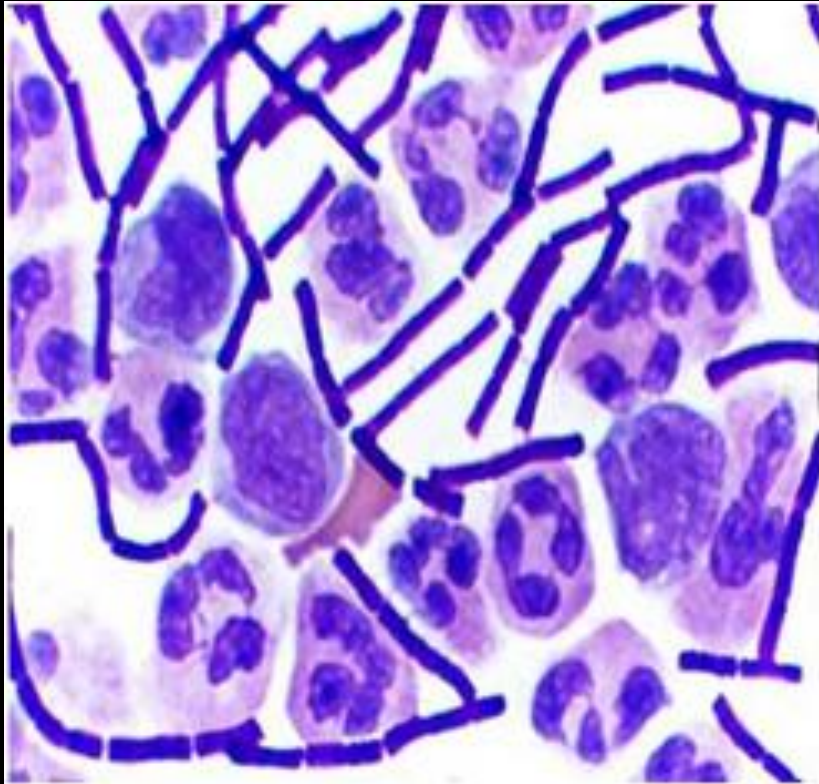
THE NATION'S THREATS  
WHEN THEY'RE



ALWAYS MOVING IN  
NEW DIRECTIONS?



## **“Amerithrax 2001”**

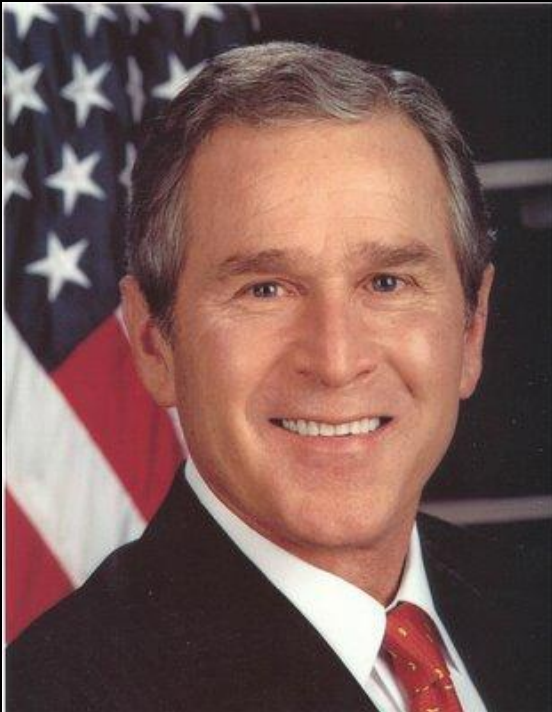


## **Project Bioshield (July 2004)**





# **“Taking the Threat Off The Table”**



- **Project Bioshield, July 2004**
- **DOD Transformational Medical Technologies (TMT)**
- **Creation of Biomedical Advanced Research and Development Authority (BARDA), December 2006**
- **All Hazards Preparedness Act (PAHPA), December 2006**

# “Taking the Threat Off The Table”



- **National Health Security Strategy, December 2009**
  - **HHS Office of the Assistant Secretary for Preparedness (ASPR) 2009**
  - **The Public Health Medical Countermeasures Enterprise (PHEMCE), 2006**
- **National Vaccine Plan 2010**
- **OSTP Report on Improved Strategies for Influenza Vaccine Production, 2010**



# Building Resilient Preparedness and Response Capabilities for Biosecurity

## Improving the Nation's Ability to Detect and Respond to 21<sup>st</sup> 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. EST  
Wednesday, July 29, 2009

## INFLUENZA PANDEMIC

Gaps in Pandemic Planning  
and Preparedness Need to  
Be Addressed

Statement of Bernice Steinhardt  
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-10-471

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

**Preparedness:  
Building Resilient Systems  
and  
The “All Hazards” Challenge**





# NATIONAL STRATEGY *for* COUNTERING BIOLOGICAL THREATS

National Security Council

NOVEMBER 2009



U.S. Department of Health and Human Services  
Assistant Secretary for Preparedness and Response

## The Public Health Emergency Medical Countermeasures Enterprise Review

*Transforming the Enterprise  
to Meet Long-Range National Needs*

August 2010



STRATEGIC PRIORITIES  
2011 – 2015

*Responding to the Public Health Challenges of the 21<sup>st</sup> Century*

DRAFT 9/29/2010



# Advancing Regulatory Science for Public Health



[www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm228131.htm](http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm228131.htm)

Department of Health and Human Services; U.S. Food and Drug Administration  
Office of the Commissioner; Office of the Chief Scientist

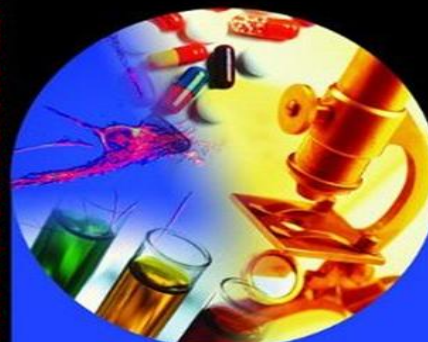
## Building a National Framework for the Establishment of REGULATORY SCIENCE FOR DRUG DEVELOPMENT

Workshop Summary

INSTITUTE OF MEDICINE  
OF THE NATIONAL ACADEMIES

## ADVANCING REGULATORY SCIENCE FOR MEDICAL COUNTERMEASURE DEVELOPMENT

Workshop Summary



INSTITUTE OF MEDICINE  
OF THE NATIONAL ACADEMIES

# MCM Development Strategy

- surveillance
- spectrum
  - threats, multi-use products
- surrogates
  - new biomarkers for Rx efficacy/toxicity and ‘animal model’ predictability
- Speed
  - R&D, regulatory review, consequence management
- scale up and surge
- sophistication
  - Experience
- silos subvert solutions

**Systems-Based Approaches:  
Integrated End-to-End Processes for Robust Solutions**



# The Fragmented Silos of USG: A Dangerous Vulnerability





# The 'Fog of Disaster': Crisis Standards of Care and Proliferation of Unanticipated Events and Consequences





# Cyber-Attacks and Vulnerable Infrastructure: Compromising Critical Systems



# **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**
- **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**



# **No Ambiguity - No Error: No Problem!**

## **The Omnipresent Dillema of Uncertainty When Political Leaders Want Certainty**



**“Insufficient data, Captain”**



**“Insufficient data is not sufficient,  
Mr. Spock.  
You’re the Science Officer.  
You’re supposed to have sufficient data  
all the time”**

**Star Trek  
The Immunity Syndrome**

# Building Resilient and Agile Systems for Biosecurity

**Bioterrorism**

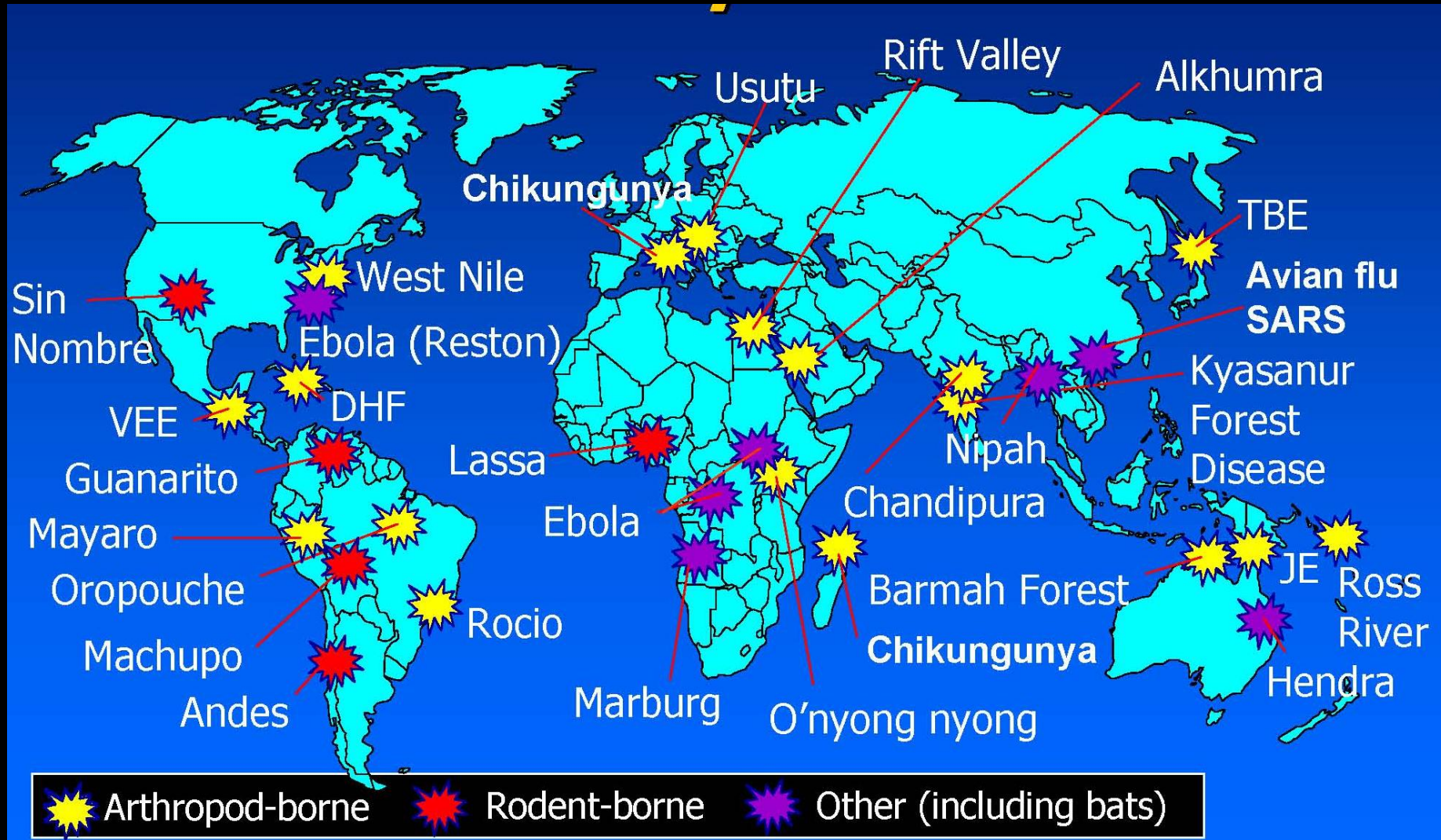
**Infectious  
Diseases  
of  
Natural  
Origin**

**Environmental  
and  
Ecological  
Impacts on  
Disease  
Emergence**



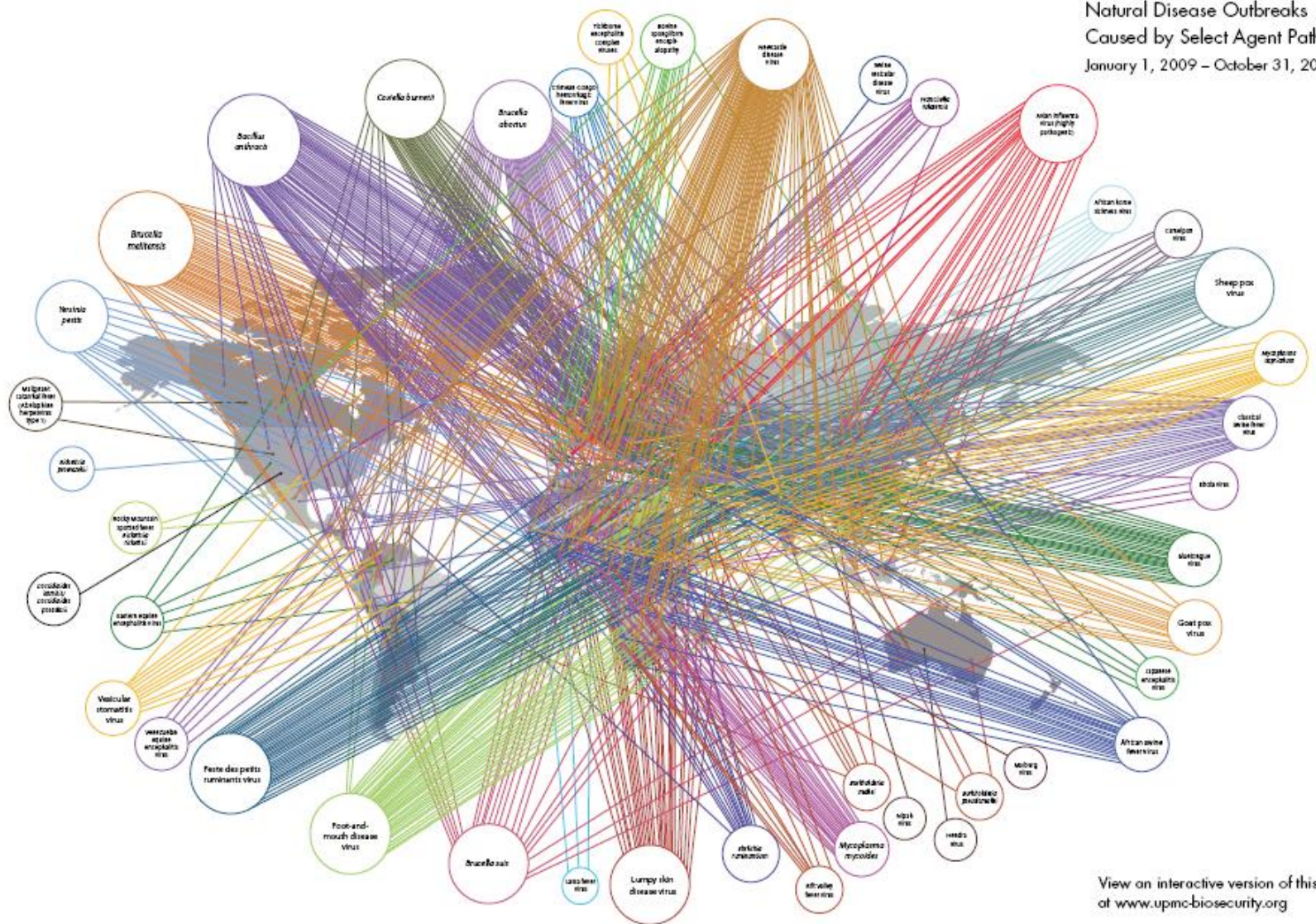


# Emerging Infectious Diseases (EIDs)





# Everywhere You Look: Select Agent Pathogens





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

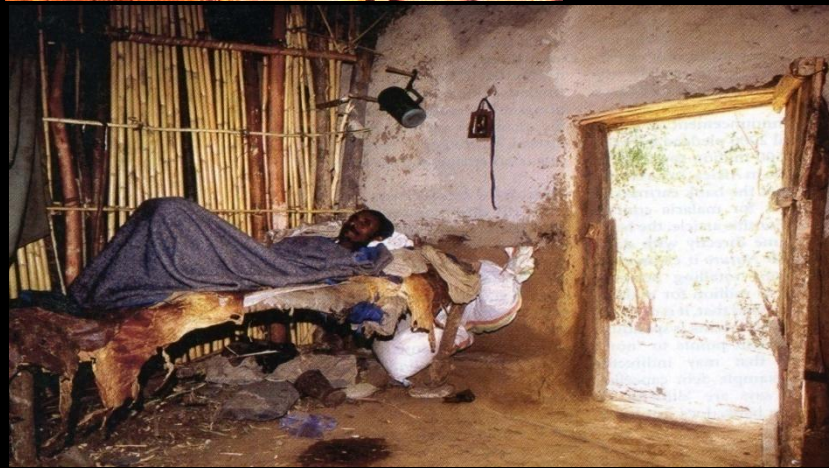
## **High Disease Transmission**



## **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

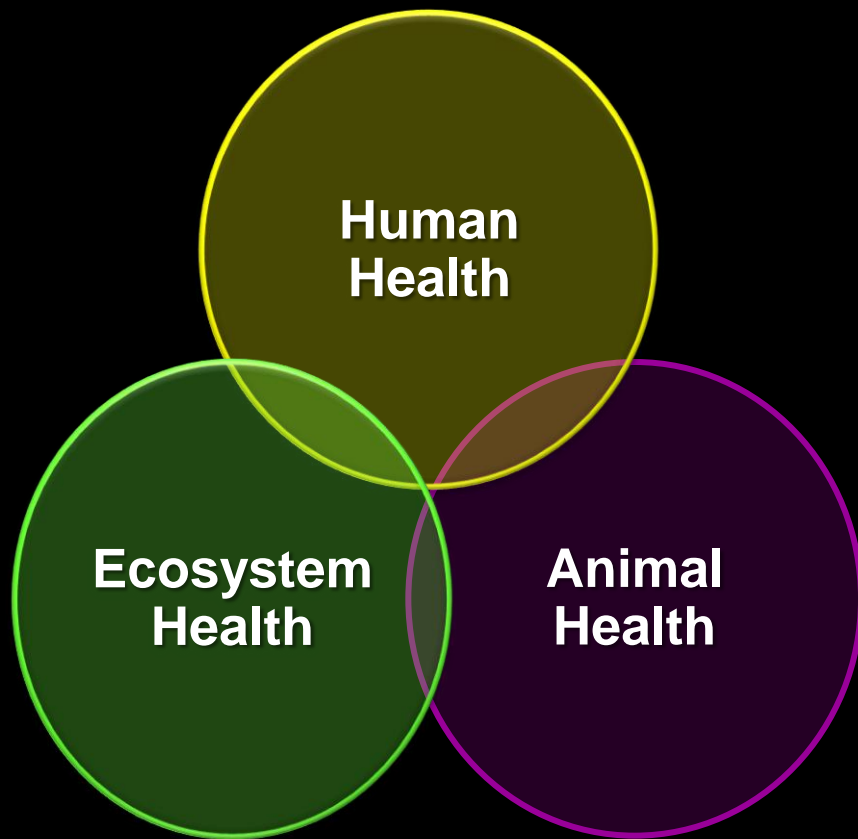
## 1407 species of human pathogens

- 538 bacteria   ● 208 viruses   ● 317 fungi
- 57 protozoa   ● 287 helminths
- 60% are zoonoses
- over 70% zoonoses arise from interactions with wildlife
- EIDs
  - 58 in last 25 years
  - viruses significantly over-represented
  - helminths under-represented



# 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 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

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

- **unidimensional, short term policies trump comprehensive analysis of multidimensional complexities with long term consequences**
- **influence of media and political populism in shaping public policy and operational constraints**
  - **zero-risk, who's to blame?, corporate vilification**



# The Delusion of Quick Fixes to Complex Problems: The Biowatch Debacle



***“It is not realistic to undertake a nationwide blanket deployment of biosensors. The most important component of a biodetection architecture in the event of an attack will be stricken Americans, not sensors”***

**JASONS  
Biodetection Architectures  
Report #JSR-02-330 (Feb. 2003)**



# Detection of Infectious Disease Threats:

## Not A Hazmat or Wide Area Sensor Net (Biowatch) Solution



**Emergency Rooms and Farms Will be the Front Line**





# **Global Surveillance Against Infectious Disease Outbreaks**

**E.H. Chen et. al. (2010) PNAS 107, 21701**

- **398 WHO-verified outbreaks 1996-2009**
- **median times**
  - **23 days for event detection**
  - **32 days for public communication**
  - **35 days for official laboratory confirmation**
  - **48 days for inclusion in WHO Disease Outbreak News**

# 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

Signatures  
of  
Pathogenic  
Organisms

Global  
Network  
of  
Surveillance  
and Diagnostic  
Testing Systems

Rapid  
Analysis  
and  
Response to  
Diagnostic and  
Surveillance  
Information

**Profile**



**Sense**



**Act**





# The Technology Matrix for Pathogen Detection and Discovery

Platform	Known Agents	Unknown Agents		Multiplex Large N		Interference from Host Comps.		Technol. Maturity	Analytical Complexity Speed		Portability Fieldability		Cost/Time	
cultivation/ animal models														
16S rRNA <sup>1</sup>														
multiplex PCR														
PCR/Mass Spec														
Microarrays <sup>2</sup>														
NGS														
Host LK/CK <sup>3</sup>														
Antibody Immunosignature														

1 = bacteria only    2 = versus immunosignatures    3 = organism class only

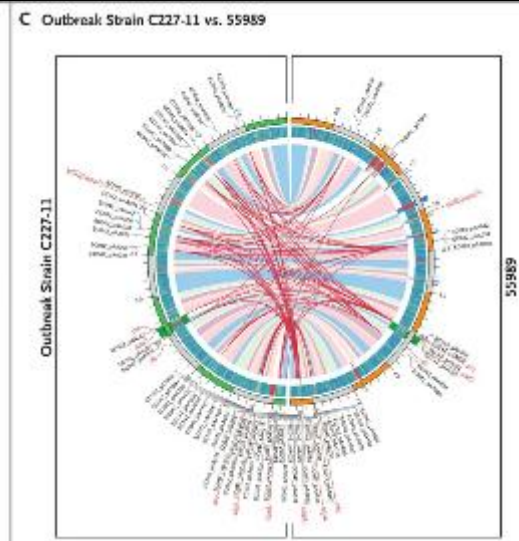
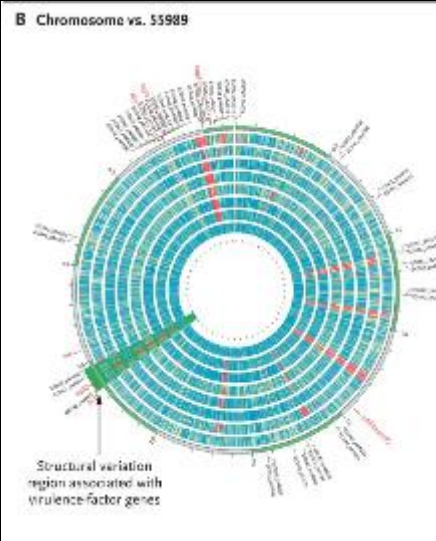
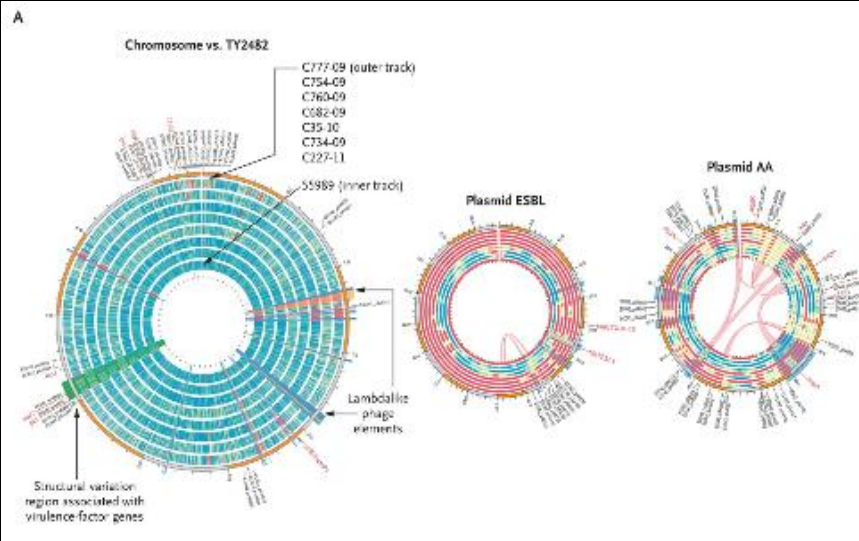
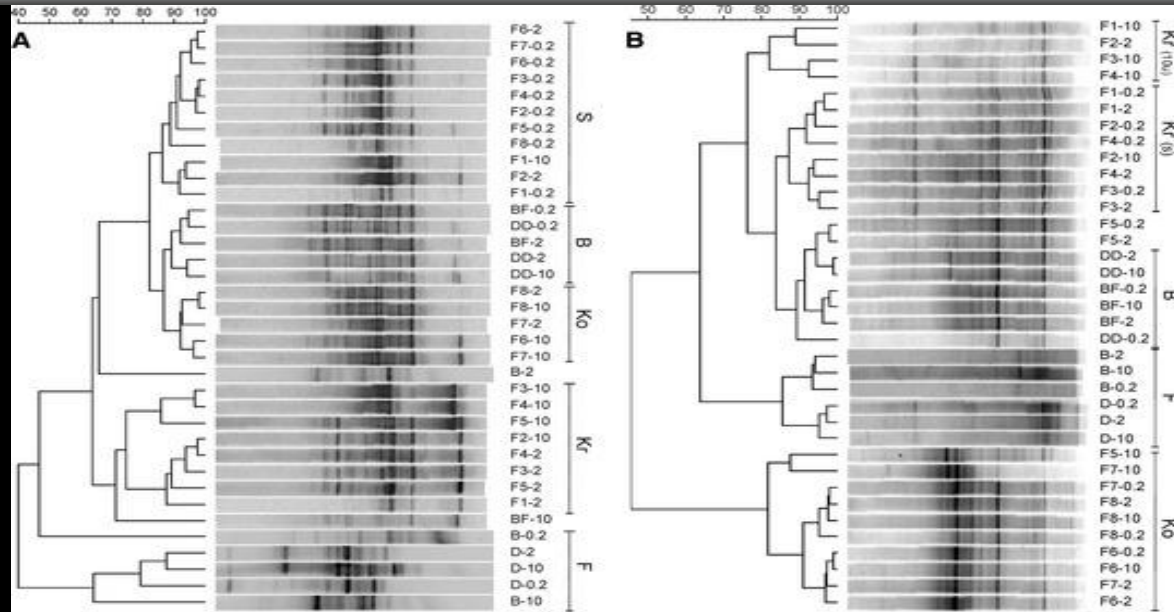
# Technology Platforms for Infectious Disease Diagnostics

## profile the organism

- microarrays and increasingly broad spectrum of pathogen detection
- detection of organism-specific genes or proteins
- limited to 'known' pathogens
- time and cost of sample preparation and pre-analytic variables and impact on TAT
- gene sequencing/mass spectrometry methods ill-suited to distributed rapid, POC detection
  - cost, 'heavy footprint', specialized training
  - value for confirmation and forensics



# E. Coli Strain STEC 0104: H4 (Germany 2011)



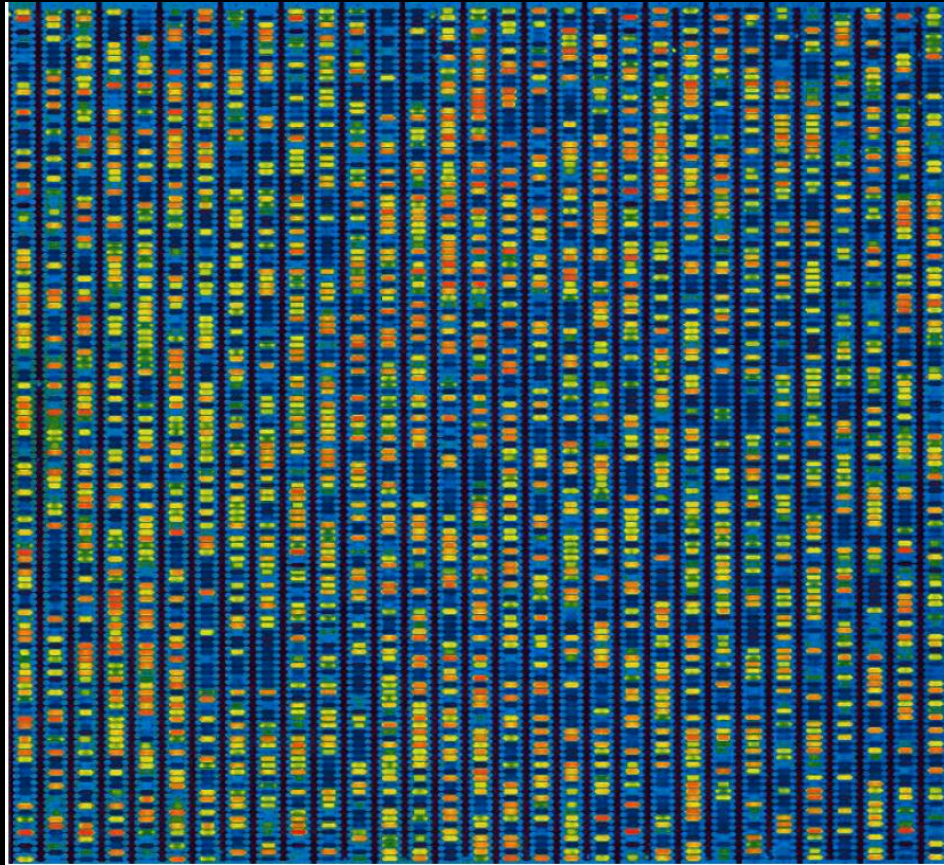
# Design of Technology Platforms for Microbial Diagnostics

## profile the host

- body defense systems as exquisite sentinel of exposure
- not limited to 'known' pathogens
- need for facile, rapid profiling from easily obtained samples (blood, saliva)
  - rapid triage in bioincident
  - population-based biosurveillance



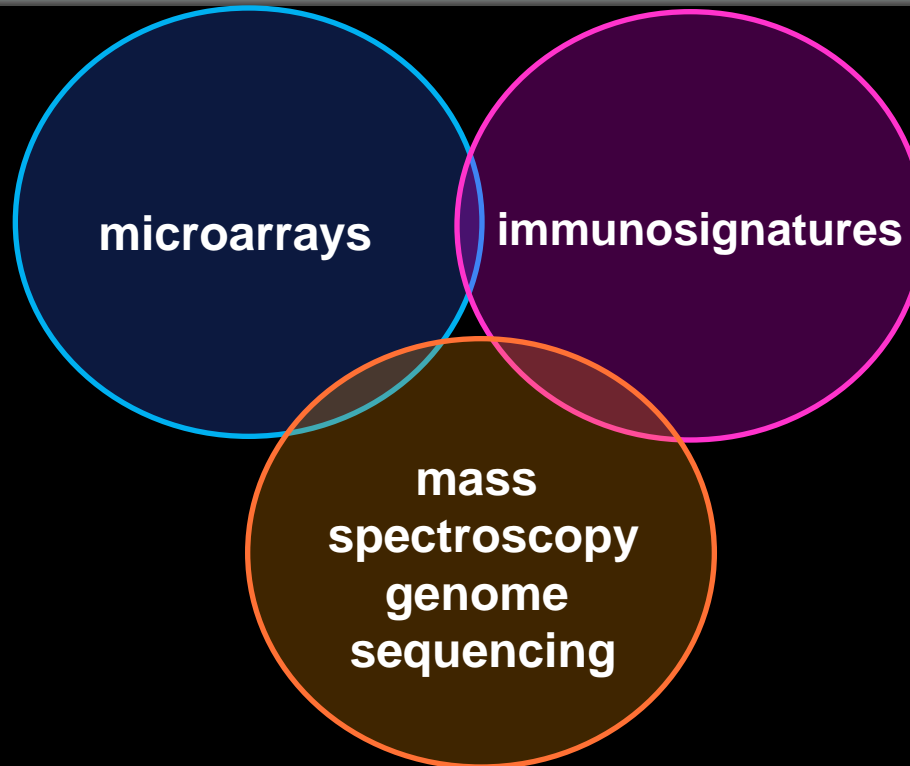
# Immunosignatures: The Sentinel Within



- approx.  $10^9$  different IgG antibodies in healthy adult
- new analytical thresholds reveal faster adaptive immune response than believed previously (pre-symptomatic)
- isotype profiling of dynamic response to infection
- IgG species with long life-time persistence and stable in prolonged specimen storage
- detection of both known and previously unknown agents

# An Integrated Framework of Pathogen Detection Assay Platforms

- known agent<sup>1</sup>
- novel agent<sup>2</sup>
- high cost for population screening
- profiling of food and environmental samples



- known agent<sup>1</sup>
- novel agent<sup>2</sup>
- low cost for population screening
- unsuitable for food and environmental sampling

- confirmatory testing
- forensics
- high cost for population screening

1 = scale of microbial probe set and pre-analytical sample processing

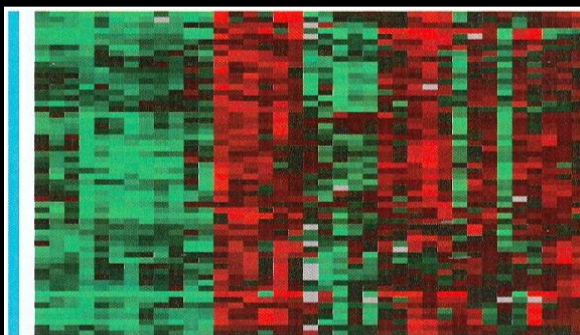
2 = assumes probes have cross-reactivity with new variants of known agents and/or novel/engineered unknowns



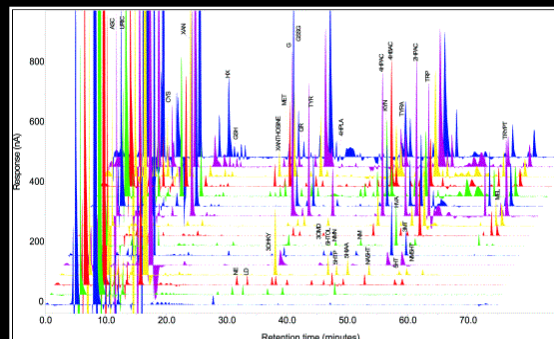
# Analysis and Validation of Multiplex Analysis/Signals from Molecular Diagnostics and Miniaturized Sensors/Devices: New Regulatory Complexities

## Complex Biosignature Profiling

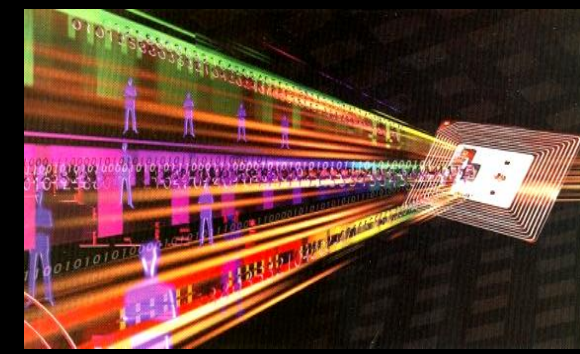
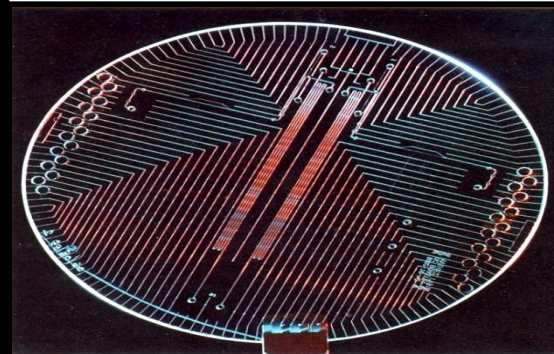
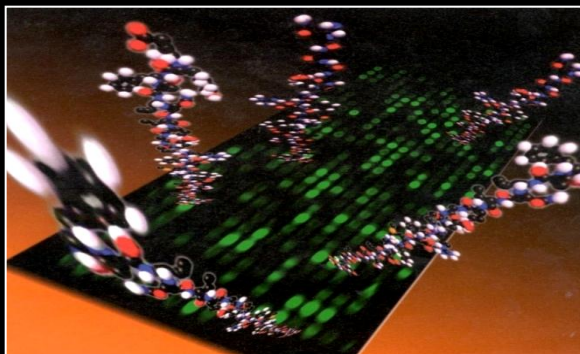
## genomics



# proteomics



## immunosignatures



**automated,  
high throughput  
multiplex assays**

## novel test formats and devices (POC)

**new algorithms  
for complex  
signal deconvolution**

## Signature Detection and Deconvolution Algorithms



# Global Disease Surveillance



**EMERGEncy ID NET**



**Public Health Department's Surveillance**



**U.S. Influenza Sentinel Provider Surveillance Network**



**Quarantine Activity Reporting System (QARS).**

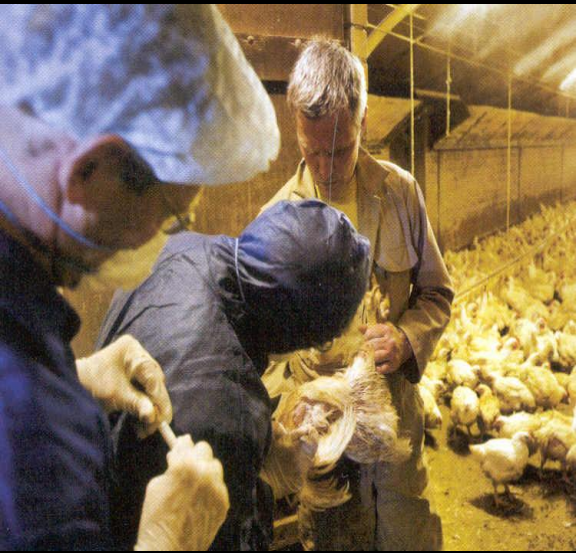




# **Strengthening International Capacity for Surveillance of Infectious and Parasitic Diseases**

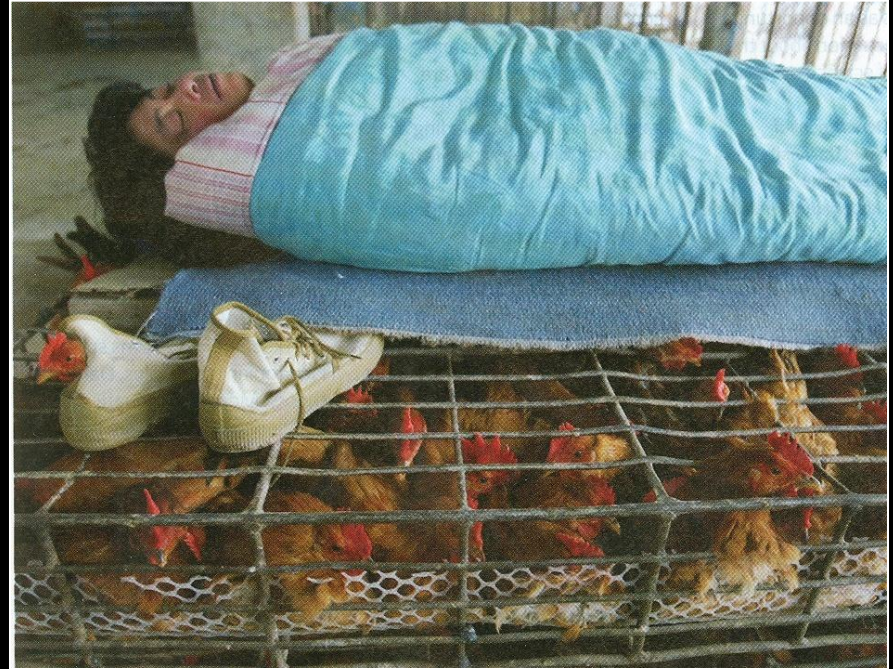
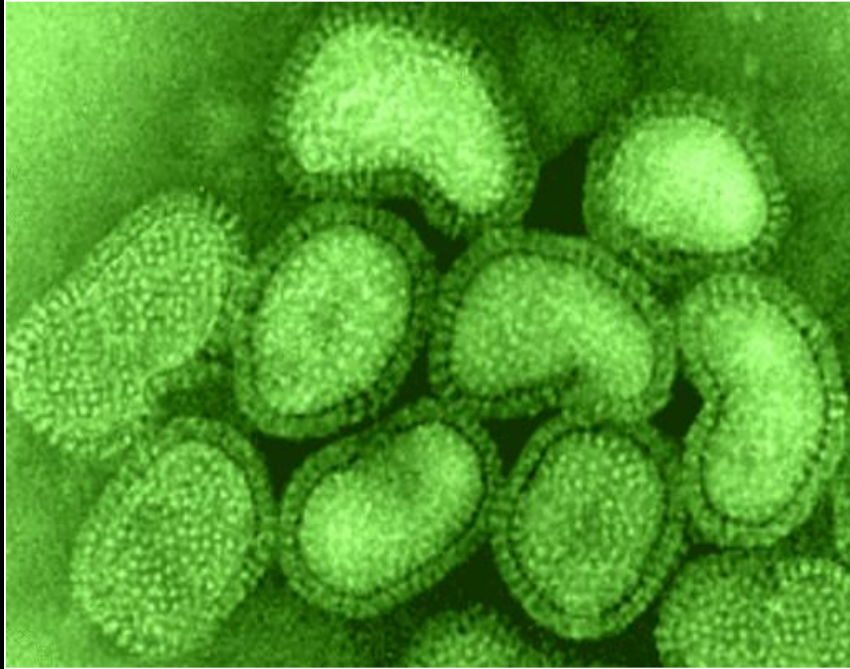
- **faster detection and ID of CBNR Threats and EIDs**
- **emergence of Rx resistance in known agents**
- **ecoshifts in host spectrum**
- **vector-borne diseases and emergence of novel vectors/altered vector range/new-intermediate hosts**
- **zoonotic diseases carried by food animals**
- **sentinel surveillance for food- and water borne diseases**

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





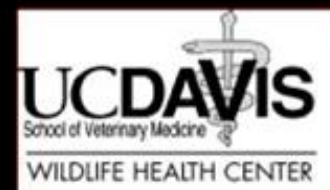
# Maintaining Global Preparedness for a High Virulence Pandemic



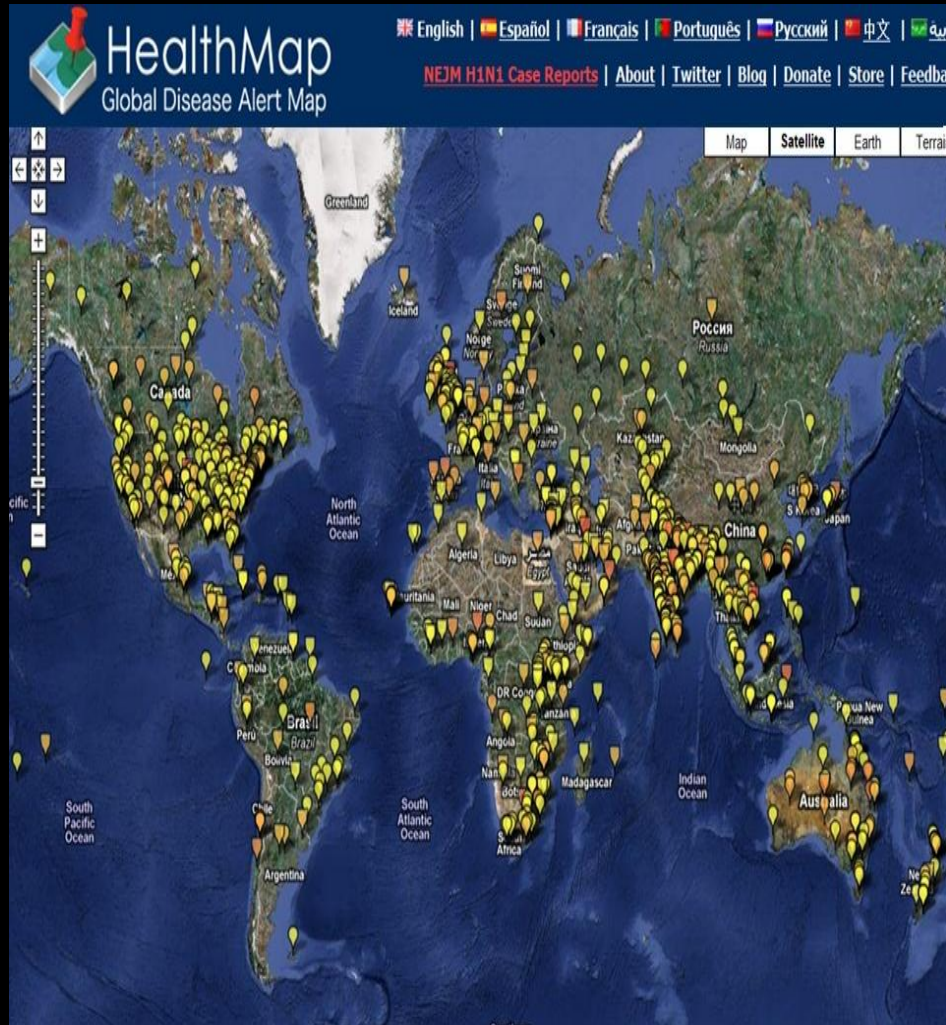
- H1N1: high transmissibility - low virulence/mortality
- H5N1: low transmissibility – high virulence/mortality
- H5N1 x (H1N1) or (X): potential for devastating pandemic



# Global Avian Influenza Network for Surveillance (GAINS)



# Sensor Networks for Remote Health Status Monitoring: Wireless Integrated Data Systems

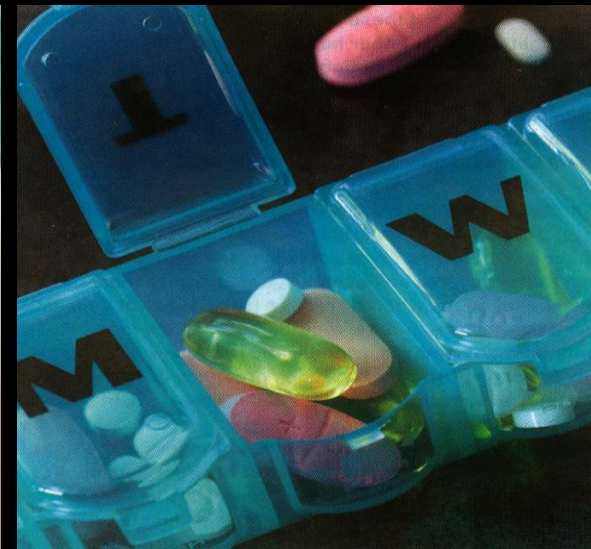
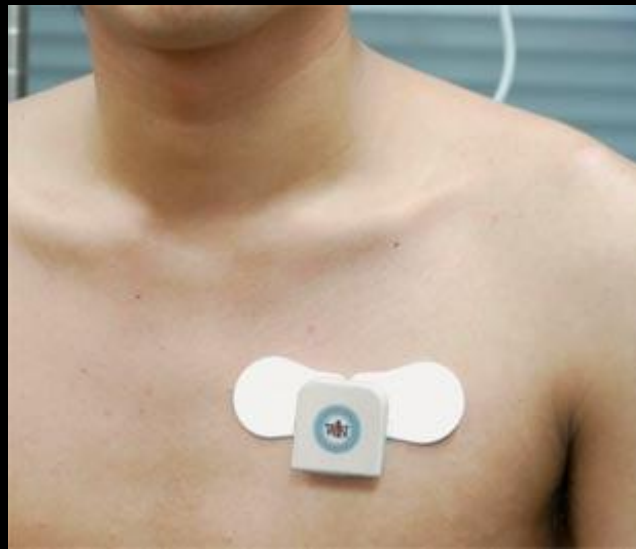


- geolocation data (where)
- temporal information (when)
- contextual information (what)
- improved decision support (action)





# Wireless Devices and Monitoring of Health Status and Rx Compliance

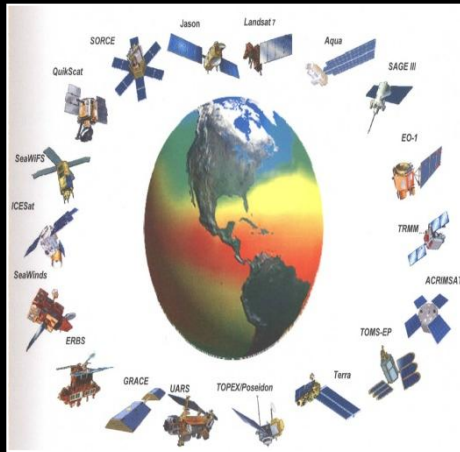
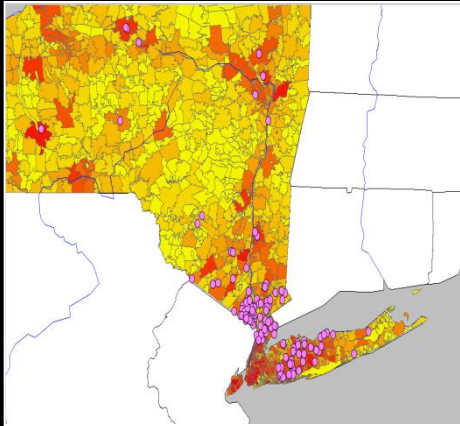


- reduction in device cost and size
- acceleration of sense-response times
- novel power sources and sensor lifetime
- connectivity and network intelligence

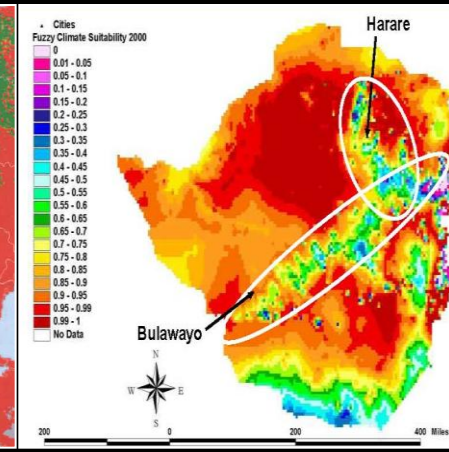
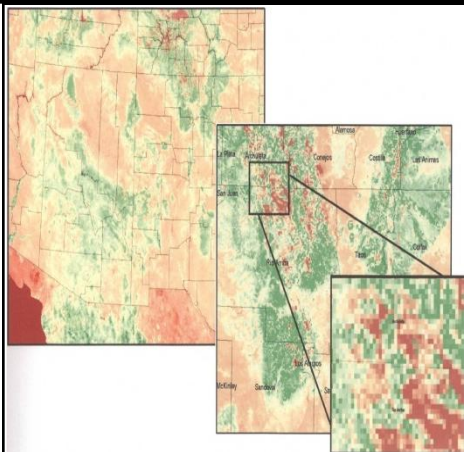
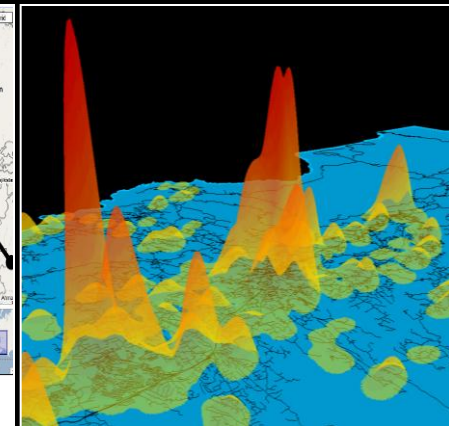
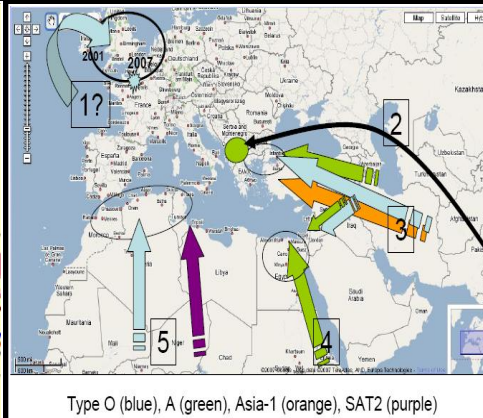
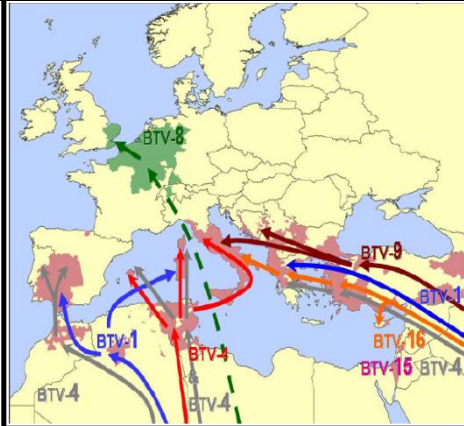


# Geodemographic Information Systems: Mapping Disease Patterns and Modeling Trends

## Anomaly Detection and Early Alert



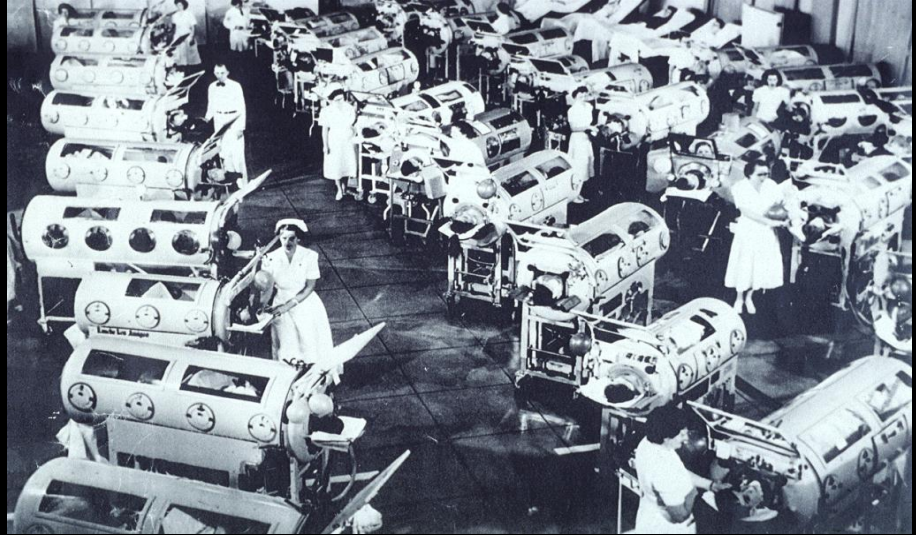
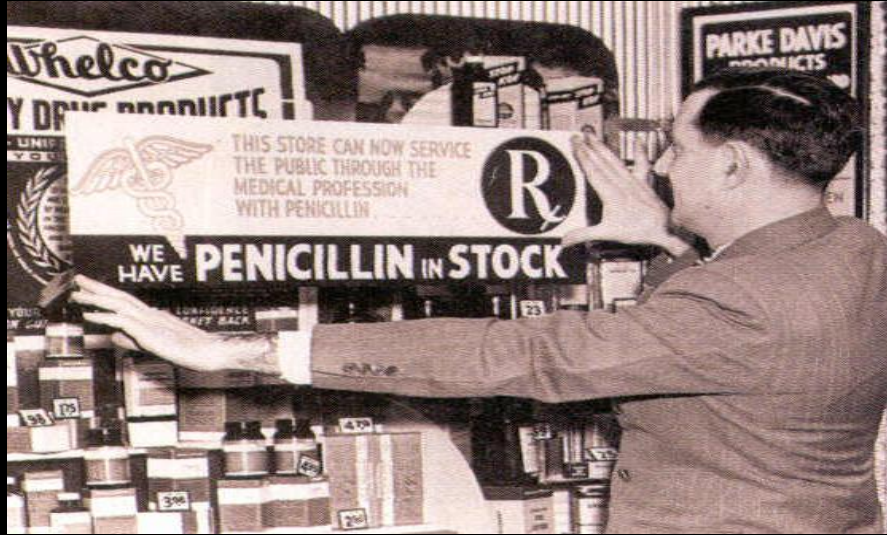
## Disease Progression



## Satellite Surveillance and Predictive Modeling of Disease Trends



# Comfort and Complacency: The Enemies of Vigilance and Preparedness





# NO ESKAPE!: Resistant Bugs and Few New Drugs



- increasing resistance in G<sup>+</sup> and G<sup>-</sup> pathogens in hospital and community settings

- the **ESKAPE** pathogens

*Enterococcus faecium*

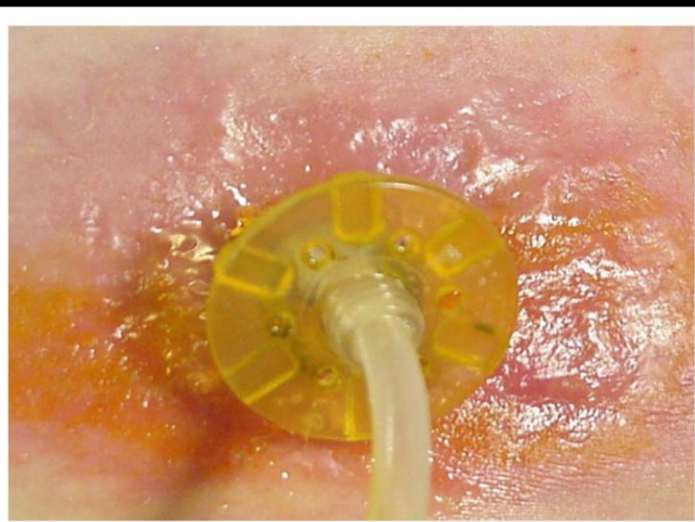
*Staphylococcus aureus*

*Klebsiella pneumoniae*

*Acinetobacter baumannii*

*Pseudomonas aeruginosa*

*Enterobacter species*





# Mobilizing New R&D Initiatives for Antimicrobials



## The 10 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



TECHNICAL REPORT

### The bacterial challenge: time to react

A call to narrow the gap between  
multidrug-resistant bacteria in the EU and  
the development of new antibacterial agents

[www.ecdc.europa.eu](http://www.ecdc.europa.eu)  
[www.ema.europa.eu](http://www.ema.europa.eu)



### Policies and incentives for promoting innovation in antibiotic research

Elias Mossialos<sup>1</sup>, Chantal Morel<sup>2</sup>, Suzanne Edwards<sup>3</sup>, Julia Berenson<sup>3</sup>,  
Marin Gemmill-Toyama<sup>4</sup>, David Brogan<sup>5</sup>



Innovative Incentives for  
Effective Antibacterials





# **The Shift from One Bug, One Drug Strategy to Broad Spectrum Solutions**



**“BARDA will have countermeasures for all of the bioterrorism threats identified by DHS within five years.”**

**“Broad spectrum antimicrobials that are the stockpile and under development will be used to treat many biothreats  
- anthrax, plague, tularemia, typhus, glanders meloidosis and antibiotic-resistant forms of the pathogens causing these diseases.”**

**Robin Robinson, Director, BARDA  
Cited in BioCentury 12 Sept. 2011 p. A2 and A5**



# **Robin Robinson, Director, BARDA**

## **Cited in BioCentury 12 Sept. 2011 p. A2 and A5**



**“BARDA will have countermeasures for all of the bioterrorism threats identified by DHS within five years.”**

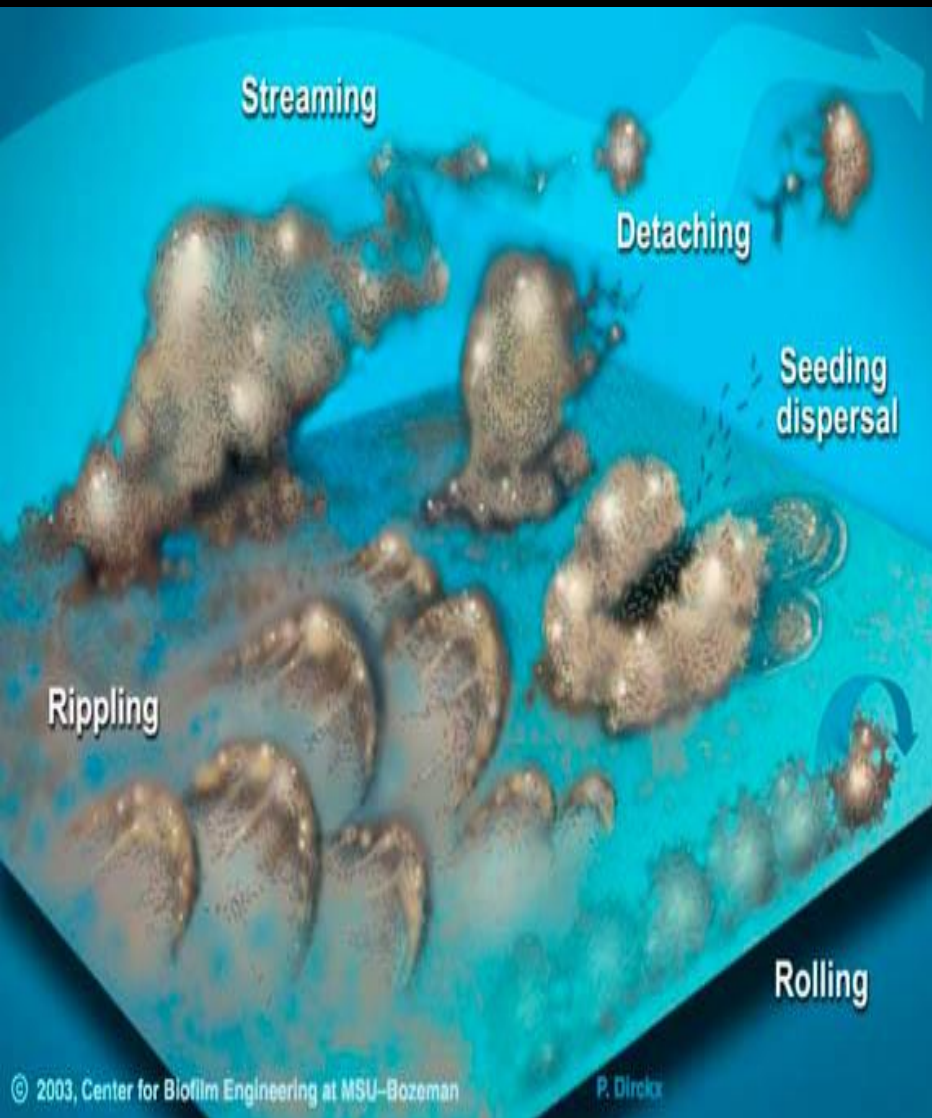
**“Broad spectrum antimicrobials that are the stockpile and under development will be used to treat many biothreats**  
**- anthrax, plague, tularemia, typhus, glanders meloidosis and antibiotic-resistant forms of the pathogens causing these diseases.”**

**“Robinson did acknowledge that combinations of new drugs will probably be needed.”**

- strategic risk from resistance to such agents not addressed**



# New Strategies for Bacterial Biofilm Formation/Disruption



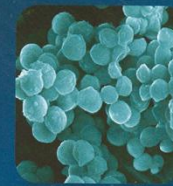
## MRS Bulletin

May 2011 Vol. 36 No. 5  
[www.mrs.org/bulletin](http://www.mrs.org/bulletin)

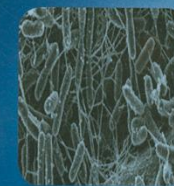


MATERIALS RESEARCH SOCIETY  
*Advancing materials. Improving the quality of life.*

**All together now: Integrating  
biofilm research across disciplines**



Social Networking



NanoWired



Walking Maps



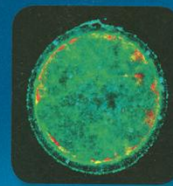
Tendrils



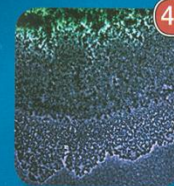
Self-Organization



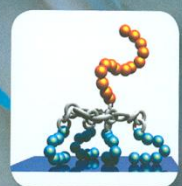
Marangoni Martinis



(bio)Film Review



Quorum Messenger



Interfaces

49

# **The Extrapolation/Predictability Challenge in Achieving “Animal Rule” Acceptability for MCM**

- **improved guidance to sponsors needed**  
**but**
- **significant unresolved ambiguities acknowledged**
  - **non-permissive refractoriness of animal species to uniquely human pathogens**
  - **cross-species variation in pathogenesis and patterns of innate/adaptive immunity**
  - **need for new biomarkers for cross-species correlations of immune protection, bioactivity, toxicity**
- **potential value but yet to be validated**
  - **ex vivo human substrates (ESC lines, “organ-on-a-chip” bioengineering”)**
  - **‘virtual human’ advanced computing for PDPK modeling**



# MCMs for Special Populations

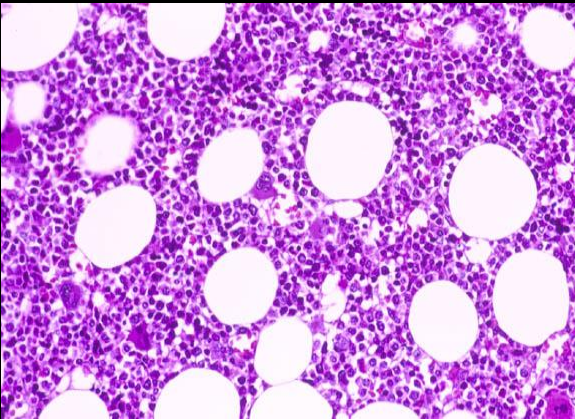
**Children**



**Pregnant**



**Aged?**



**Immunosuppressed**



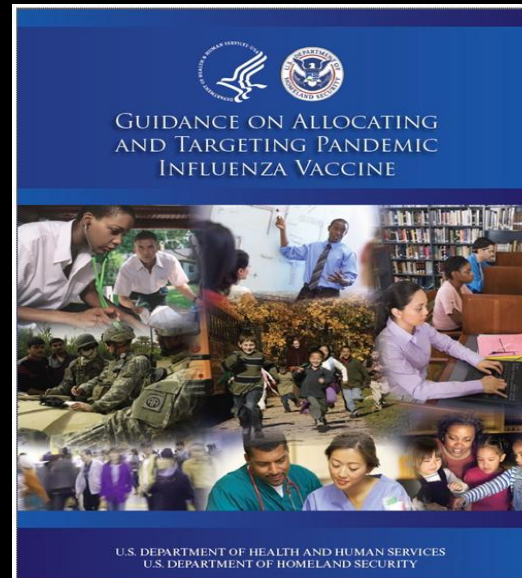
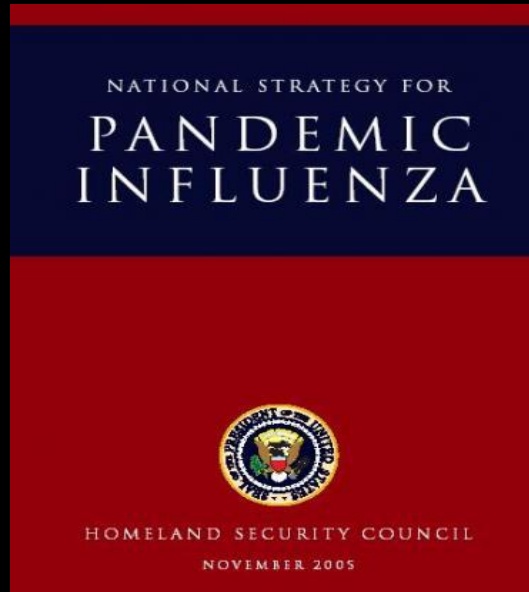
**Impaired Major  
Organ Function**



**ICU-Critical Care**



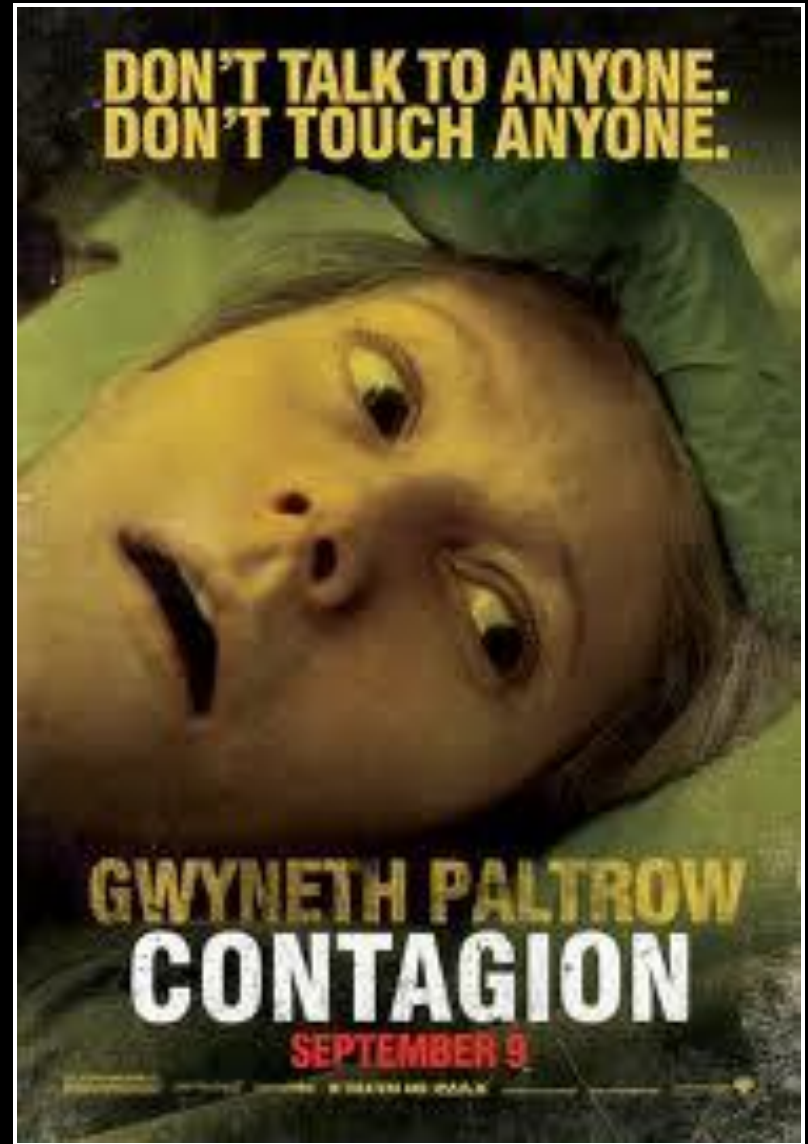
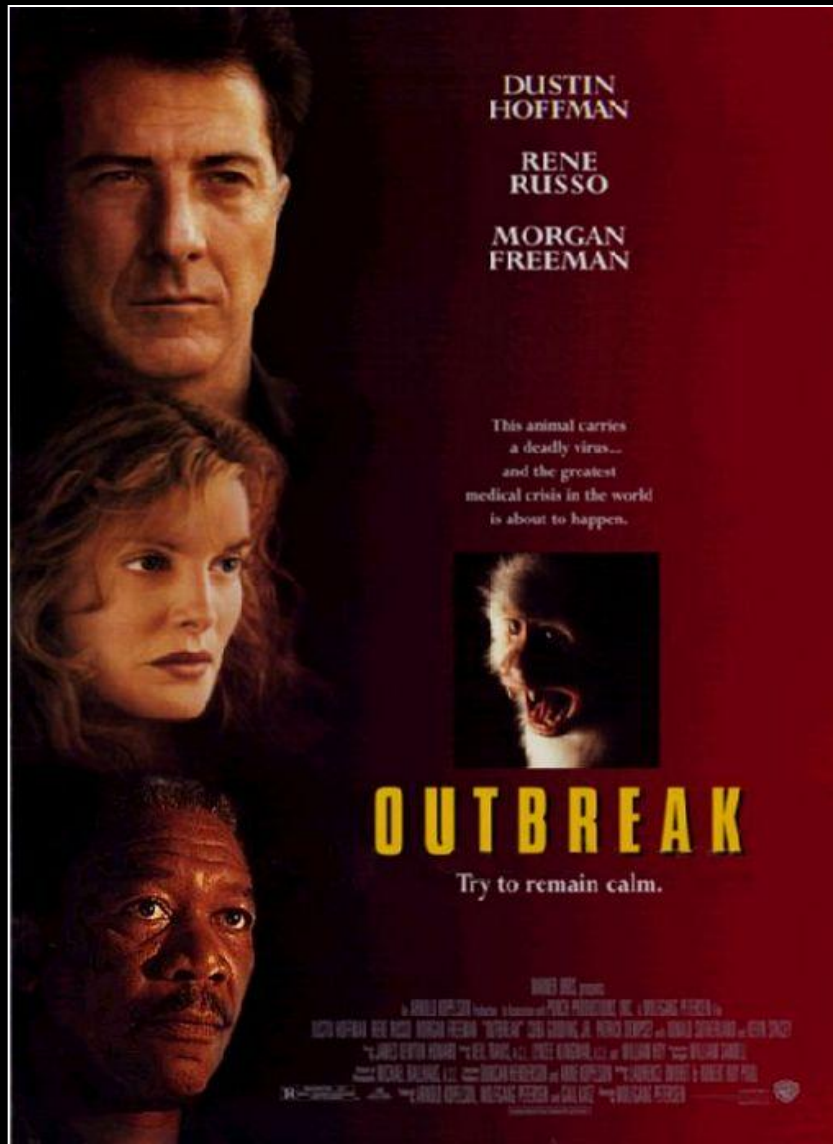
# The Imperative for Innovation in Vaccine Production Technologies



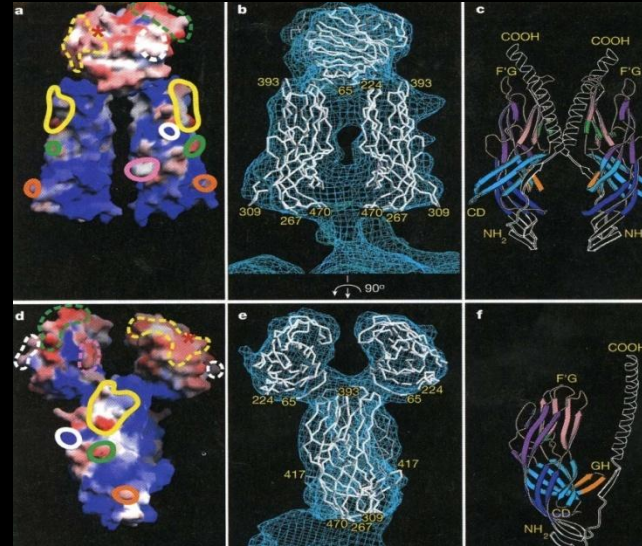
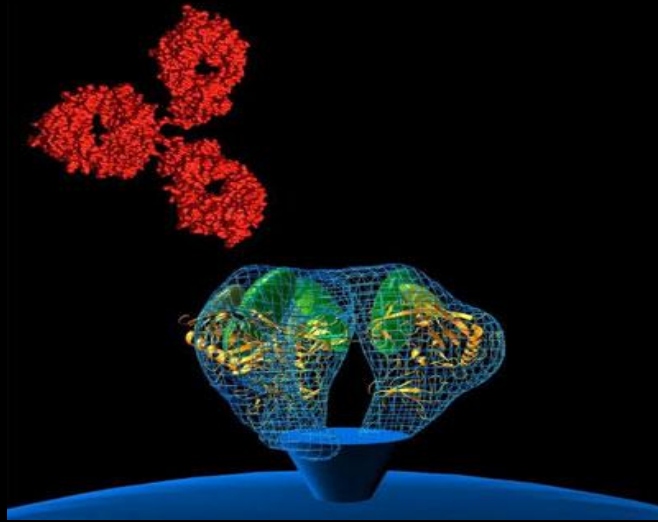
**“If this virus was killing more of its victims,  
there’d be lots of questions about whether  
this vaccine was produced soon enough”**

**Dr. Michael Osterholm  
Director, CIDRAP, Univ. Minnesota  
USA Today 8 Oct. 2009**

..... and then a technical miracle cure occurs with dramatic rapidity  
..... and always created by an individual scientific genius



# Combating 'Agent X': Transforming Vaccine Development

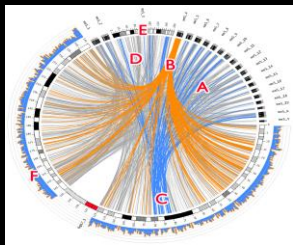


- convert vaccine production from a 'biologics' process to a 'chemical' manufacturing process
- reduce R&D cycle from 10-25 years to less than 1 year
- shorten production cycles run-time from 6-12 months to days/weeks



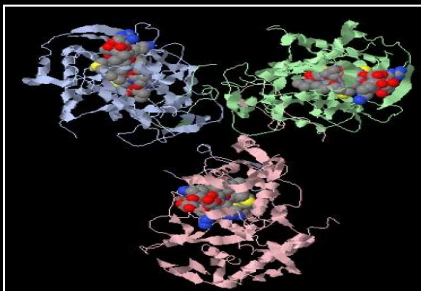
# Combating 'Agent-X'

## The Imperative for Next-Generation Vaccine Technologies



- rapid genome sequencing of the new pathogen
- computational bioinformatics to identify genes coding for proteins with features likely to trigger immunity plus epitope mapping
- profile 'early survivors' for immune response to vaccine candidates identified by bioinformatics
- produce candidate vaccine protein(s) candidates by rDNA/synthetic biology
- evaluate immunogenicity in animals/people

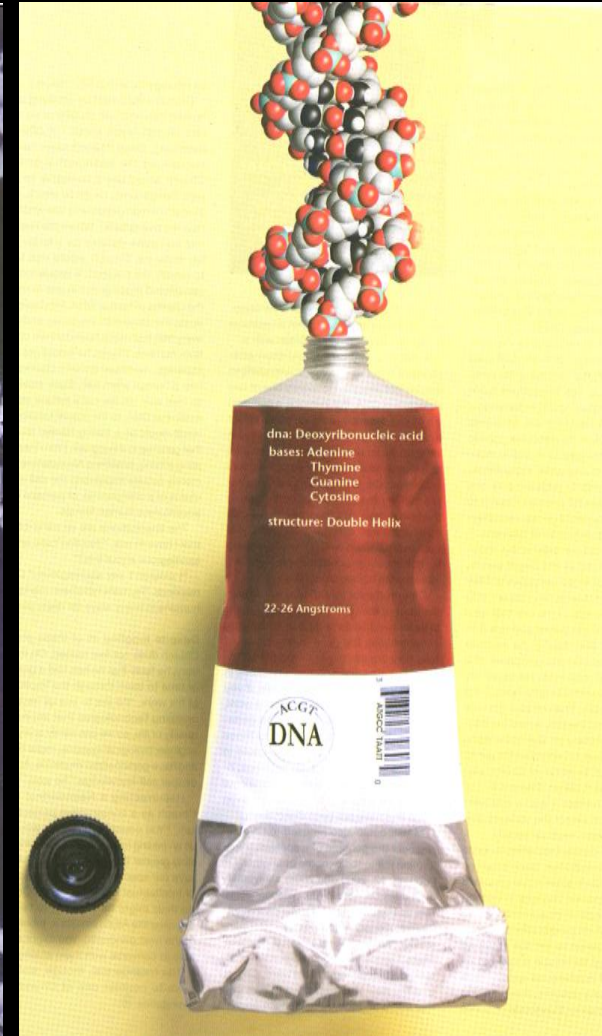
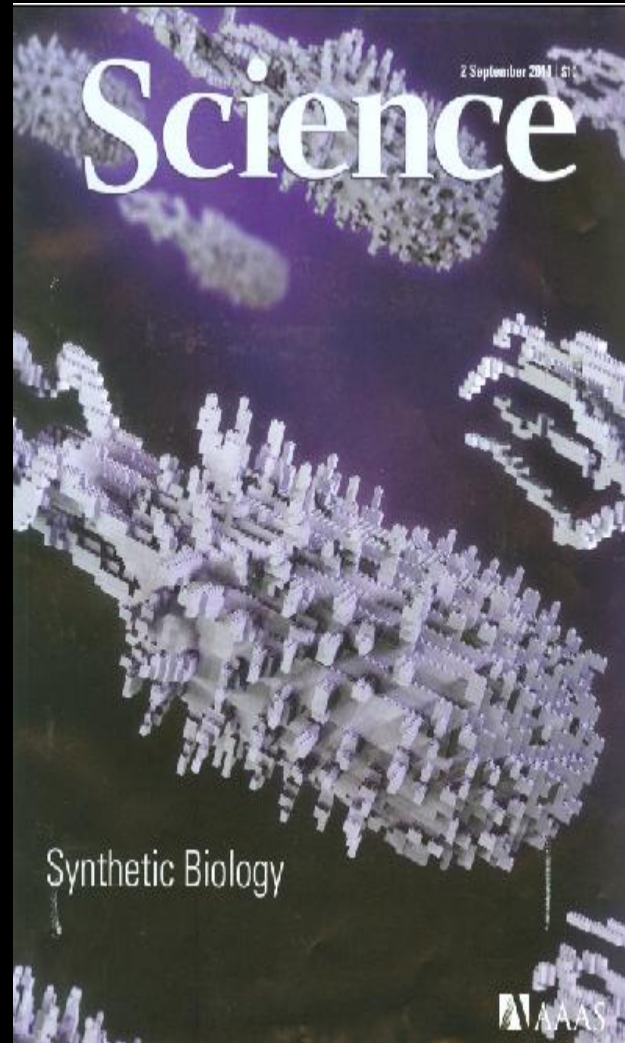
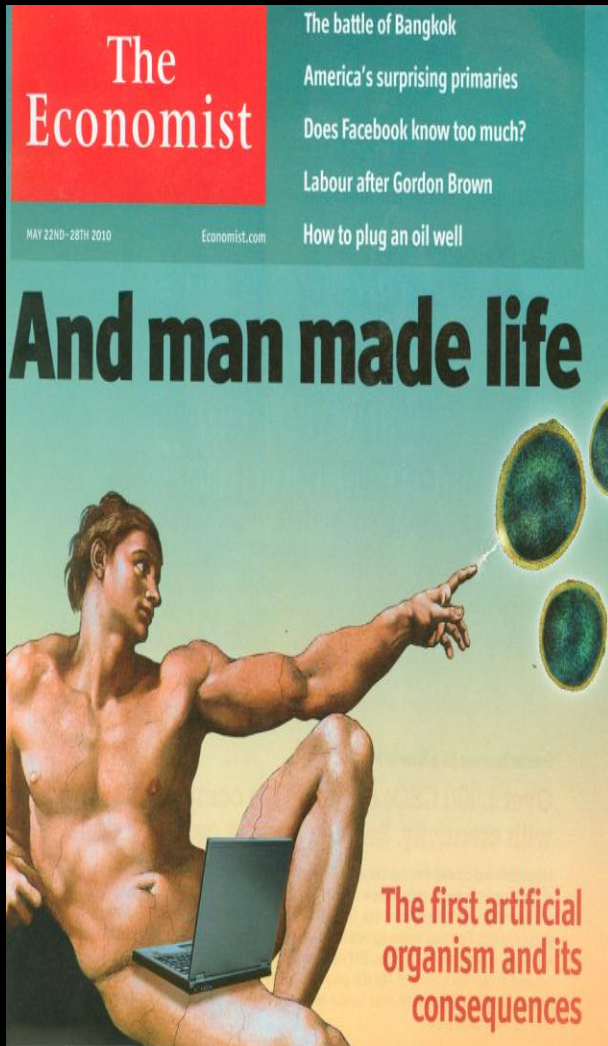
# Combating 'Agent-X'



- **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)**



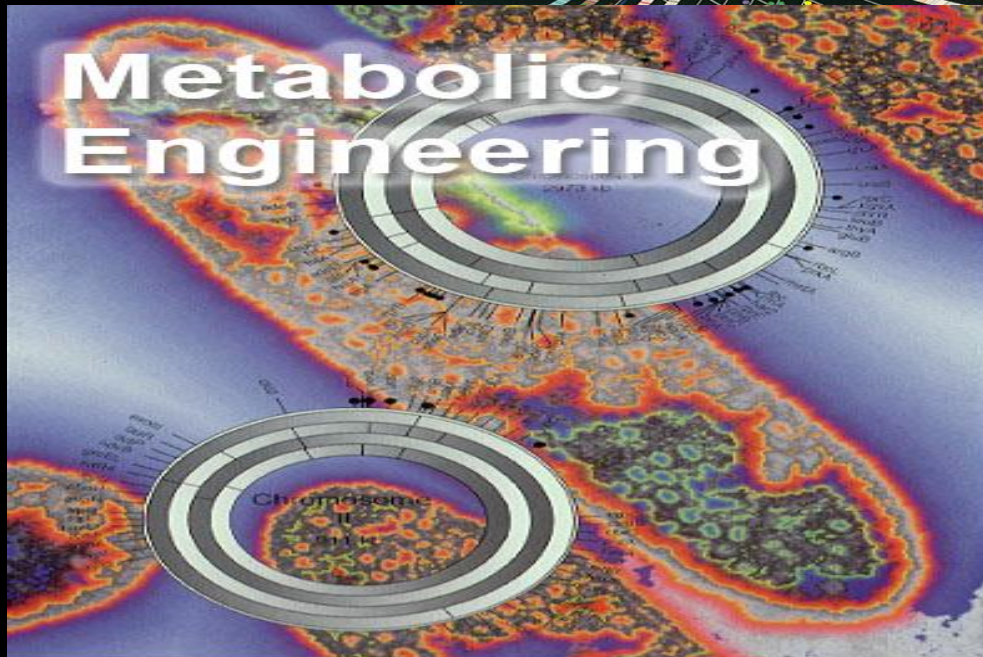
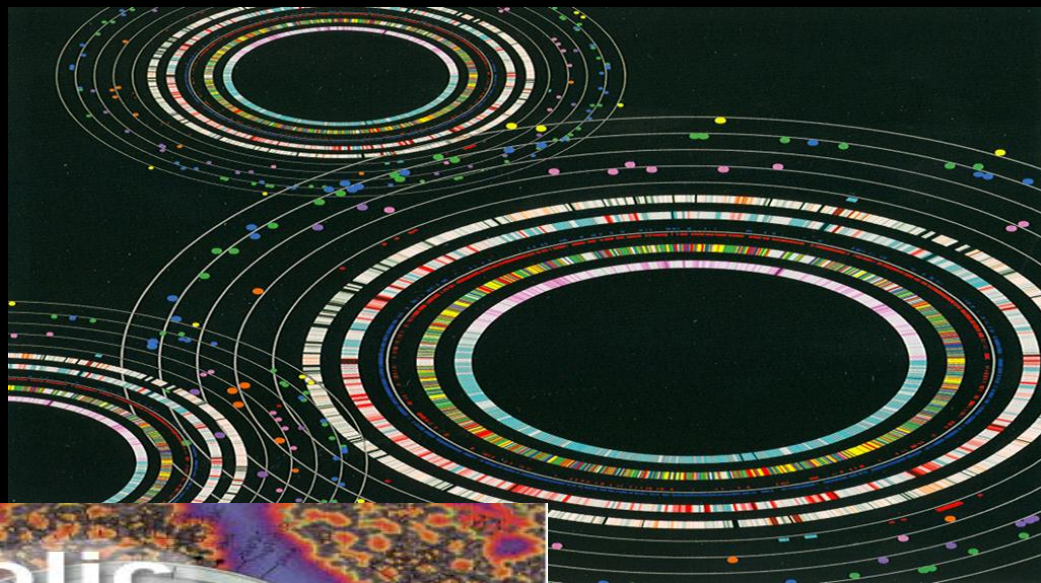
# Synthetic Biology





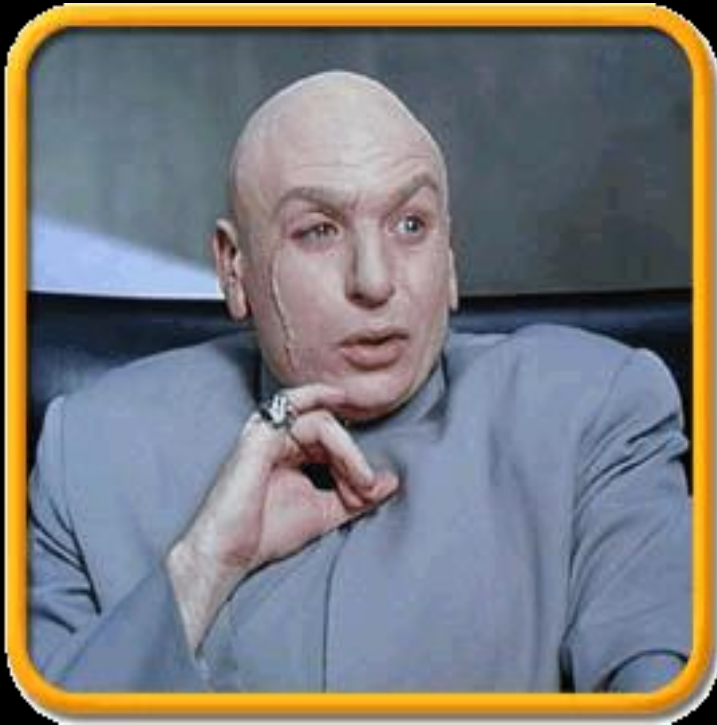
# Synthetic Biology: Engineering Novel Organisms with Novel Functions

**Programmable  
Genomes**



**A New Industrial  
Ecology and Novel  
Biosynthesis**

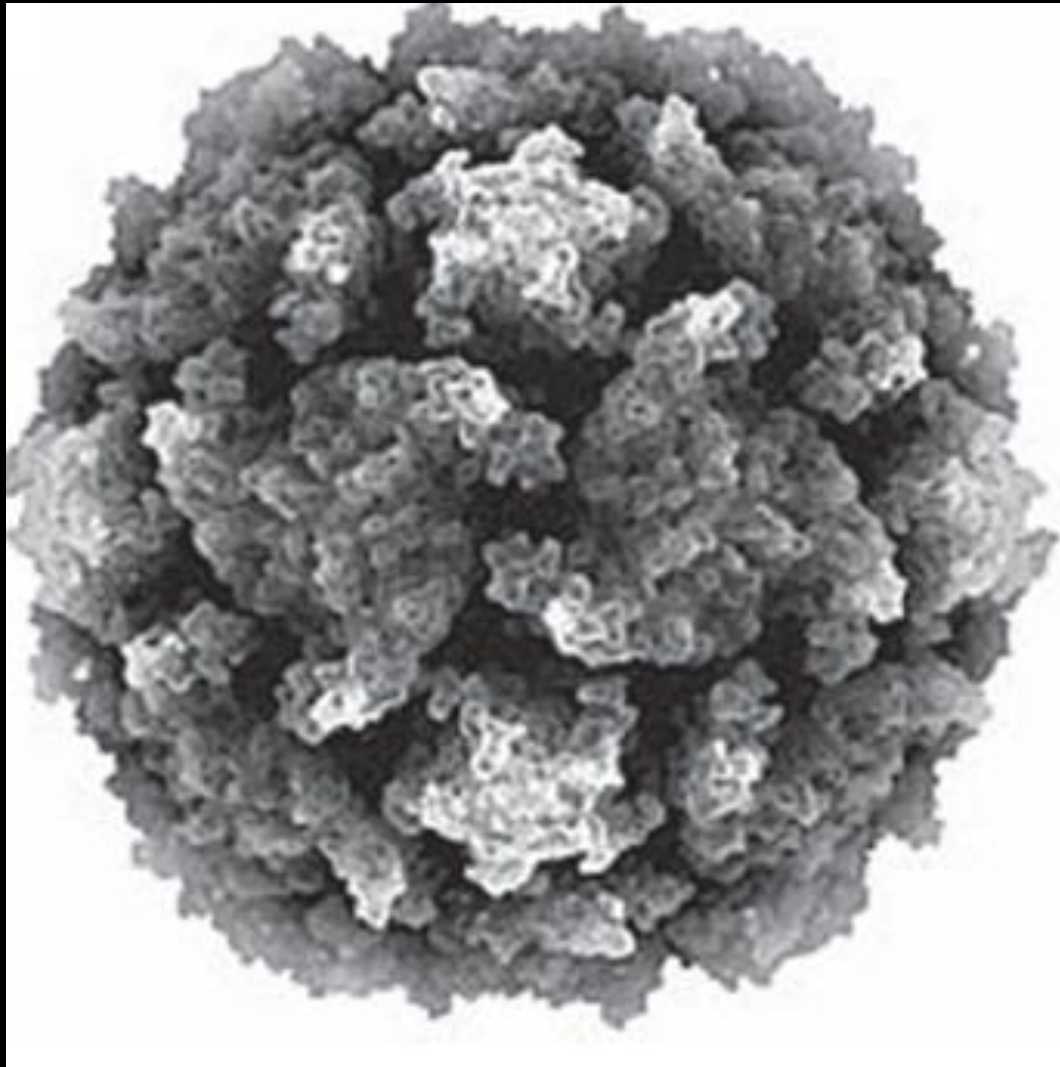
# Future Trajectory Trends and Threat Expansion



**New 'Dual-Use' Technologies**

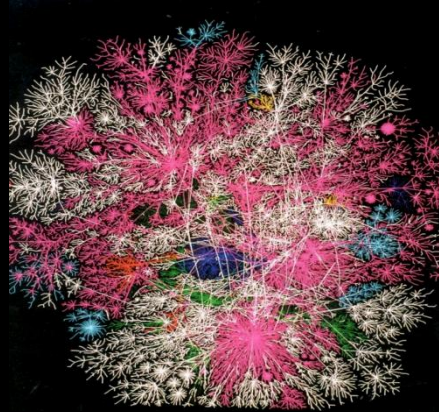
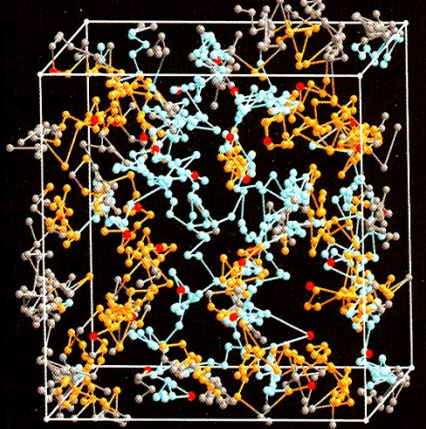


**C332,652; H492, 388; N98, 245; O131, 196 P7, 501; S2,340  
(a.k.a. poliovirus)**



**ATTGACTGCAA .....(design specifications)**

# The Dual Use Dilemma in Life Sciences R&D



- **future biothreats will not be limited to microorganisms**
- **mapping of genetic control circuits/networks for key homeostatic functions**
  - **major advances in medicine**
  - **simultaneous ID of “nodes” for perturbation**
- **creation of biological circuit disrupters (BCDs) will be easier than microbial modification**
  - **screening of large combinatorial chemical libraries**
  - **small molecule BCDs**



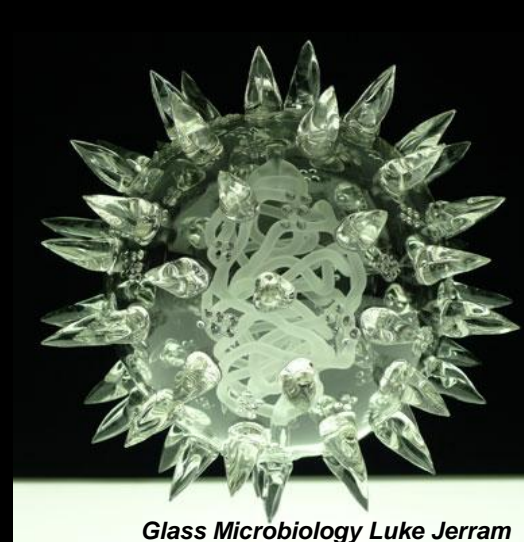
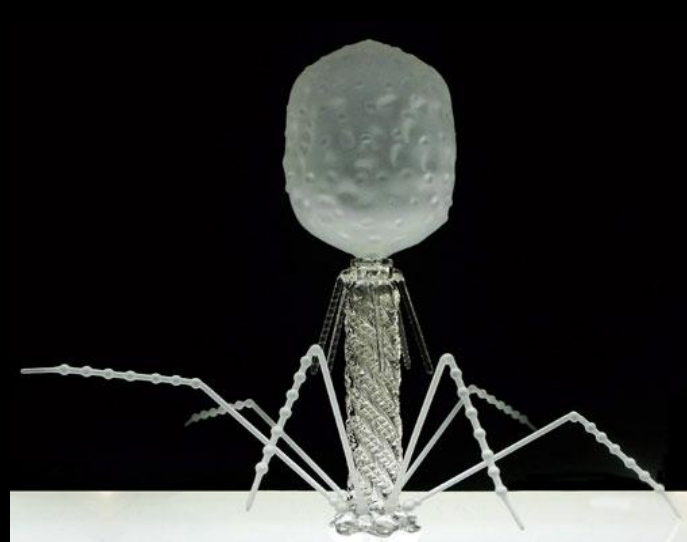
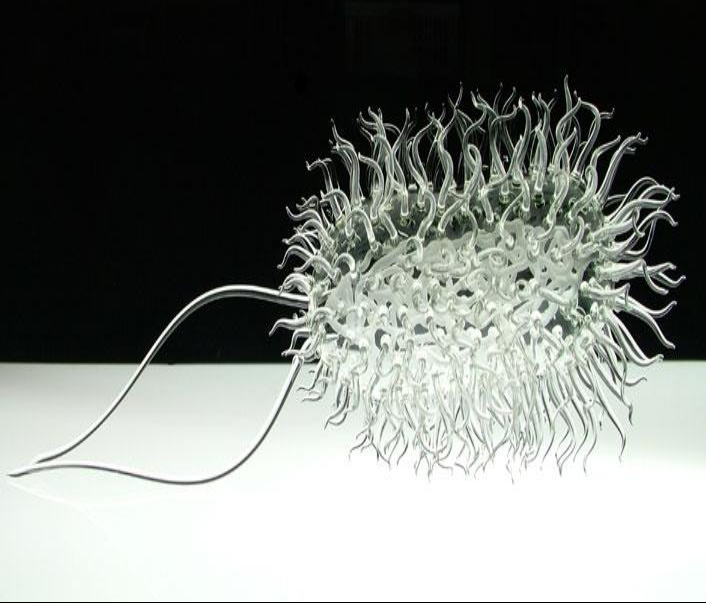


## Chemo-Genomics

- identification of chemical structures (or series) as ligands for specific binding to every human gene product
- new repertoire of research tools for perturbation of specific proteins, pathways, and networks

Instructive Template for New Generation of Chem-Bio Weapons:  
Biological Circuit Disrupters (BCDs)?

# Engineered Microorganisms as Health Status, Sentinels and Therapeutic Delivery Systems



*Glass Microbiology Luke Jerram*



# GLOBALIZATION, BIOSECURITY, AND THE FUTURE OF THE LIFE SCIENCES

## New approaches to biological risk assessment



Science  
Policy Centre  
INTERNATIONAL  
WORKSHOP

web: [royalsociety.org/policy](http://royalsociety.org/policy)

twenty ten | 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 NATIONAL ACADEMIES

# Synthetic biology

2 and 3 June 2008



scientific  
DISCUSSION MEETING  
SUMMARY

web: [royalsociety.org](http://royalsociety.org)

twenty ten | 350 years of  
and beyond | excellence in science

# SYNTHETIC BIOLOGY

A NEST PATHFINDER INITIATIVE

# postnote

July 2009 Number 340

## THE DUAL-USE DILEMMA



Department of Health and Human Services

## SCREENING FRAMEWORK GUIDANCE FOR PROVIDERS OF SYNTHETIC DOUBLE-STRANDED DNA





# Novel Materials for Warfighter Protection and Performance Enhancement



- medical management capabilities
- minimize kinetic injuries
- shock management
- traumatic brain injury



- light weight composites
- novel power sources
- organic photovoltaics



- rapid detection CBW
- interface with networked sensors



- switchable surfaces
- metamaterials
- tag signature for MOUT



## Who Pays for Preparedness?



## The Obligate Role of Private-Public Partnerships in Biosecurity Policy



# Who Pays for Shared Global Risks from Infectious and Parasitic Diseases?

**“Fewer countries have discovered, developed and registered drugs to an international standard, than have developed atomic bombs”**



**Chris Hentshel**

**Medicines for Malaria Venture**

**Lancet (2004) 363, 2198**



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

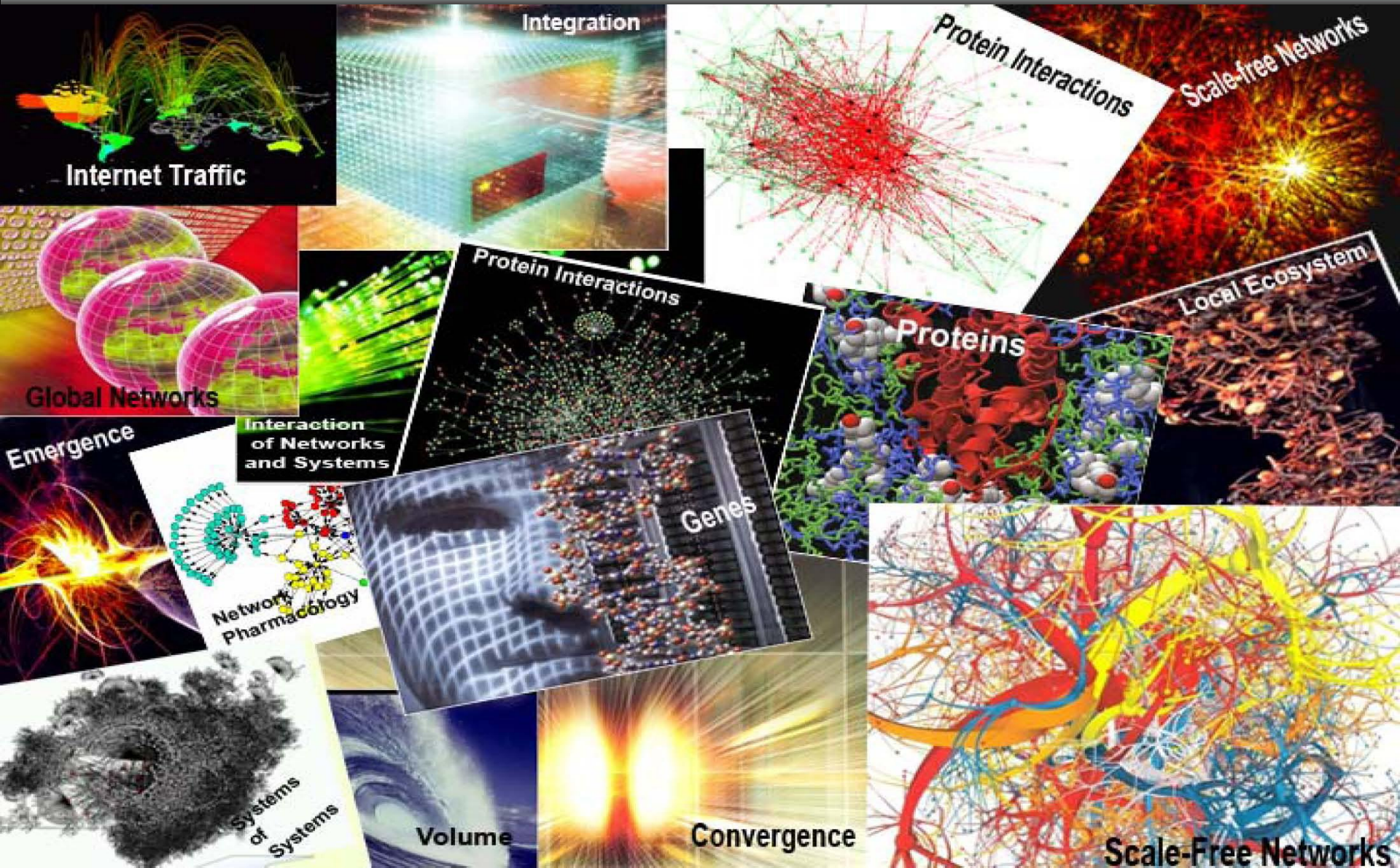
**Sen. J. Lieberman (I-CT)  
2006**



# **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’**

# Data: The Fastest Growing Resource on Earth





# “Managing Mega-Data”

volume



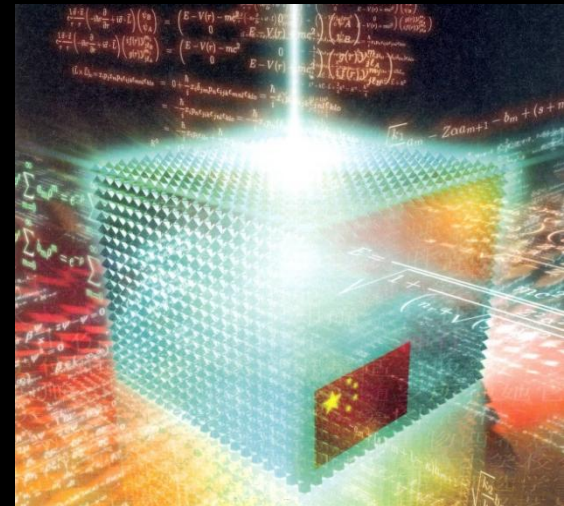
infrastructure



global networks



multiscale heterogeneity



integration

Key Policy Issues:

Funding and Priorities

Plus

Transparency, Accomplishments and Accountability

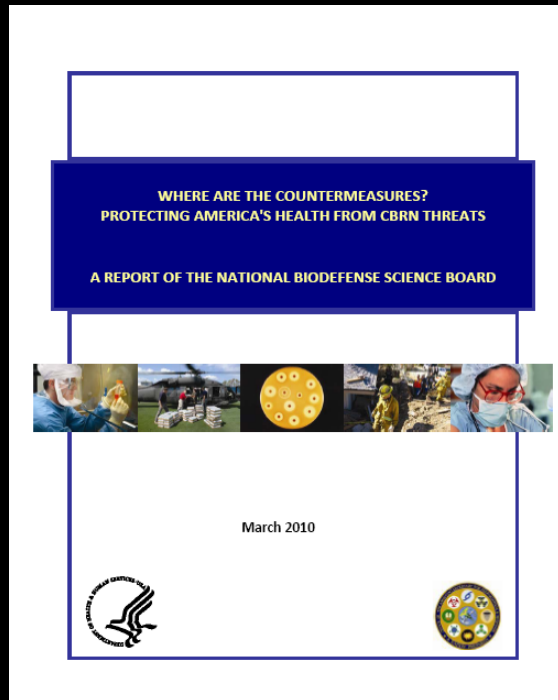


# Where Are The Countermeasures?

NATIONAL ACADEMY OF SCIENCES  
THE NATIONAL ACADEMIES

**“Biowatch faces serious technical and operational challenges”**

**US National Academies Report:  
Biowatch and Public Health Surveillance, 2010**

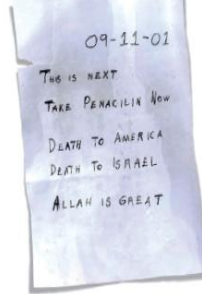


**“America expects orchestration within HHS’s scientific endeavors, not cacophony”**

**Where Are the Countermeasures?  
National Biodefense Science Board Report 2010**

# Assessing ROI from USG Biodefense Investments

Nature (2011) 477, 150



Since the anthrax attacks in 2001, some \$60 billion has been spent on biodefense in the United States. But the money has not bought quite what was hoped.

## THE PRICE OF PROTECTION

BY ERINA GREGG HAYDEN

From: Nature (2011) 477, 380



## BioCentury

U.S. biodefense score card 10 years and \$20B after 9/11 and the anthrax attacks

### Biodefense report card

By Steve Usdin  
Washington Editor

Published on Monday, September 12, 2011



# Broad Objectives But No Milestones or Metrics



U.S. Department of Health and Human Services  
Assistant Secretary for Preparedness and Response

## The Public Health Emergency Medical Countermeasures Enterprise Review

*Transforming the Enterprise  
to Meet Long-Range National Needs*

August 2010



U.S. Department of Health & Human Services

## 2010 National Vaccine Plan

*Protecting the Nation's Health through Immunization*



Testimony  
Committee on Health, Education,  
Labor, and Pensions  
United States Senate

## A Nation Prepared: Strengthening Medical and Public Health Preparedness and Response

Statement of  
**Nicole Lurie, M.D., M.S.P.H.**  
Assistant Secretary for Preparedness and Response  
RADM, U.S. Public Health Service  
U.S. Department of Health and Human Services



For Release on Delivery  
Expected at 2:30pm  
Tuesday, May 17, 2011

# **The Need for Defined Goals, Timelines and Performance Transparency**

**“The report (Transforming the Enterprise to Meet Long Range National Needs)” doesn’t tell us exactly what vaccines and countermeasures we need to buy .....how much money it will take, doesn’t give timelines or place them in order of priorities.”**

**Tom Ingelsby, UPMC Center for Biosecurity  
Biocentury, 12 Sept. 2011, A7**

**“NIAID hasn’t invested in the development of public databases, reports or studies that would help Congress or the public track its investments in countermeasures or link grants and contracts to tangible results.”**

**S. Udin, Biocentury 12 Sept. 2011, A1-A10**



## Key Policy Issues:

Roles, Responsibilities and Authorities  
in  
Cross-Agency Integration  
and  
Building/Sustaining Critical MCM Capabilities

# From Silos to Systems





# Addressing Global Challenges in Biosecurity

- **mobilize new expertise networks to achieve end-to-end solutions**
  - from concept to fielded product
- **funding support dependent on assembly of requisite expertise**
  - cross-disciplinary, cross-sector
  - obligate role of industrial partners
- **sophisticated management of complex skills network whose composition will change with technology maturation**
- **financial incentives for industry for product classes with no civilian markets**
- **harmonization of regulatory policies to allow accelerated review and adoption**



## **Daunting Responsibilities as the Principal Custodian of the Nation's Trust For Oversight of Assets Representing c.25% GDP**

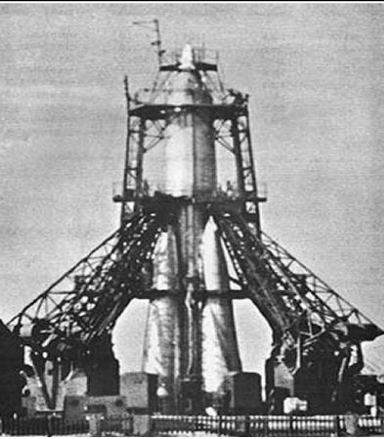
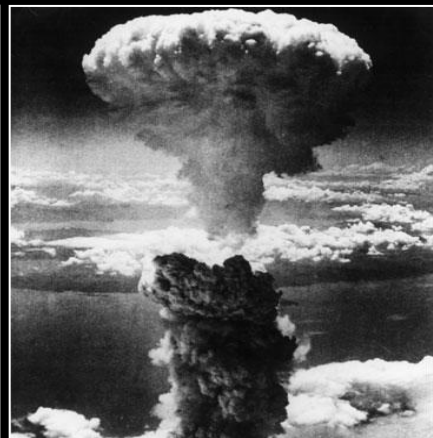
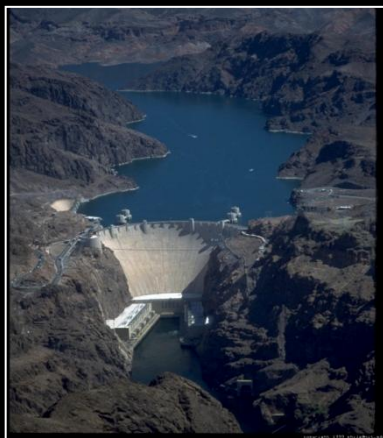
- **burgeoning agenda of increasingly diverse products and services**
  - **maintaining technical, clinical, statistical and legal expertise and critical mass**
- **agile adaptation to acceleration of scientific introduction of discovery, new technologies and trans-sector convergence**
  - **life sciences, engineering, electronics, telecommunications, computing**
  - **new combination products and new metrics**
- **QA/QC for increasingly outsourced global supply chains for products/intermediates and escalation of counterfeit materials**



# Essential Attributes (5A's) for Development of Robust MCM Capabilities

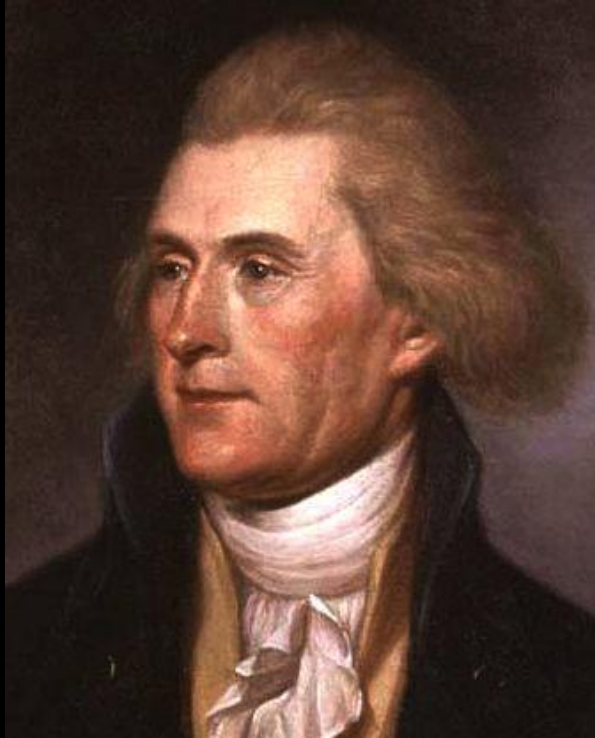
- **all hazards**
  - diverse natural and malevolent threat spectrum
  - daunting product needs catalog and diverse technologies
- **awareness**
  - material threats, dynamic risk assessment and mastery of complex S&T advances
- **anticipatory**
  - priorities and access to requisite expertise
- **agility**
  - fluid expertise networks and new partnerships
- **action oriented**
  - goal and mission-oriented, aggressive timelines
- **accountability**
  - Transparent lead authority, goals and metrics, deliverables
- **authoritative advocacy**
  - leadership, successful mobilization of resources, creation of P3 consortia and seamless inter-agency coordination

# Meeting Previous Grand Challenges





# An Age of Enlightenment



**“Science is a tool against despotism  
and feudal barbarisms  
I rejoice that the American mind  
is already too much opened to retreat  
from it’s commitment to science”**

**Thomas Jefferson, 1799**

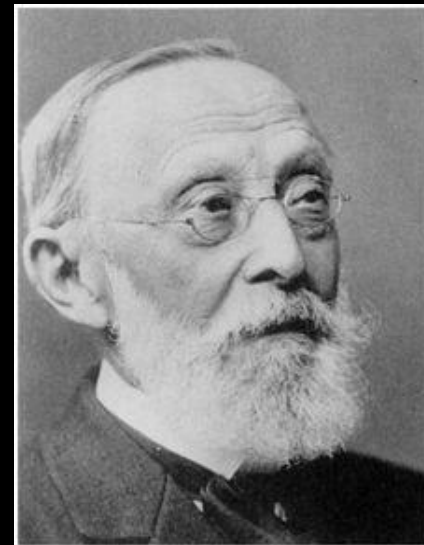
**“Politics is the art of the possible,  
the calculated science of survival”**

**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/>

