Biosecurity:
Enhancing Security in an Unsecure World

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

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
- New capabilities for threat ID and pre-emption
- Robust homeland defense
- 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:

- Chikungunya
- Rift Valley
- Sin Nombre
- West Nile
- Ebola (Reston)
- DHF
- Lassa
- Marburg
- O’nyong nyong
- TBE
- Avian flu
- SARS
- Kyasanur Forest Disease
- Nipah
- Chandipura
- Barmah Forest
- Hendra
- Ross River
- JE

Legend:
- Arthropod-borne
- Rodent-borne
- Other (including bats)
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

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

World Container Traffic Doubled Since 1997

Billion Cross-Border Travelers

Global Food Networks
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.
The Global Food Supply and Food Borne Pathogens

- Food chain increasingly complex, international and inter-dependent
- Food production over next 25 years ≅ 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
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)¹²³, J Huang⁴, Z Xie⁴, the Foresight China Project Group⁵

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
“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 acceleration

technology convergence

dual-use applications

• new strategic spaces

• new strategic surprises?

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

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<thead>
<tr>
<th>Systems and Synthetic Biology</th>
<th>Ubiquitous Sensing</th>
<th>Brain: Machine Interactions</th>
<th>Infocosm and the Metaverse</th>
<th>Militarization of Space</th>
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<td>“Biospace”</td>
<td>“Connected Space”</td>
<td>“Smart Space”</td>
<td>“Cyberspace”</td>
<td>“Outer Space”</td>
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- 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
avoiding technology surprise for tomorrow’s warfighter
a symposium report

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

[Images of various technologies and biological concepts related to the listed domains]
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<tr>
<th>Molecular Foundries</th>
<th>Novel Materials</th>
<th>Micro-Devices</th>
<th>Ubiquitous Sensing</th>
<th>Robotics</th>
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<th>Ambient Intelligence</th>
<th>Digital Anthropology</th>
<th>Cogint</th>
<th>Intelligent Machines</th>
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**Massive Computing Power and Analytical Parsing**
RESPONSIBLE RESEARCH
WITH BIOLOGICAL SELECT AGENTS AND TOXINS

NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES
Strategic Plan for Outreach and Education
On Dual Use Research Issues

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

December 10, 2008

Synthetic biology

scientific
discussion meeting
summary

SYNTETIC
BIOLOGY

THE DUAL-USE DILEMMA

July 2009 Number 340
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

GAO 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

GAO 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
Improved Diagnostic Tests for Infectious Diseases
Earlier Diagnosis and Intervention Saves Lives

The Single Most Important Leverage Point
For Rapid Mobilization of Resilient Responses to Epi-/Pan-demics and WMD Bioterrorism

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

- Signatures of Pathogenic Organisms
- Global Network of Surveillance and Diagnostic Testing Systems
- Rapid Analysis and Response to Diagnostic and Surveillance Information

Profile  Sense  Act
Global Disease Surveillance

EMERGEncy ID NET

World Health Organization

Infectious Diseases Society of America

Public Health Department's Surveillance

HealthMap
Global Disease Alert Map

U.S. Influenza Sentinel Provider Surveillance Network

DoD - GEISWeb
Global Emerging Infections System

GIDEON

Quarantine Activity Reporting System (QARS).

BioPortal

U.S. Influenza Sentinel Provider Surveillance Network

Biocaster

ARGUS Research Operations Center

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

Human and Animal Rabies

Emergency Reference Systems
Geodemographic Information Systems (GIS): Real-Time, Front Line, Ground Zero Data from Field Sampling and Sentinels
Geodemographic Information Systems: Mapping Disease Patterns and Modeling Trends

Anomaly Detection and Early Alert

Disease Progression

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

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

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

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

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

\[ 1 = X(t) + \sum_{i=1}^{4} Y_i(t) + \sum_{i=1}^{4} X_i(t) + \sum_{i,j=1, i \neq j}^{4} Y_{ij}(t) + Z_i(t) \]

- 1,800,000 projected deaths
- 900,000 projected deaths
- 450,000 projected deaths
- 90,000 projected deaths
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

Command and Decision Authorities

Healthcare System and Public Health Capabilities

Maintenance of Civil Order and Public Trust

- 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
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

- “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

Logos of various pharmaceutical and research companies including GlaxoSmithKline, Sinovac, RIMD, Omnivest Pharmaceuticals, The Kitasato Institute, KAKETSUKEN, Denka Seiken Co., Ltd., Baxter, Novartis, Sanofi Pasteur, and CSL.
“Millions demand it, millions refuse it, and millions don’t know what to think”

John Carroll
Editor, FierceBiotech (23 Oct. 2009)
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

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
CDC-HAN-00304-09-12-23-ADV-NÁ
MedImmune announces limited, voluntary, non-safety-related recall
Summary
On December 18 and 21,

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
“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

Incentives for R&D Investment in Antibiotics

Policies and incentives for promoting innovation in antibiotic research

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

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

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
“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
- political correctness (PC)

- tractable, actionable, measurable policies
- accountability
- 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
- Vulnerabilities created by highly variable national and global preparedness capabilities
- Prioritizing global health as a key component in investment, trade, diplomacy and military policies
- 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 availability 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)
Free Swim: UNITAID Request for 19 Drugs for Patent Pool for AIDS Medicines

**Abbott**
Norvir (ritonavir)

**Boehringer Ingelheim**
Viramune (nevirapine)

**Bristol-Myers Squibb**
Reyataz (atazanavir)

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

**MERCK**
Stocrin, Sustiva (efavirenz)

**Roche**
Invirase (saquinavir)

**tibotec Johnson & Johnson**
Prezistae (duranavir)
Intelence (etravirine)
Rilpivirine

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

Challenges

- resistance
- emergence
- globalization
- urbanization

Innovation and Solutions

- molecular biology
- nanotechnology
- materials
- computing
- terror
- and conflicts
- economic disparities

- public health infrastructure
- political will
- investment incentives
- national security
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)