



**Biosecurity:
A Multi-Dimensional Challenge of
Escalating Complexity and Urgency**

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and Regents Professor of Health Innovation

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www.casi.asu.edu

BIOSECURITY AND BIOTERRORISM RESPONSE Winter 2020:

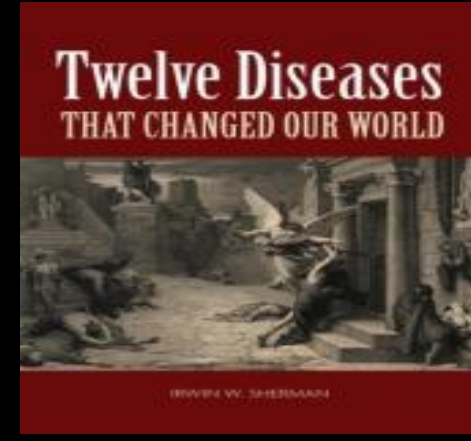
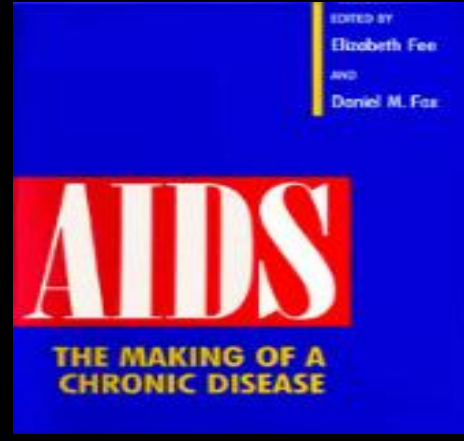
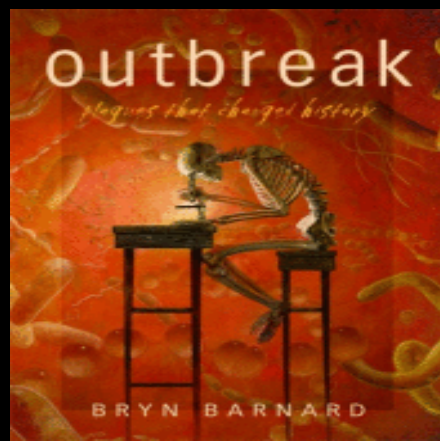
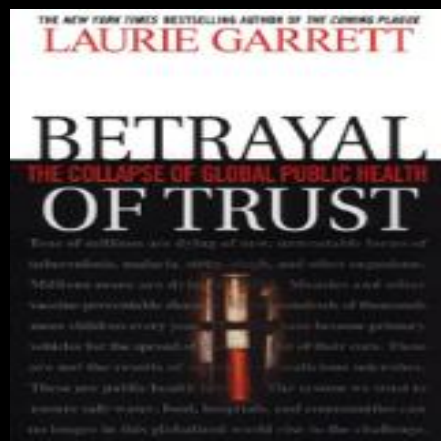
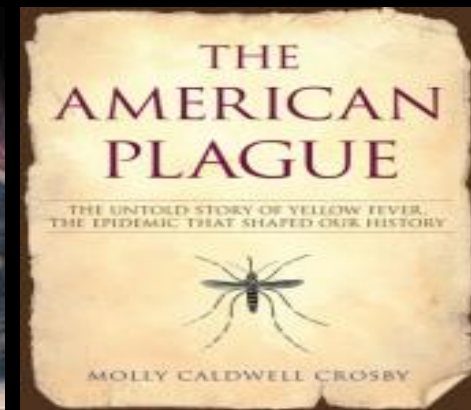
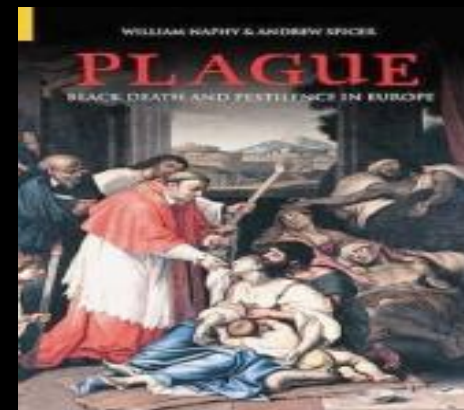
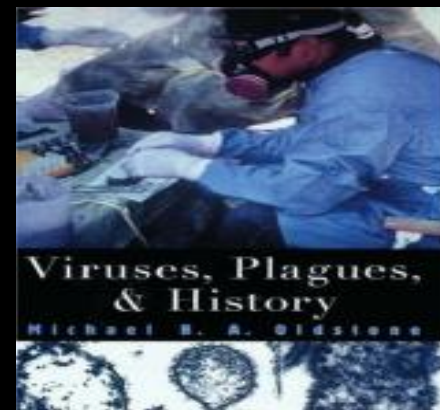
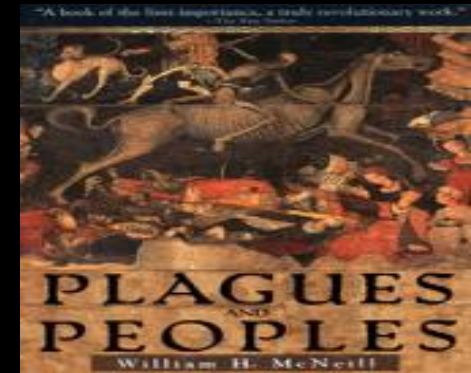
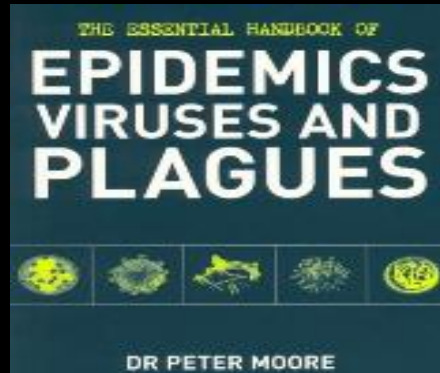
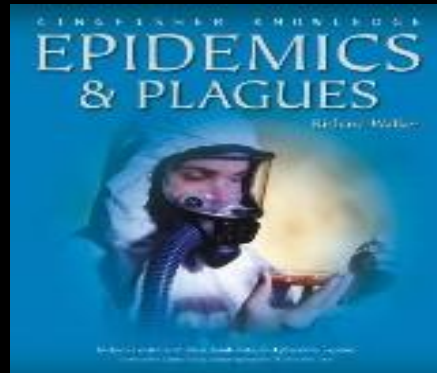
BIOE 122, EMED 122/222, PUBLPOL 122/222

Stanford University School of Medicine, Li Ka Shing Center (LKSC) room 130

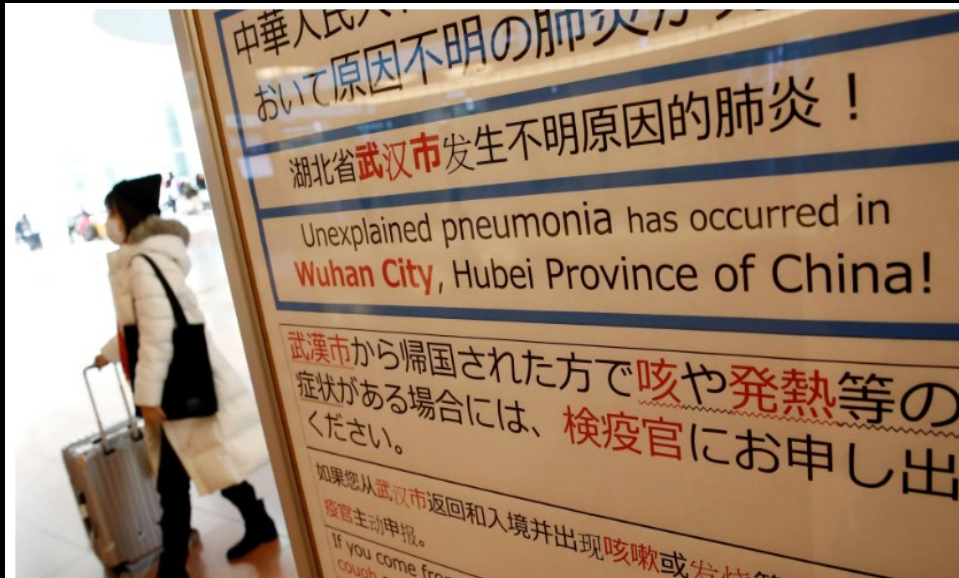
22 January 2020

*** WARNING: CONTAINS GRAPHIC BIOMEDICAL IMAGES**

Infectious Diseases: A Powerful Force in Human Evolution



Wuhan, China Coronavirus (Dec 2019--?)



The Relentless Changing Dynamics of Infectious Diseases

**old foes resurgent:
Rx – resistance**



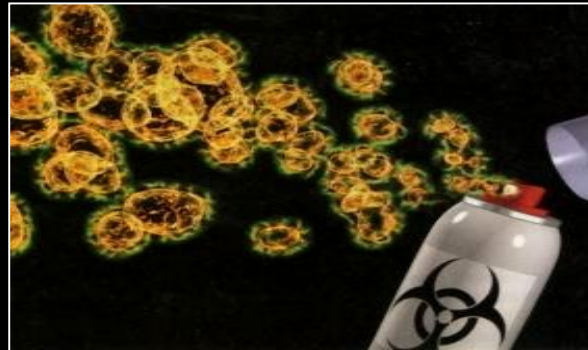
**omnipresent
pandemic threats**



**new foes:
emerging infectious
diseases**



global connectivities



**bioterrorism and
bioweapons**



**expansion of dual-use
technological risks**

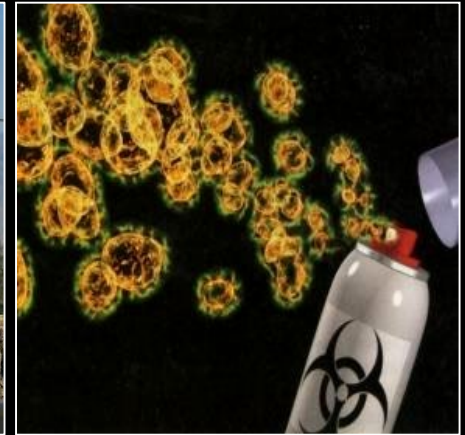
The Biosecurity Quartet

**Infectious
Diseases
of
Natural
Origin**

**Urbanization
and
Environmental
Impacts on
Disease
Emergence
(EIDs)**

**Military and/or
Humanitarian
Missions in
Dense Urban
Areas
and
'Hot Zones'**

**New Dual-Use
Technologies
and the
Expanded Threat
Spectrum for
Biowarfare/
Bioterrorism**



- shared dimensions in deterrence, prevention, detection, treatment and recovery
- additional requirements in forensics, attribution and retribution for bioattacks

Biosecurity

Shared Feature of Natural and Nefarious Threats

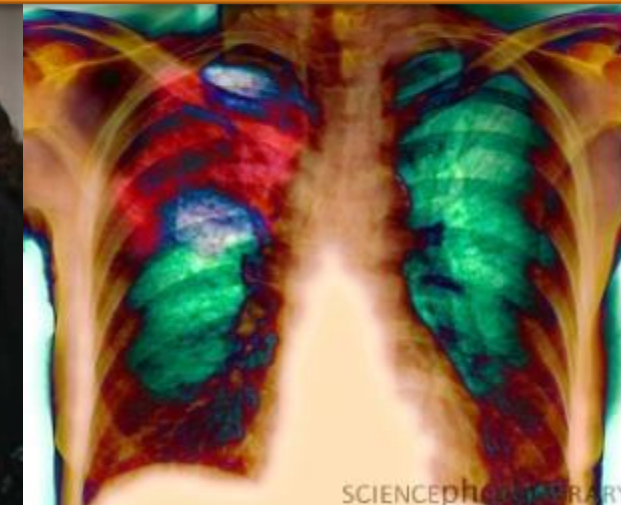
- **surprise, stealth, spread and speed**
- **‘all hazards’ and ‘resilience’ the foundations of response preparedness and planning**
- **cross-agency coordination (within government)**
- **cross-sector inter-dependencies (public, private, NGOs)**
- **local events can quickly become global**
- **global coordination (public health, diplomacy, media, law enforcement, intelligence communities, military, industry supply chains)**

Fundamentally Different Threat Categories:

Bombings and Hazmat-Incidents: Immediate Damage Assessment



Bioincidents: An Unfolding (Rolling) Event - EDs and Farms Will Be the Front Line



Media Sensationalism, Public Fear and Irrational Decisions by Political Leadership



Ugly Realities

- **media sensationalism fueling public panic**
- **pressure on governments to make illogical but politically expedient decisions**
- **in a severe outbreak the shock factor from any major level of fatalities will be unprecedented in modern peace times with unpredictable consequences for public responses and societal stability**
- **unpredictable unilateral decisions by other governments, restricting trade, travel and shipment of goods**
- **extended supply chains might break down completely**

PROCEEDINGS OF A WORKSHOP

**UNDERSTANDING THE
ECONOMICS OF
MICROBIAL THREATS**



The National Academies of
SCIENCES • ENGINEERING • MEDICINE



COMMITTED TO
IMPROVING THE STATE
OF THE WORLD

White Paper

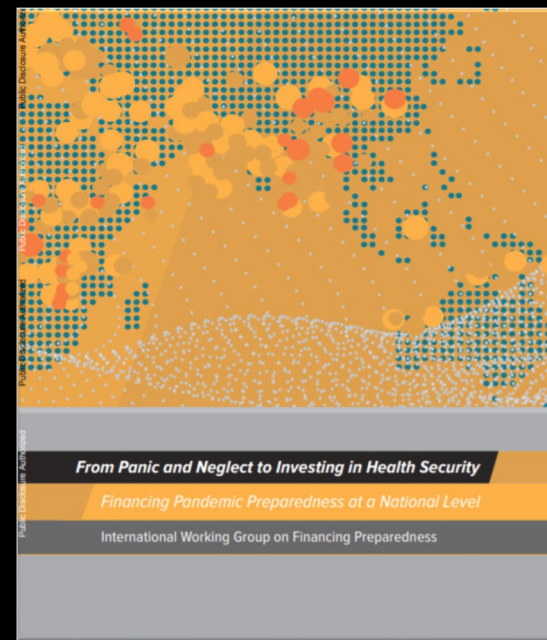
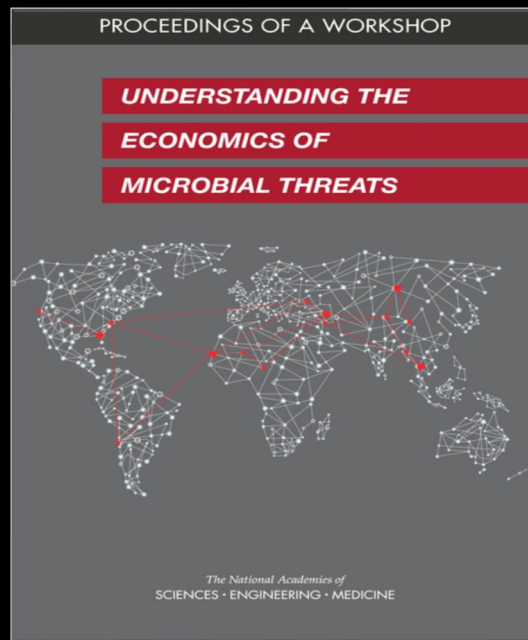
Outbreak Readiness and Business Impact

Protecting Lives and Livelihoods across the Global Economy

In collaboration with Harvard Global Health Institute

January 2019





- **SARS \$ 30 billion**
- **Ebola W. Africa \$ 53 billion**
- **Ebola U.S. \$ 2.4 billion**
- **Amerithrax decontamination \$320 million**
- **Projected cost of 1918 influenza – type pandemic**
 - **\$683 billion US economy**
 - **\$ 4 trillion global economy and 5% drop in GDP**

Cost of US Response to 10 Cases of Ebola 2014

- **\$1.1 billion on domestic preparations, including \$119 million on screening and quarantine**
- **\$1.2 million cost to Univ. Nebraska Medical Center for care of three patients**
- **Nebraska patients generated 3,700 pounds of contaminated linens, gloves and biological waste**



Supply Chain

The Daunting Logistics of Ebola Response



- **DRC is 4x size of neighboring Rwanda**
- **Shipped over 900 metric tons of supplies from 8/18 to 11/19**
- **17 million gloves**
- **2 million surgical masks**
- **909,000 gowns**
- **200,000 doses of Ebola vaccine (new Arktek refrigeration technology)**
- **Rebuilt 15 miles of roads and four bridges to reduce travel time**

Availability of Resources for Biocontainment and Epidemic Control



Ebola in West Africa (2014-15)



Ebola West Africa: 2014-15

The Logistics (and Risks) of Waste Disposal



Burial Practices



African Swine Fever Epizootic in the PRC (2018 - ?)



- estimated loss of 50% of farm pig population
- pork is 70% of meat consumption in PRC
- impact on global prices, protein source shifts and import costs
- global epizootic risk

The Biosecurity Threat Spectrum

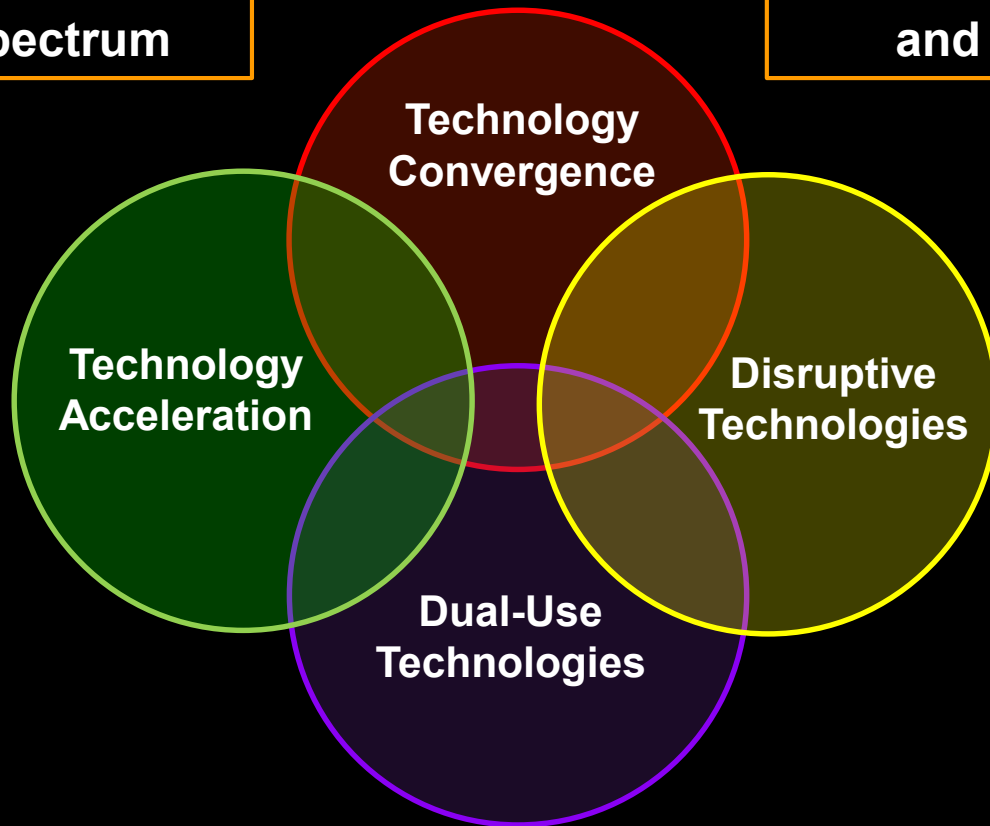
Time	Low Probability: High Consequence	High Probability: High Consequence
today		
• bioterrorism	X	
• natural infectious diseases(pandemic)		X
2029 (?)		
• bioterrorism		?
• natural infectious diseases (pandemic)		?
• convergent technologies		
- synthetic biology		?
- artificial intelligence		
- robotics/autonomous systems		
- error/accident		

The Strategic Environment for Biosecurity

Risk Assessment and Mitigation

**Expanded
Threat Spectrum**

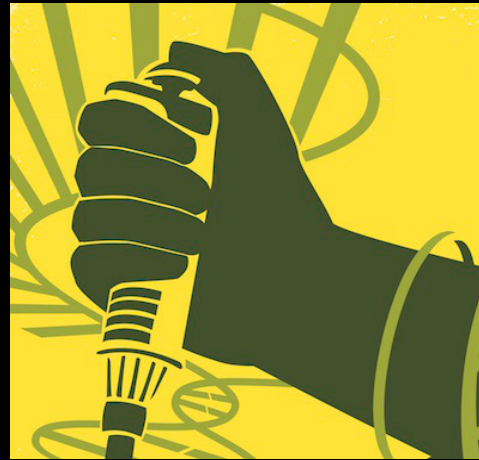
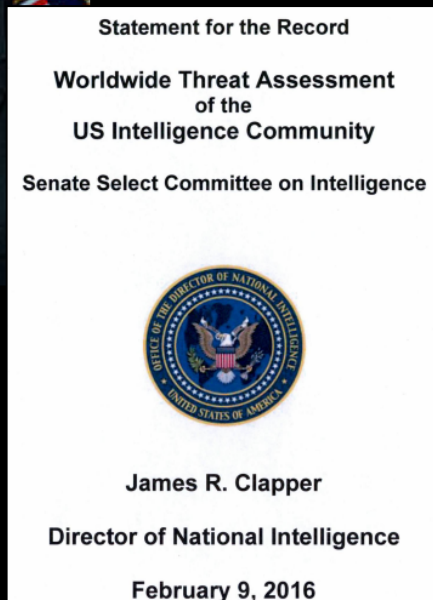
**Strategic Surprises
and Dislocations**



**Rapid Technology Diffusion
and New Global Competitors**

**Proliferation of
Dual-Use Risks**

Dual-Use Applications of Synthetic Biology and the Expanded Threat Spectrum



**Technology Diffusion,
Automation,
Simplification and Cost
Reduction**



**New Oversight
Mechanisms and
International
Harmonization**

- **beneficent and maleficent applications of same knowledge**
- **potential to cause profound societal disruptions based on deliberate misuse, error or accident**

“Exploring Biospace”

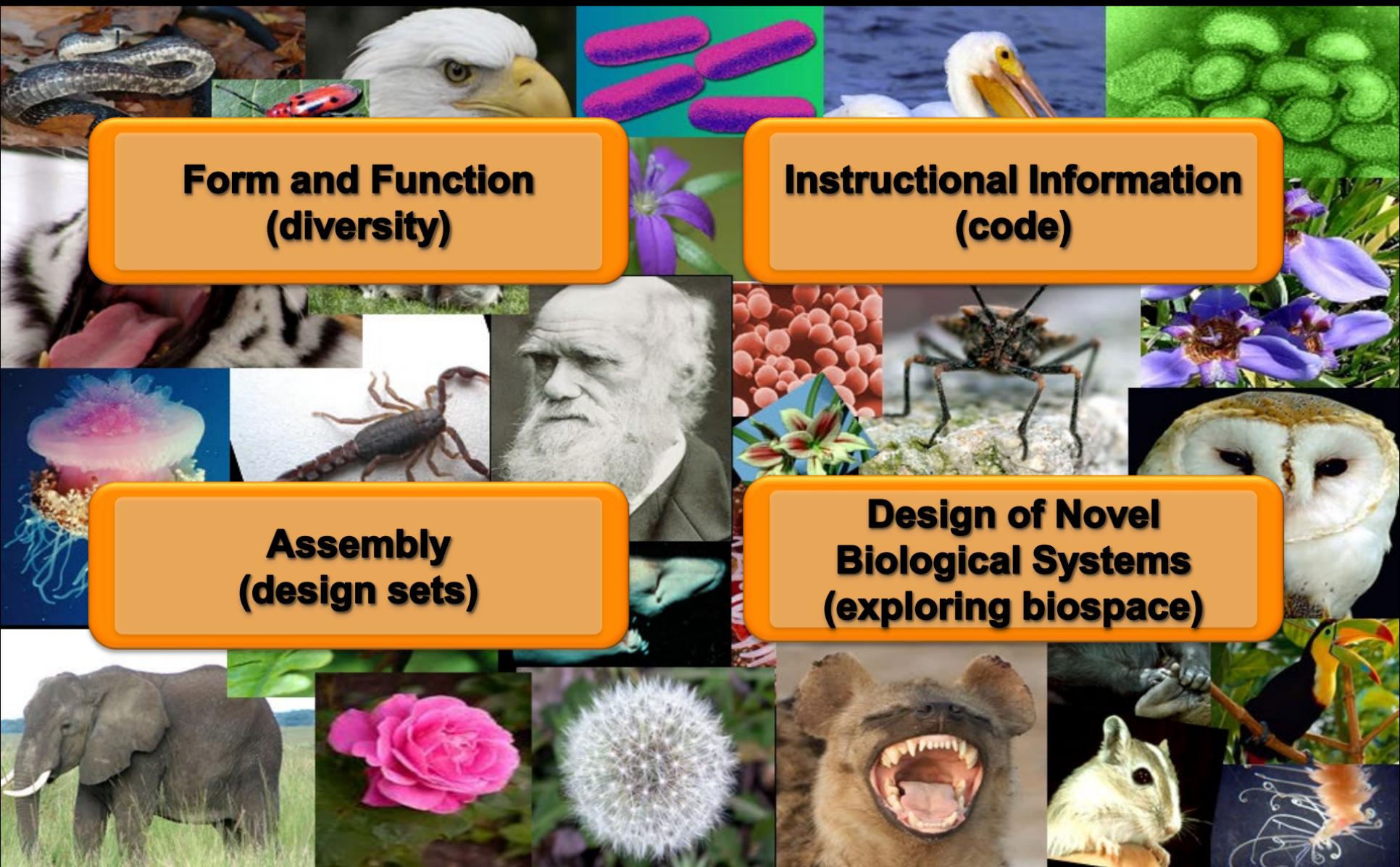
Understanding the Principles of Biological Design

Synthetic Biology and Digital Biology

**De Novo Construction of Unique Biological
Structures, Functions and Modified Organisms
With No Known Evolutionary Precedents**

Biological Diversity and Variation: “Endless Forms Most Beautiful”





**Form and Function
(diversity)**

**Instructional Information
(code)**

**Assembly
(design sets)**

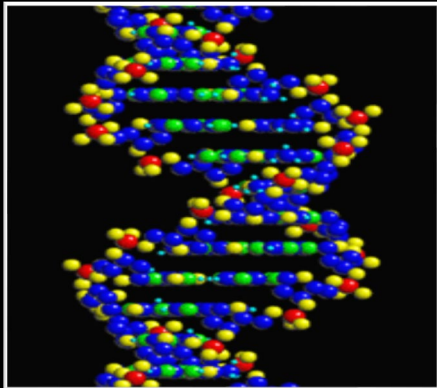
**Design of Novel
Biological Systems
(exploring biospace)**

Instructional Information (code)

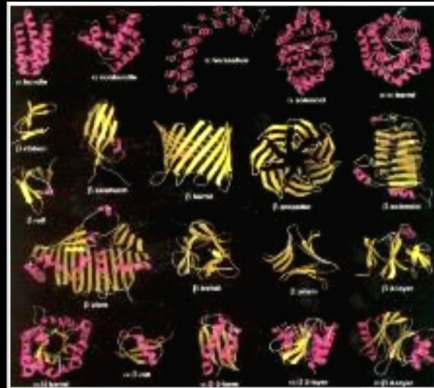
Design of Novel Biological Systems (exploring biospace)

Mapping the Design Principles of Biological Systems: The Construction of Increasing Hierarchical Complexity

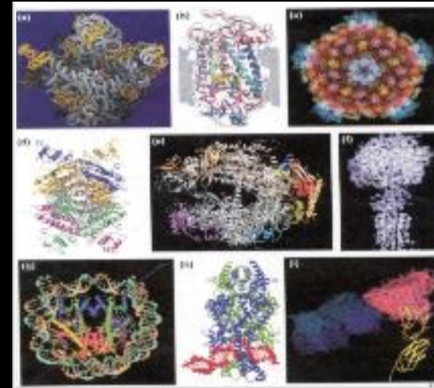
common genetic
(digital) code
in all life forms



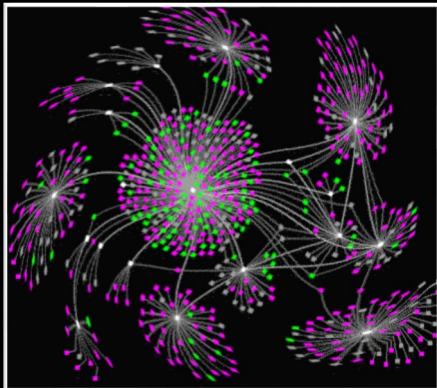
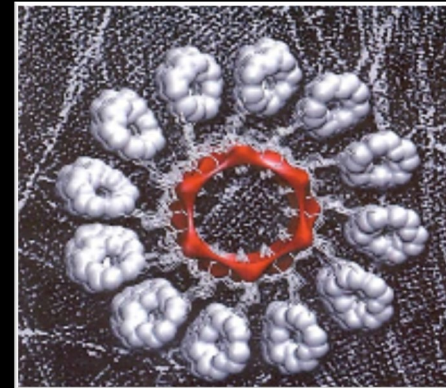
toolbox of
protein motifs
for combinatorial
assembly
("molecular lego")



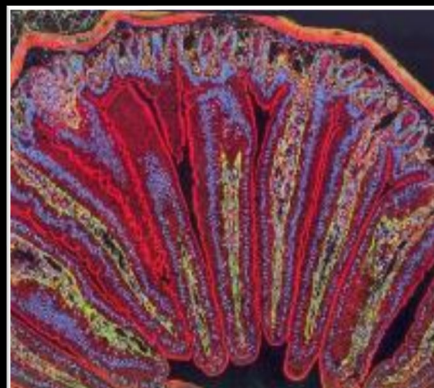
assembly of
structurally and
functionally
diverse proteins



protein interactions
and nanoscale
intracellular
structures



molecular signaling
networks



cells and tissues



organs



organism

Digital Biology (Code) and Synthetic Biology (Construction): “It from Bits”

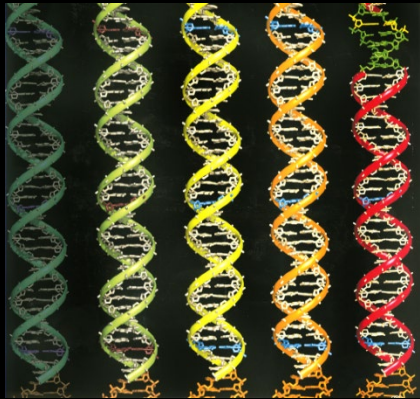
- **program and assemble new biological functions and organisms based on knowledge of the instructional ‘rules’ for synthesis and assembly**
- **reprogramming existing biological systems**
- **expanding “biospace”**
 - **design, simulation and construction of novel functions/organisms with no known natural evolutionary counterpart**
 - **novel biotic: abiotic combinations**
- **“directed evolution” and “accelerated evolution”**

“Exploring Biospace”: The Power of Combinatorial Interactions and Molecular Assembly

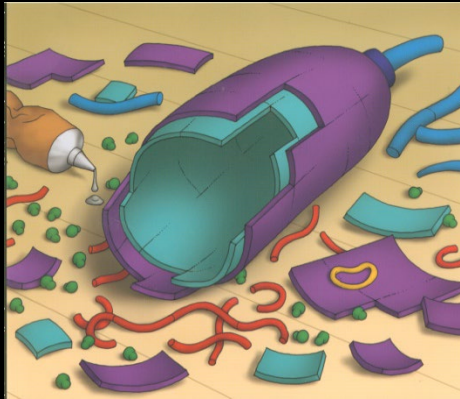
- **estimated 22,000 genes in human genome**
- **two genes cooperate to create a function**
 $= (22,000 \times 21,999) / 2 = 241,989,000$ potential combinations
- **100 genes generate a complex function**
 $= 10^{65794}$ potential combinations
- **number of theoretical possibilities for synthetic assembly (biospace) far exceed the narrow molecular space sampled in 4 billion years of evolution**

Synthetic Biology Mirrors Engineering Principles: Design-Build-Test

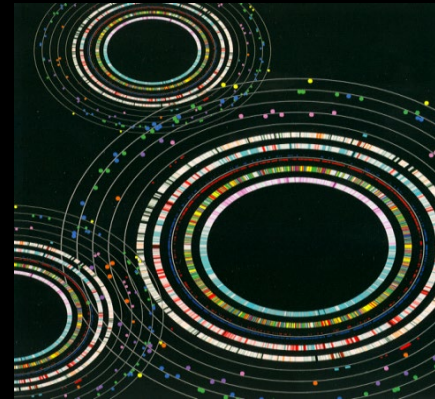
Code ("blueprint")



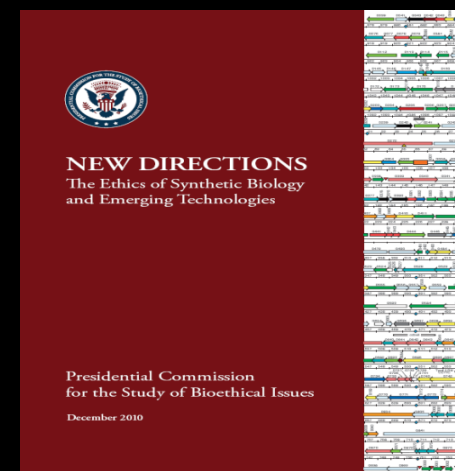
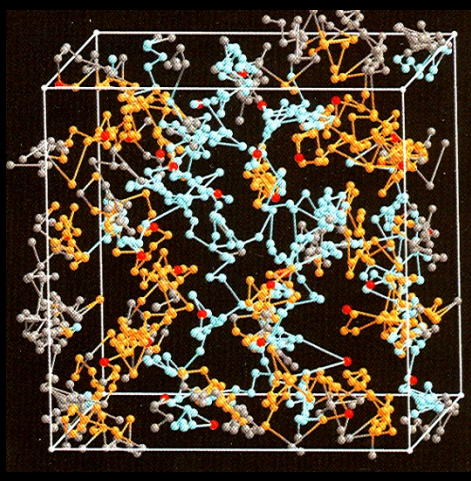
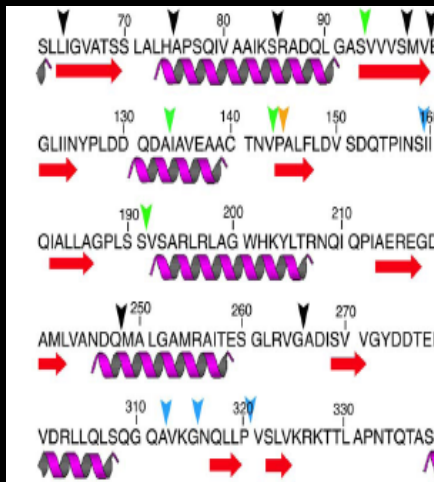
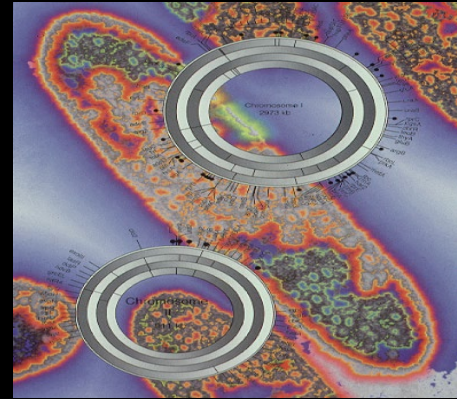
Parts



Genome-Encoded Assembly



Recipient "Chassis"



Efficient Insertion of Design Code

Pathway and Network Optimization

Scale Up and Economic Production

Oversight: Risk, Regulation and Responsibility

Synthetic Biology: Myriad Applications in Diverse Industrial Sectors

Healthcare



**Public
Health**



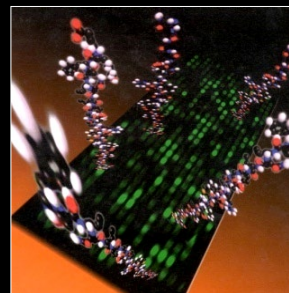
Agriculture



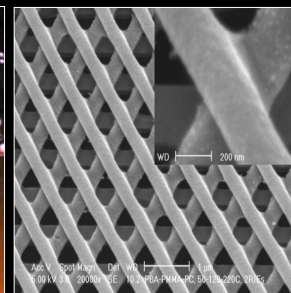
**Functional
Foods**



**Novel
Materials**



Textiles



**Bioenergy
and
Biofuels**



**Industrial
Enzymes**



**'Green'
Mfg**



**Bio-
remediation**



**Clean
Water**



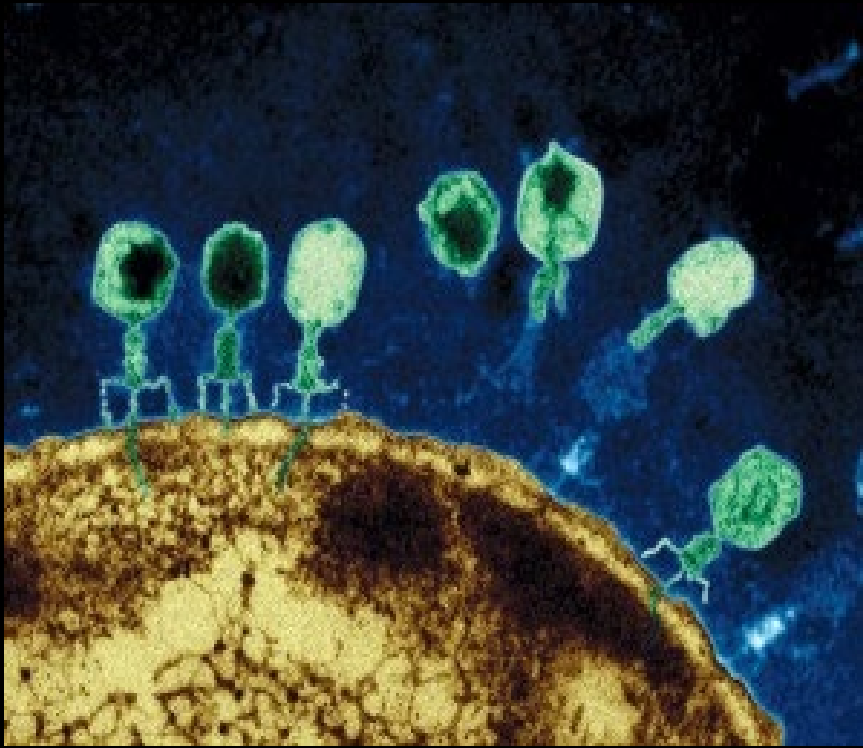
**Sensor
Networks**



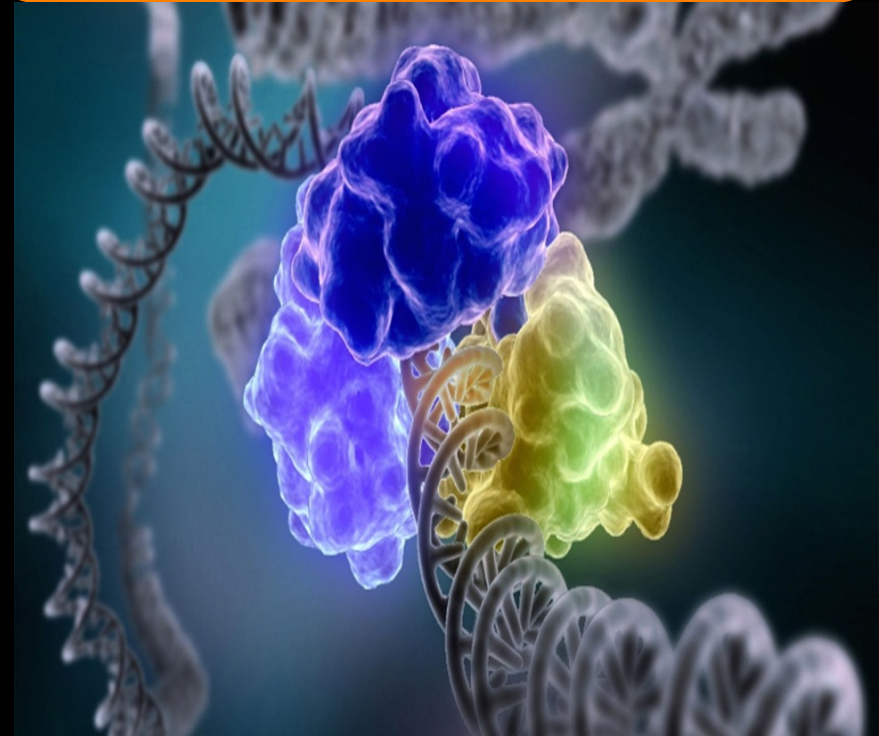


Programmable Nucleases and Genome Editing: A Game Changer in Synthetic Biology

Microbial CRISPR Defense System Against Viruses



CRISPR-Cas Guided Excision and Insertion of New Genes and Substitution of Individual DNA Bases



- using an evolutionary mechanism from 3-4 billion years ago for twenty first century genome design
- delete, replace or change genes in any living species, including humans

Explosion of the Gene Editing and Gene Therapy Ecosystem

Gene Therapy (20+)



Gene Editing (8+)



CAR/TCR/T Cell (25+)



Worldwide DNA Sequencing Capacity and Massive Data Flows



- doubling every 6 - 9 months
- 250K human genomes = 35 petabytes
- projected growth of global sequencing information to exabyte/zettabyte scale in 5 years

Gene Editing and Base Editing

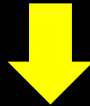
- **‘knockout’**
 - delete or render non-functional
- **‘silence’**
 - switch off expression but DNA code unchanged
- **‘activate’**
 - switch on expression of silent genes
- **somatic modification (augmentation)**
 - changes in non-germ line cells with no inheritance by progeny
- **germ line modification (enhancement)**
 - changes in gametes (sperm/egg) with inheritance by progeny

Genetic Modification

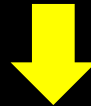
- trial and error



- precise and programmable



- non-heritable change of somatic cells (augmentation)
- heritable change of germ line cells (enhancement)



- gene drives (widespread insertion of a trait)

- any organism, including humans
- any cell type
- any biological function

Digital Biology

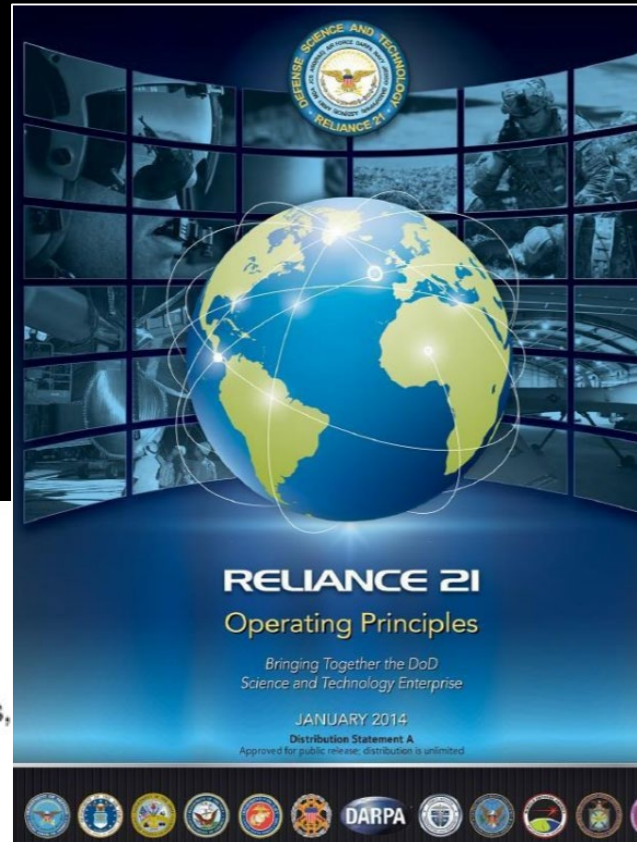
- DNA is a digital code
- biology at internet speed
 - transmission of digital instruction code to any location
 - geographic uncoupling of design (code) from manufacture (synthesis and assembly)
- technology diffusion and 'democratization' of technology
- dramatic expansion of dual-use risks
 - monitoring, control, legal and ethical issues

Synthetic Biology and US Military Science and Technology



www.darpa.mil

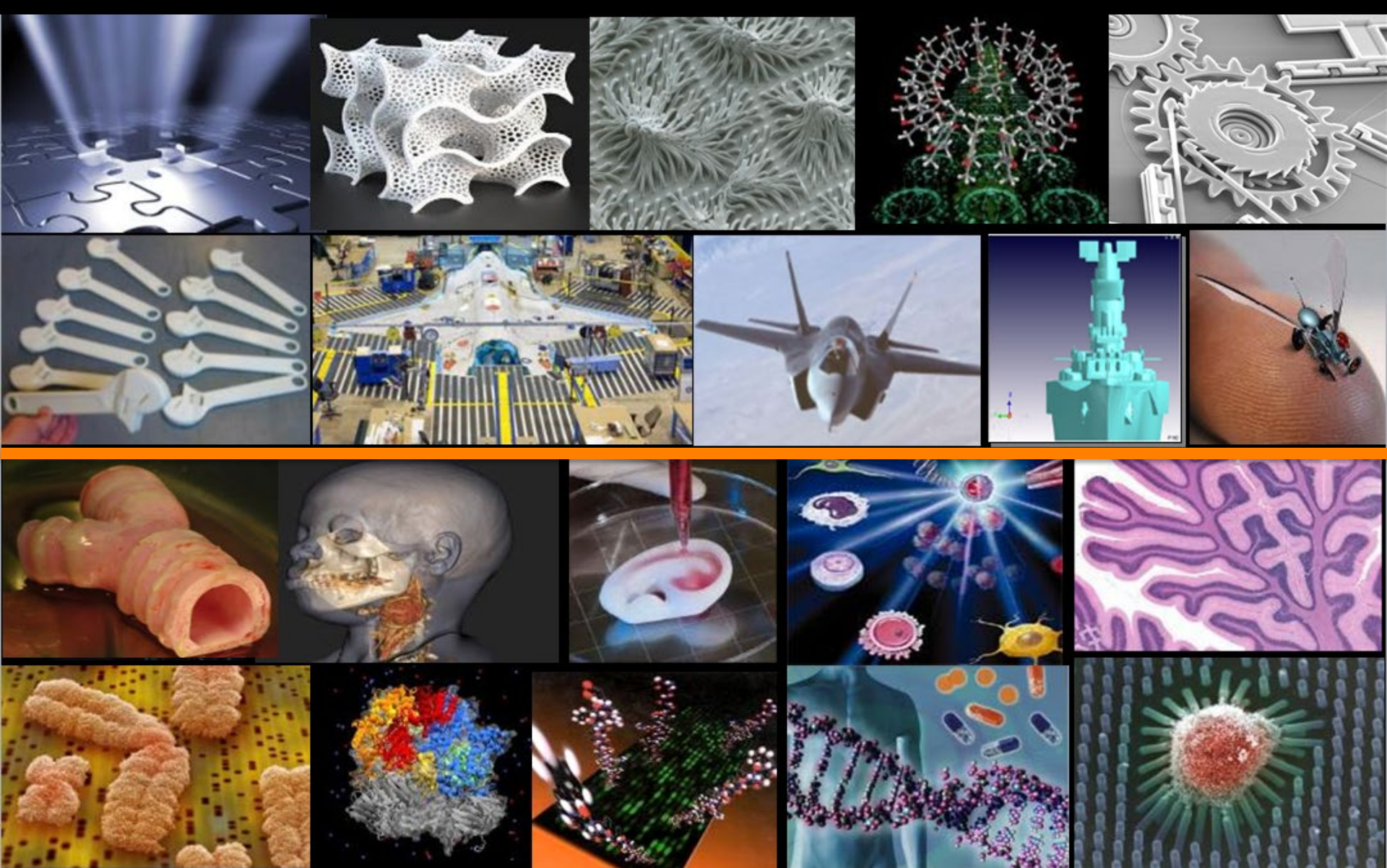
- Biowarfare defense – advanced diagnostics, decontamination, medical therapies
- Tactical Biomedical Technologies – mobile trauma stabilization, novel therapeutics, generation and storage of blood products
- Restorative Biomedical Technologies – restore complex tissues after traumatic injury, neural-controlled prostheses
- Bio-inspired Platforms and Systems – mimic locomotion and chemical/visual/aural sensing
- Microphysiological Systems – organs-on-chip to mimic human physiological systems
- In Vivo Nanoplatfroms for diagnostics and therapeutics
- Living Foundries – create engineering framework for synthetic biology



www.dtra.mil

- Reduce, eliminate, counter, mitigate weapons of mass destruction
 - WMD sensing and recognition
 - Threat containment, filtering, shielding
 - Decontamination
 - Forensics
 - Neutralization of CBRNE materials

Advanced Manufacturing Digital Programming of New 3-D Fabrication and Assembly Technologies



Biodefense in an Era of Synthetic Biology and Precision Gene Editing

- **what are the implications for the future biothreat spectrum?**
- **what are the timeframes that particular novel threat categories are likely to evolve?**
- **what new surveillance and counter-measures will be needed?**
- **how do current international agreements regarding WMD/CBW need to be updated to address the changing threat spectrum?**

Strategic and Operational Objectives of Purposeful Bioattacks

- **civilian and military targets**
- **evade or confuse diagnosis**
- **treatment resistance**
- **circumvent vaccine immunization protections**
- **overload healthcare and other incident response capacities**
- **economic disruption of supply chains of essential goods**
- **spread public panic and erode trust in authorities**
- **deception to hide attribution**
- **multi-focal strikes with different agents and /or combinations of agents**

The Appeal of CBW for Asymmetric Warfare and Terrorism



松本智津夫(63)
(麻原彰晃)



早川紀代秀(68)



土谷正実(53)



遠藤誠一(58)



新実智光(54)



井上嘉浩(48)



中川智正(55)

سنجعلكم تخافون من الهواء الذي تتنفسونه
WE WILL MAKE YOU FEAR THE AIR YOU BREATHE



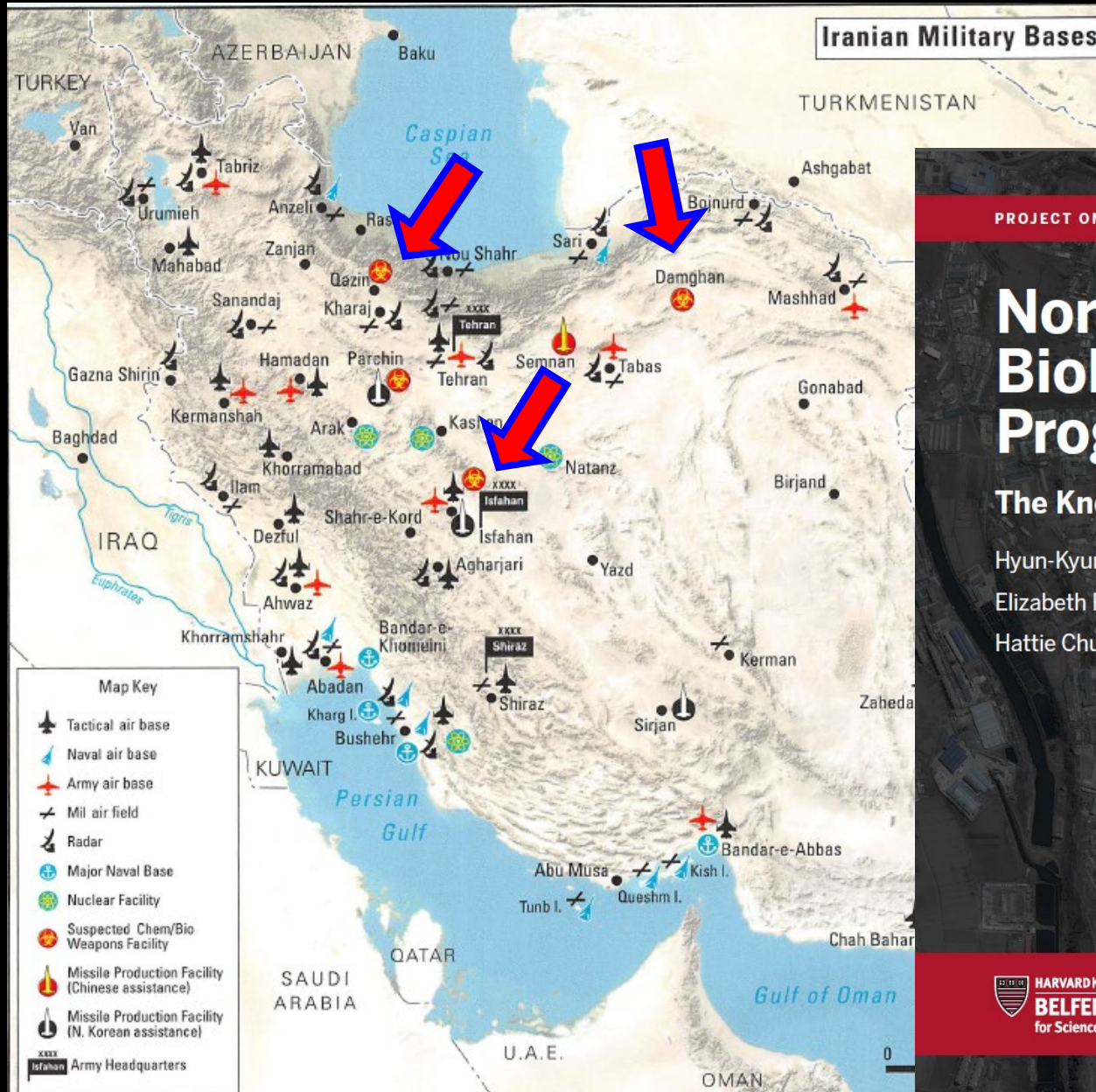
Provided by
MEMRI JTMM



الارهاب البيولوجي
BIO TERROR



The Appeal of CBW for Asymmetric Warfare and Terrorism



PROJECT ON MANAGING THE MICROBE

North Korea's Biological Weapons Program

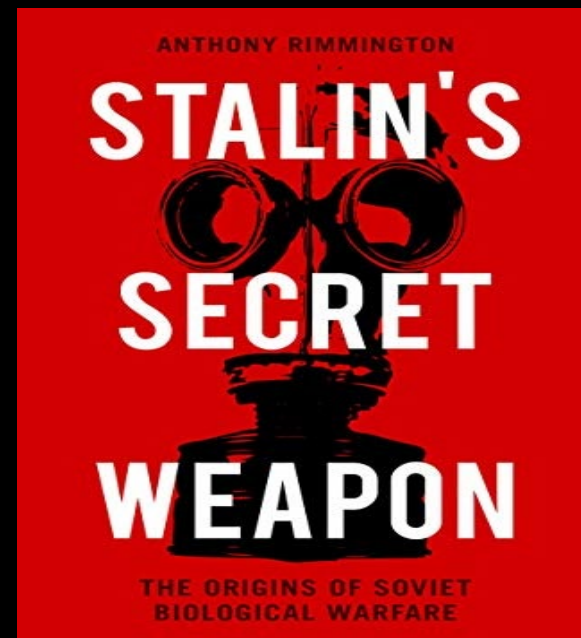
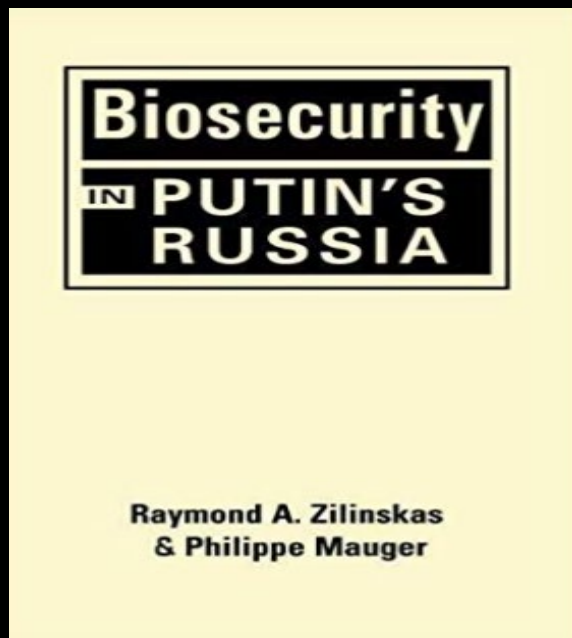
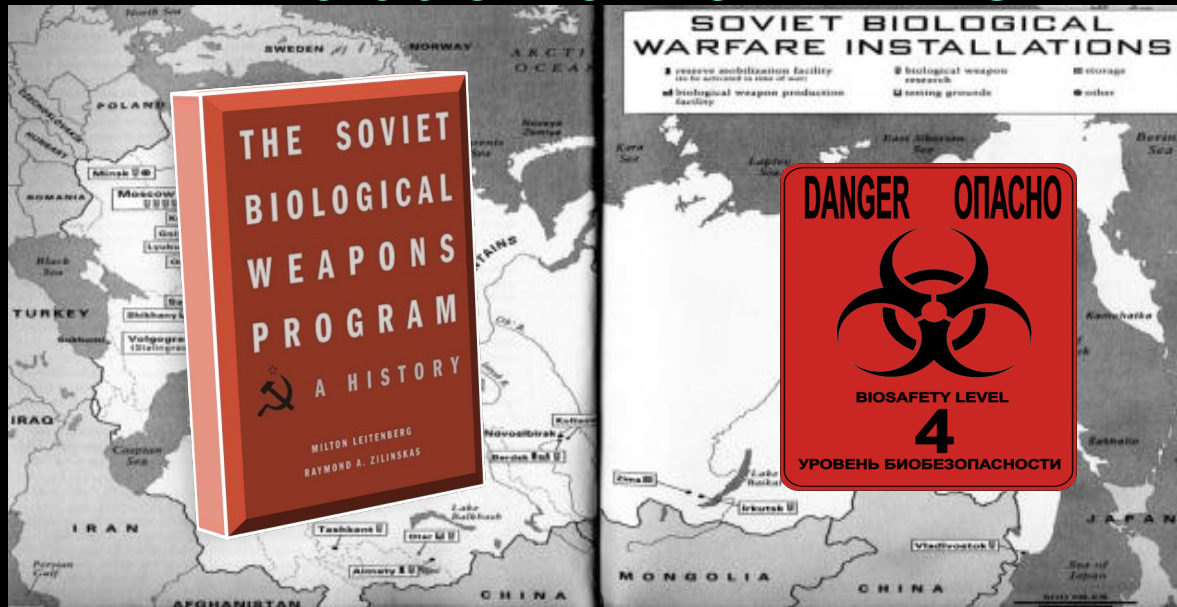
The Known and Unknown

Hyun-Kyung Kim
Elizabeth Philipp
Hattie Chung

HARVARD Kennedy School
BELFER CENTER
for Science and International Affairs

REPORT
OCTOBER 2017

The FSU Covert Biopreparat Program: Violation of 1972 BWC



Domestic Activists, Lone Wolf and Biohackers

"Win McCormack has put a penetrating spotlight on Indian guru Bhagwan Rajneesh and his bizarre and very dangerous cult. An utterly fascinating work."

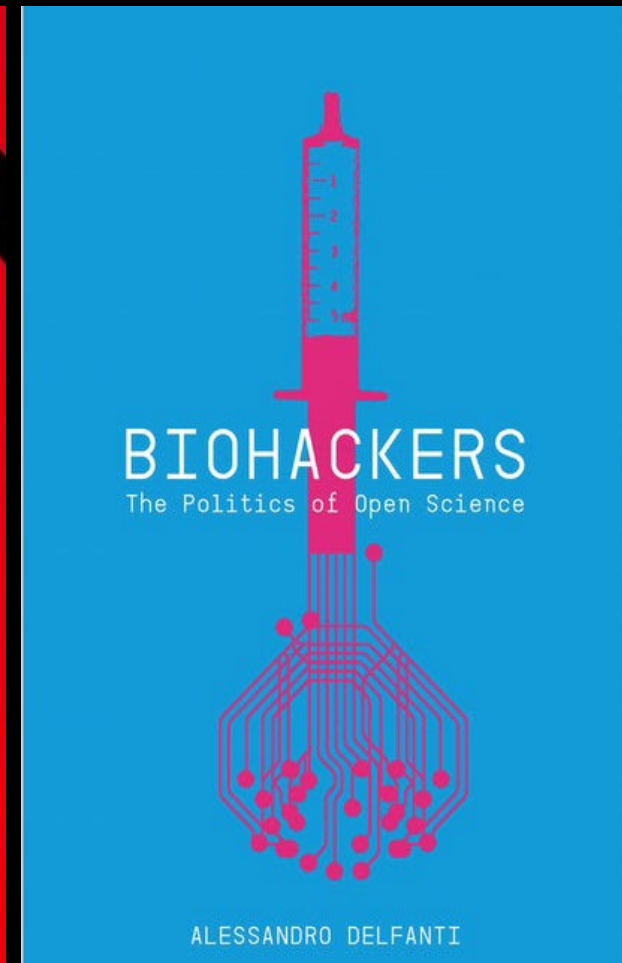
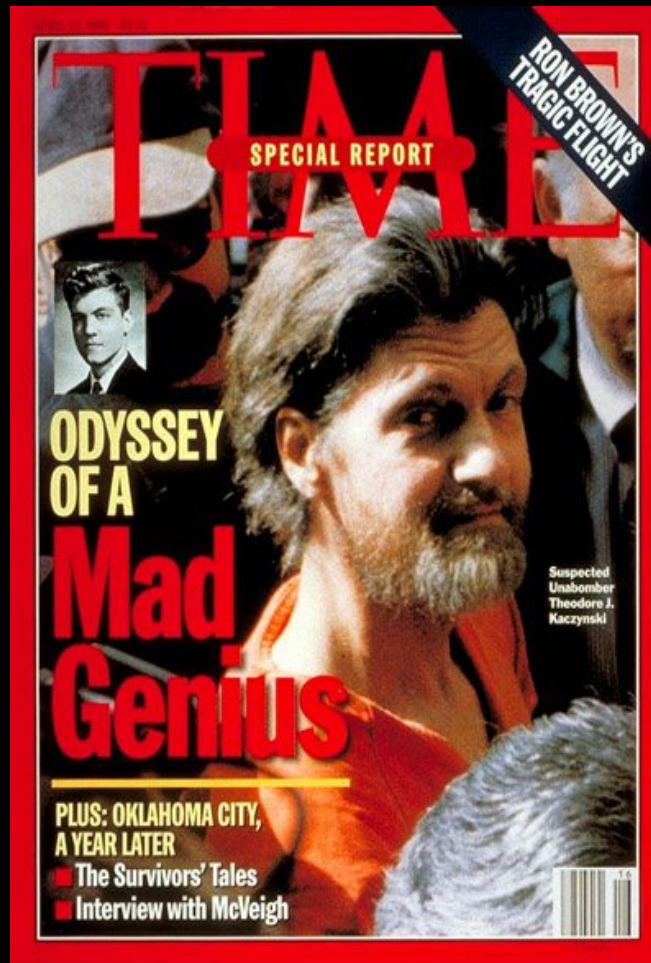
—VINCENT BUGLIOSI, author of *Helter Skelter*



THE RAJNEESH CHRONICLES

The True Story of
the Cult That Unleashed the First
Act of Bioterrorism on U.S. Soil

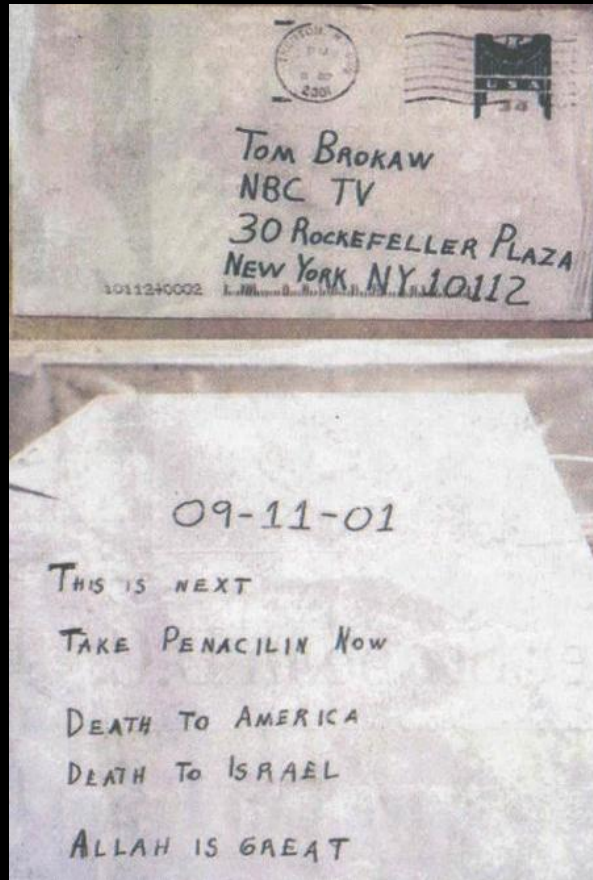
WIN MCCORMACK



“Amerithrax” October 2001

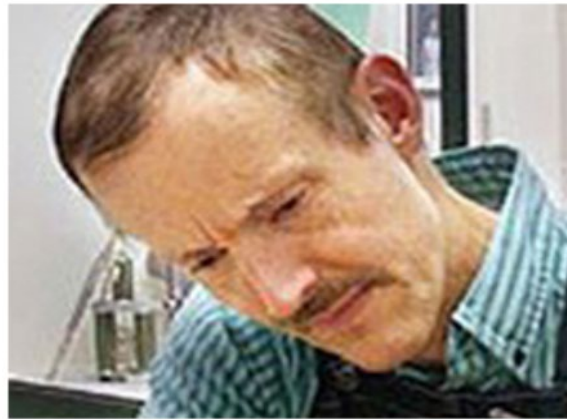
“I will show you fear in a handful of dust”

-T. S. Elliot



GAO

U.S. Government Accountability Office



Bruce Ivins,
the Anthrax Attacks,
and

America's Rush
to War

THE
**MIRAGE
MAN**

DAVID WILLMAN
WINNER OF THE PULITZER PRIZE



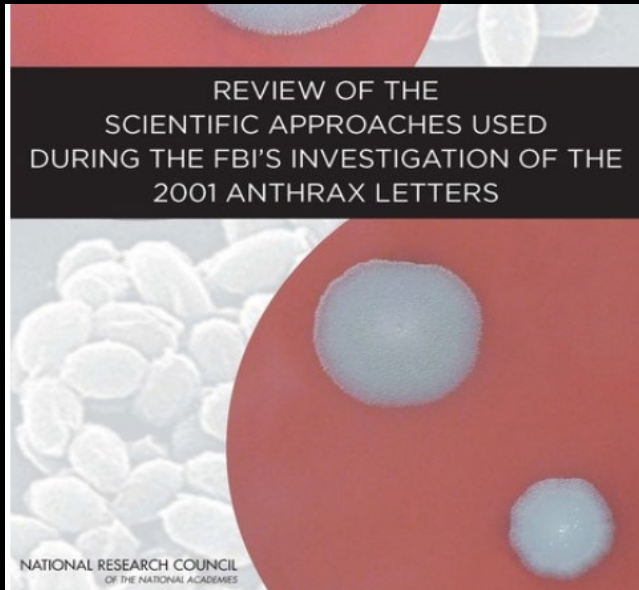
R. SCOTT DECKER

RECOUNTING THE ANTHRAX ATTACKS

TERROR, THE AMERITHRAX
TASK FORCE, AND THE EVOLUTION
OF FORENSICS IN THE FBI



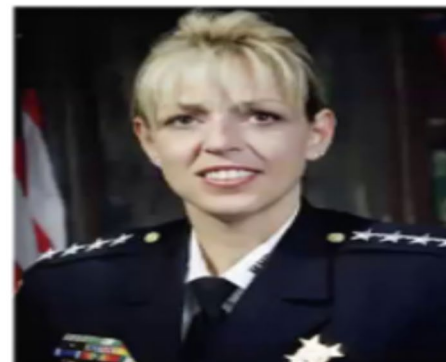
The Need for Stringent Forensics and Robust Evidence for Event Attribution



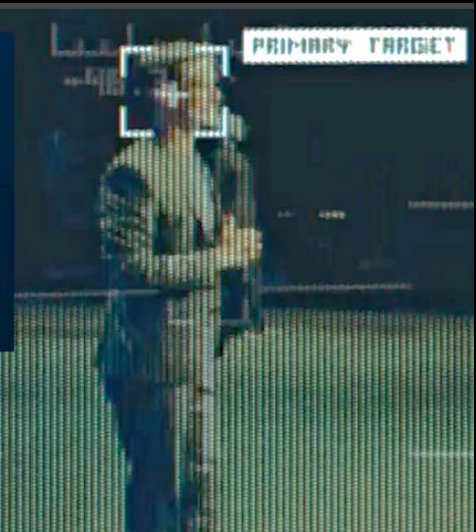
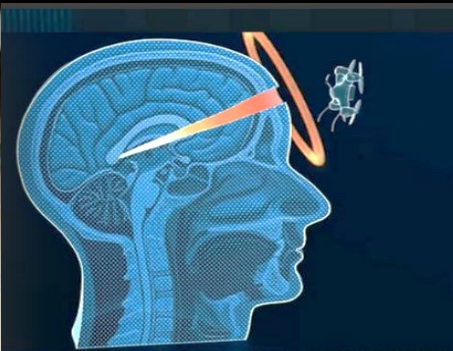


A dramatic increase in the number of threats, incidents, and incursions by drones at NFL stadiums. We are all very fortunate that the drone over Levi's Stadium dropped only leaflets.

CATHY LANIER
Senior VP of Security, NFL



Drone Swarms with Ordinance or CBW Payloads and Facial Recognition Homing

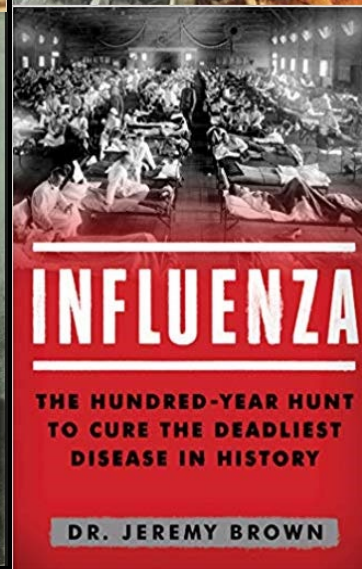
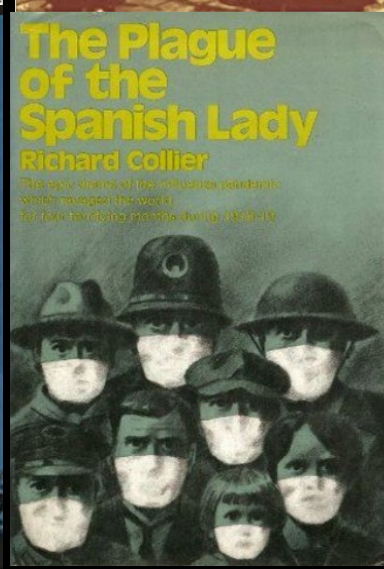
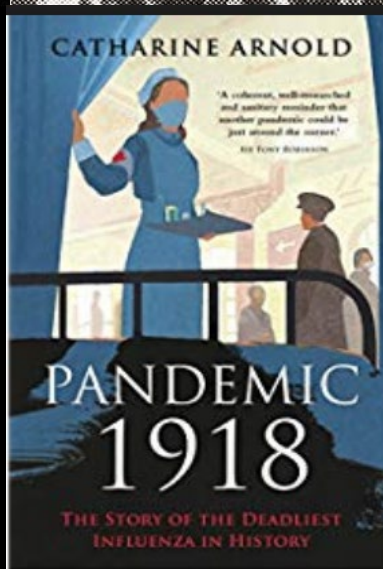
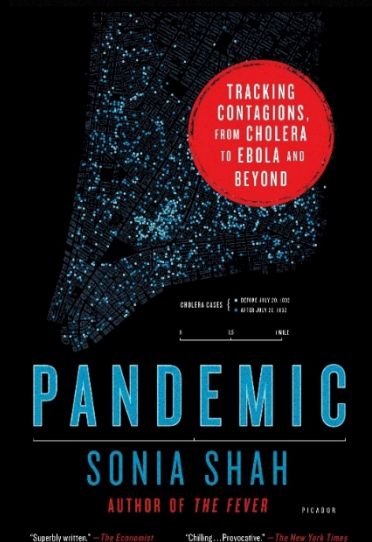
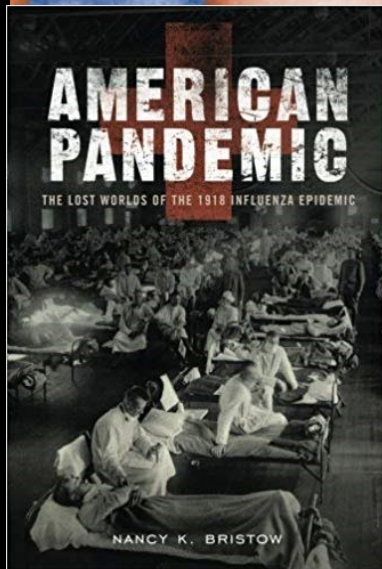
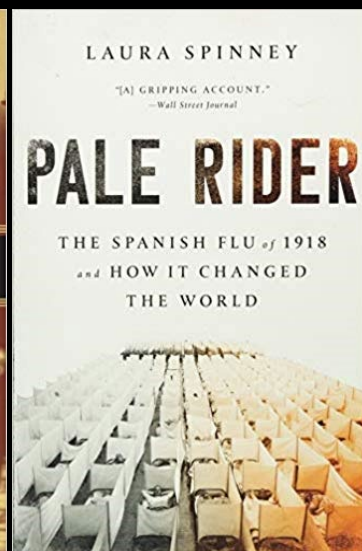
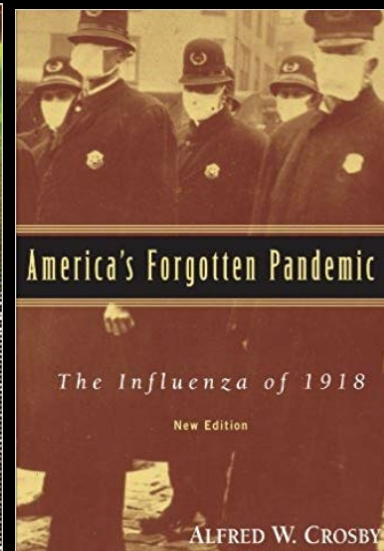
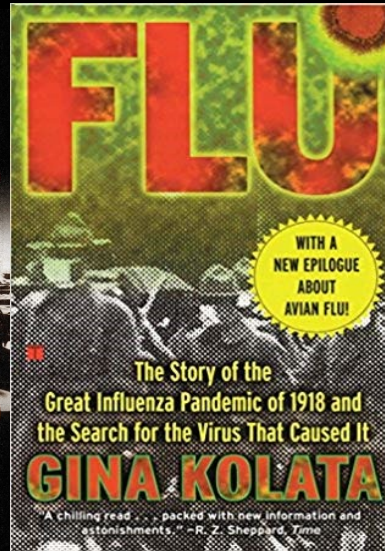
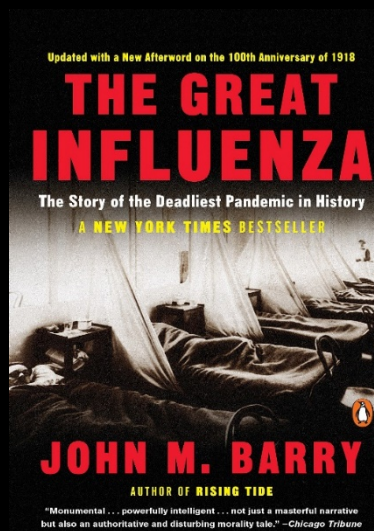
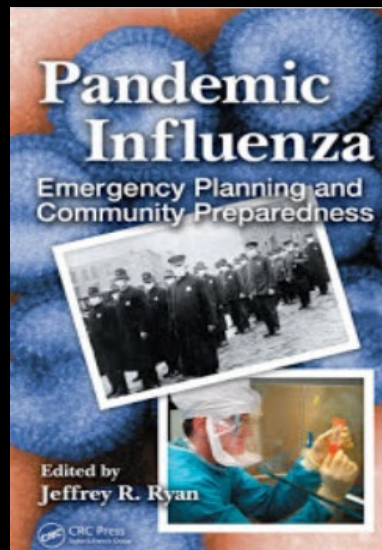


**Mapping the Global Inventory of Natural Microbial Threats
to Humans and Vital Agriculture/Ecological Resources**

**Natural Pathogens as Convenient Substrates for
Engineering New Vectors for Bioterrorism and Biowarfare**

The #1 Global Pandemic Threat?

The Omnipresent Risk of Pandemic Influenza





Global Disease Surveillance



EMERGENCY ID NET



U.S. Influenza Sentinel Provider Surveillance Network



Quarantine Activity Reporting System (QARS).



Public Health Department's Surveillance

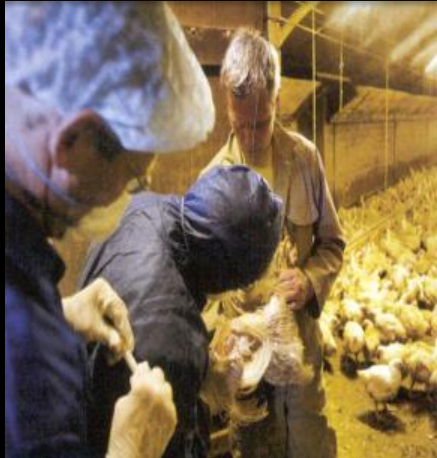


GEIS



Ground Zero Biosurveillance Data

Comprehensive Front Line Sampling of Sentinel Species



Real-time Intelligence and Faster Preparedness

'One Health' Biosurveillance

Natural reservoirs and ecological niches of emerging viruses



Susceptible human host



- range and physical contact
- environmental factors

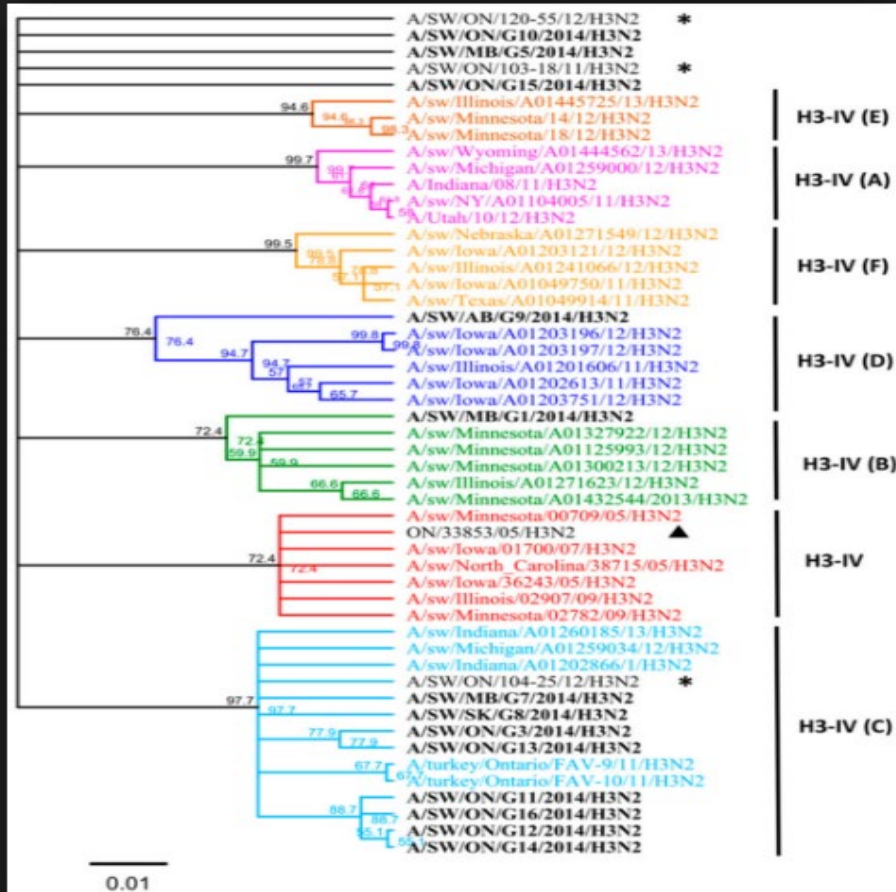
- demographics
- cultural, political and economic factors
- health system capacity to detect/respond

Global Biosurveillance (BSV)

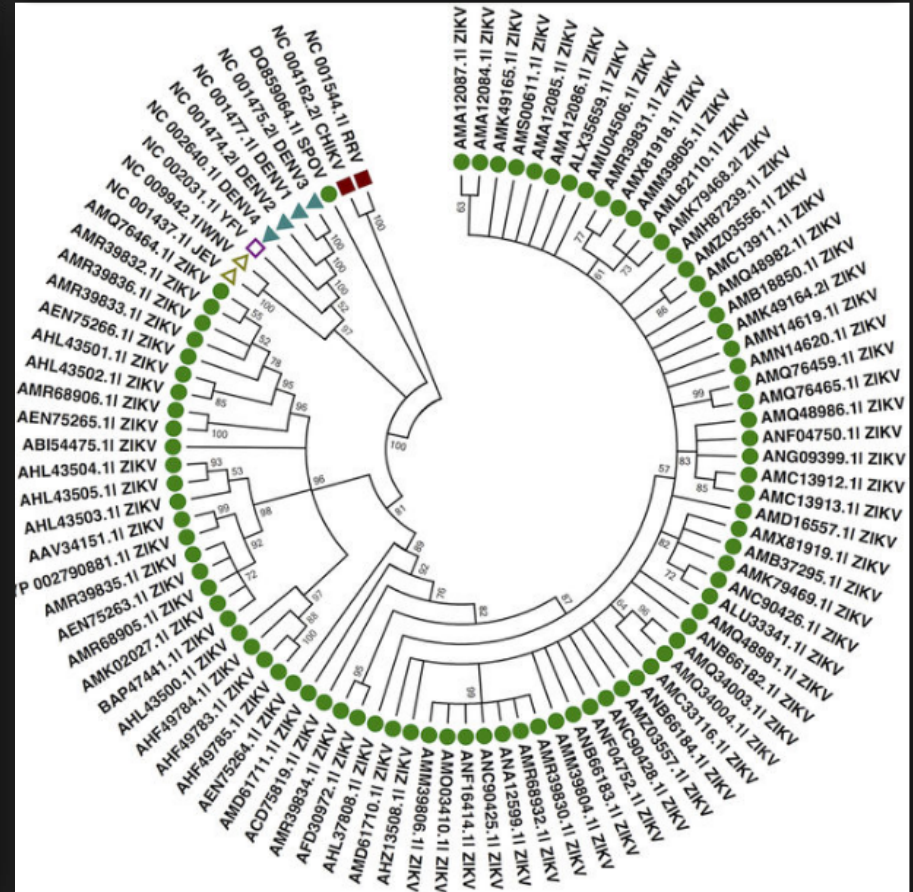
- huge gaps in our understanding of infectious disease ecology and zoonotic risk
- 1400 human pathogens, 335 new EIDs since 1940
- increasing number of EID events each decade
- Project PREDICT, Global Virome Project and DARPA PRE-EMPT have identified over 1000 viral species with the potential to infect humans with rodents, bats and primates as major reservoirs of future zoonotic risks
- target BSV capability to 'hot spots' for zoonotic 'spillover'
 - defined by specific environmental, ecological and socio-economic characteristics
 - urbanization-megapoli-push into virgin ecoterrain
 - breakdown/inadequate public health infrastructure/sanitation/hygiene
- eastern and southeastern Asia, India and equatorial Africa

Metagenomic Profiling of Pathogens and Their Evolution

Influenza Virus



Zika Virus



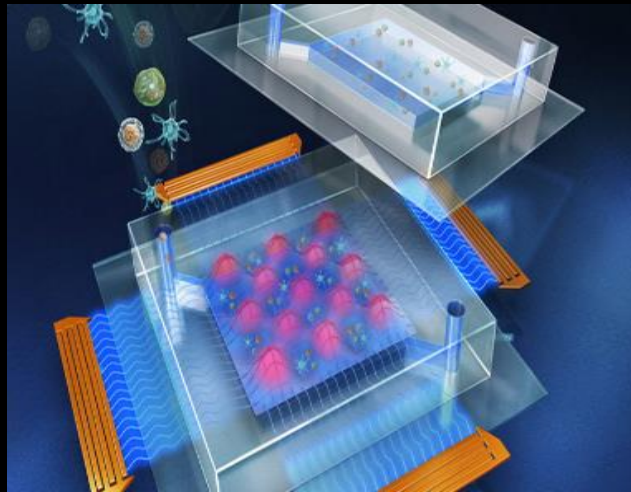
Faster Detection Saves Lives:

The Primacy of Diagnostics in Biosurveillance and Preparedness Mobilization

Profile:
signatures of infectious agents



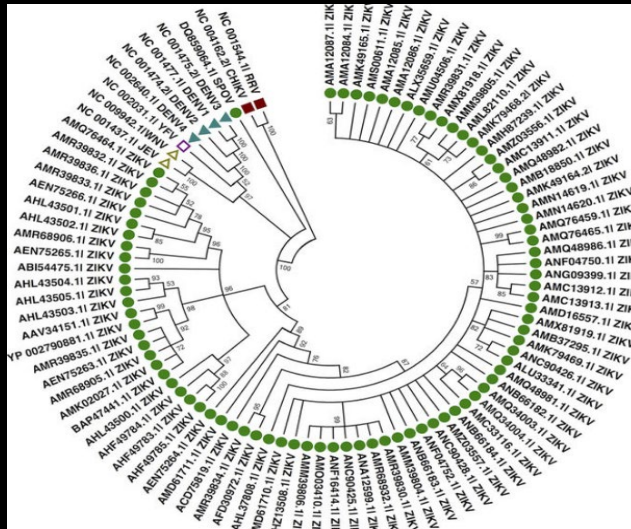
Detect:
rapid automated PON/POC diagnostics



Act:
real-time situation awareness, decisions



**surveillance
sans frontières**

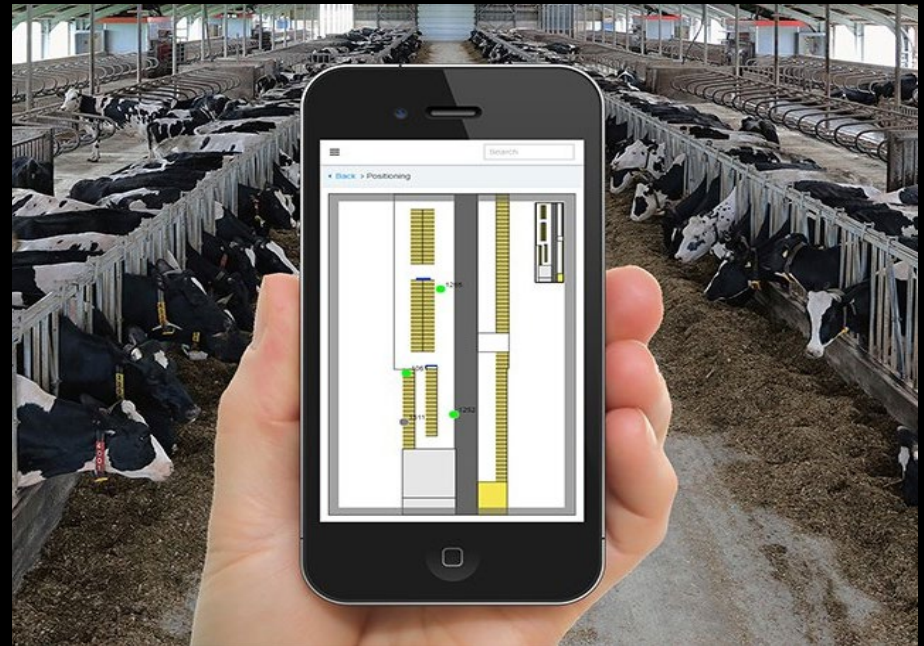
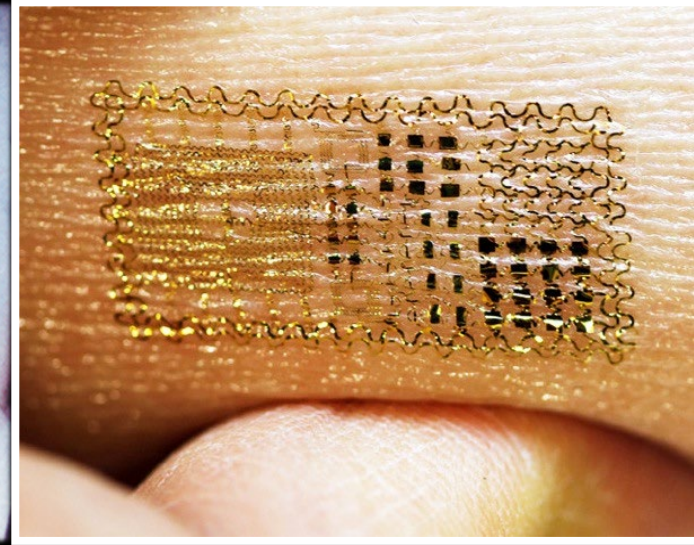


pathogen evolution

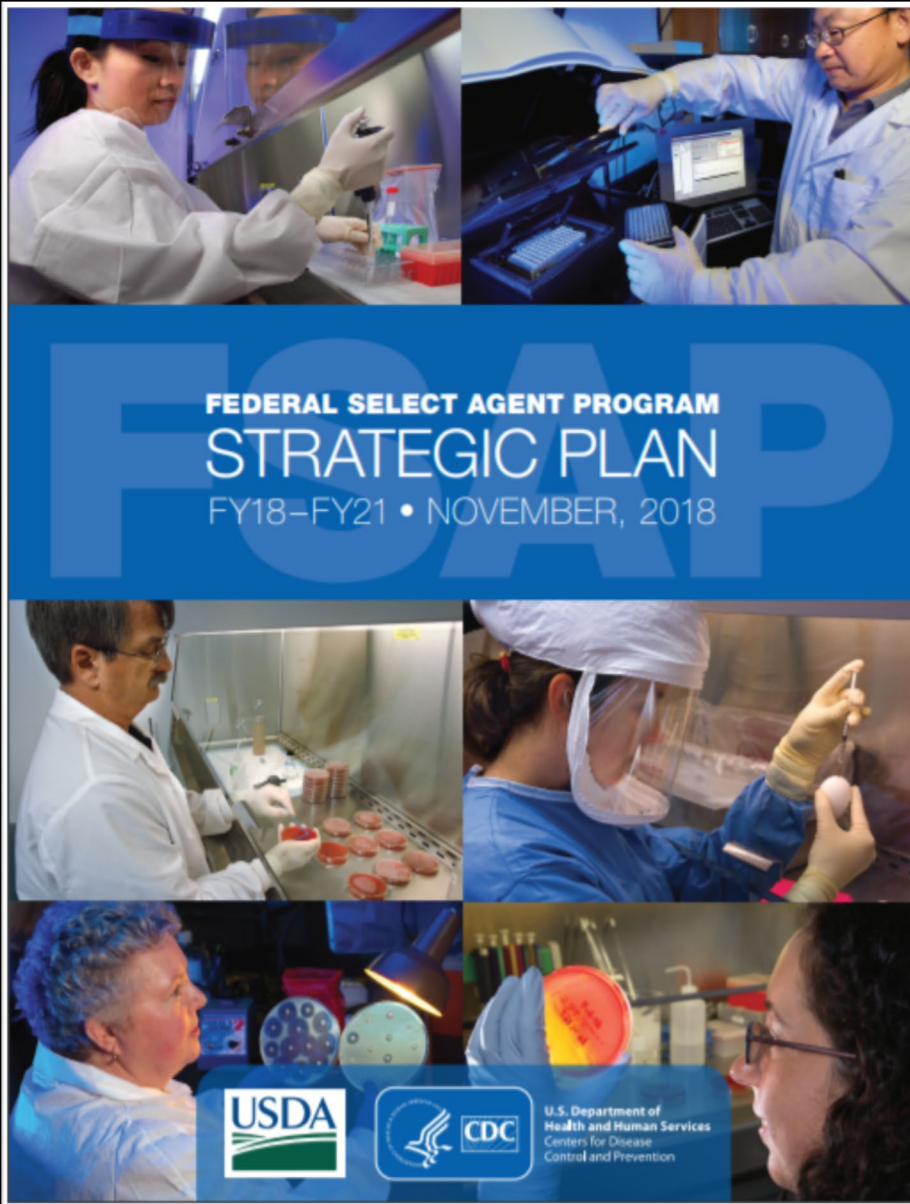


**dual-use research and
engineered biothreats**

Remote Monitoring of Health Status: Faster Detection of Prodromal Infections Saves Lives



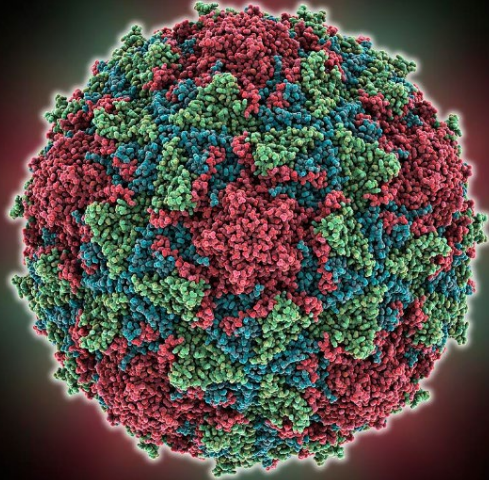
Beyond Select Agents: The Expanded Threat Spectrum



AGENT X

- exotic natural EID/zoonose ?
- deliberately engineered bioterror agent ?
- Bioerror ?

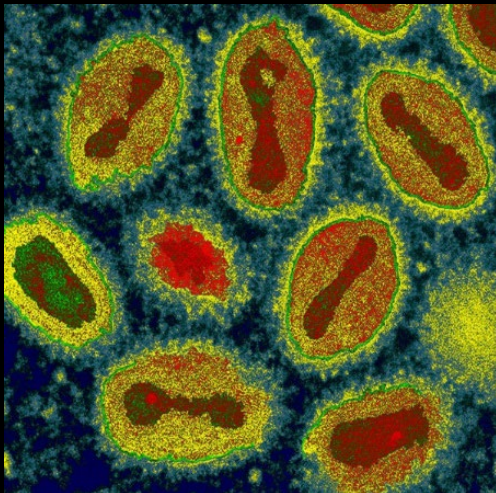
De Novo Synthesis of Pathogens



Science (2002) 297, 1016

Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template

Jeronimo Cello, Aniko V. Paul, Eckard Wimmer*



PLOS ONE <https://doi.org/10.1371/journal.pone.0188453>
January 19, 2018

Construction of an infectious horsepox virus vaccine from chemically synthesized DNA fragments

Ryan S. Noyce¹, Seth Lederman², David H. Evans^{1*}

¹ Department of Medical Microbiology & Immunology and Li Ka Shing Institute of Virology, University of Alberta, Edmonton, Alberta, Canada, ² Tonix Pharmaceuticals, Inc., New York, New York, United States of America

Therapeutic Oncolytic Viruses Designed to Circumvent Immune Detection

- **Onco-Vex-GM-CSF (Amgen)**
- **Reolysin (Oncolytics Biotech)**
- **JX-594-Jennerex (Biotherapeutics)**

Risk, Restraint and Responsibility: Claims By Some In The Academic Community for Unconstrained Publication

- **‘academic freedom’ and intrinsic value of “knowledge”**
- **scientists are not responsible for harmful uses of their research (the gunmaker’s defense)**
- **individual scientists cannot affect the overall trajectory of a research field**
- **publication is a deterrent to misuse and critical vehicle to inform countermeasure development**
 - **so who really needs to have access to this information to develop countermeasures?**

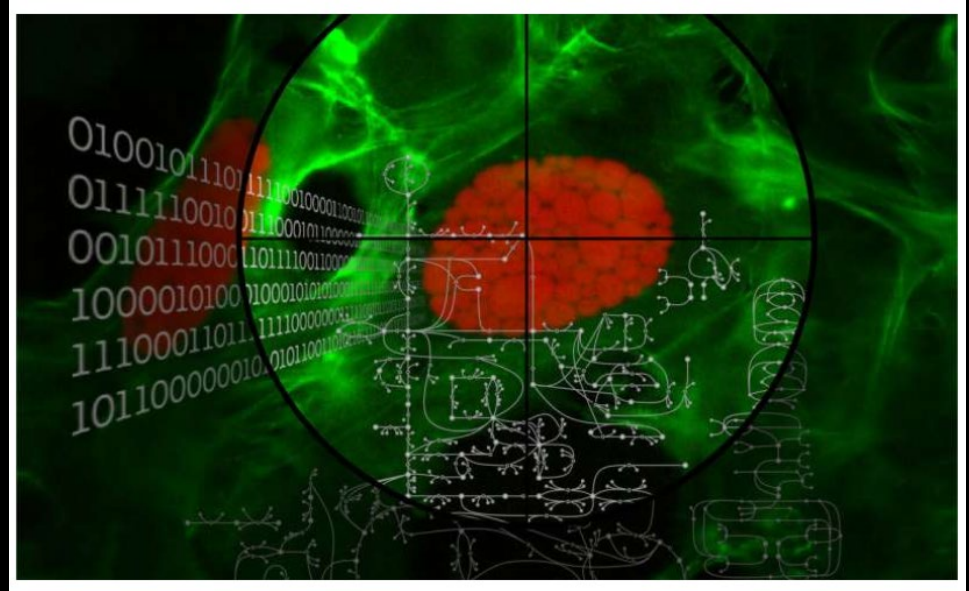
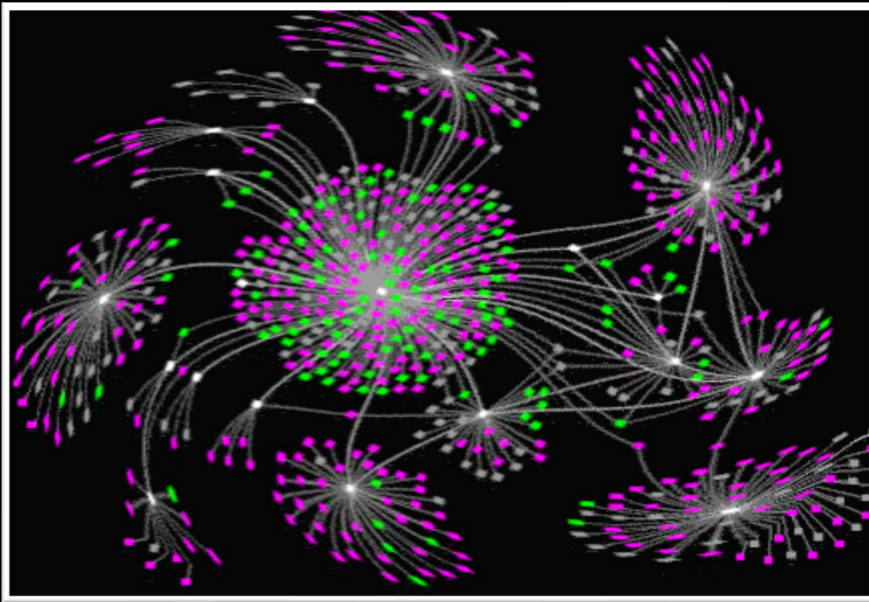
Engineering Microbial Pathogens: Shifting the Disruption Impact from Acute to Chronic

- **cause delayed but inevitable mortality (4-6 weeks) to overwhelm preparedness resources and paralyze healthcare delivery systems**
- **high chronic morbidity in survivors and resulting clinical burden (human) or economic loss (agriculture and disruption trade supply chains)**
- **racial and ethnic selectivity (human) and genetic bottlenecks (agricultural crops)**
- **acute panic and progressive erosion of trust in government**
- **long term psychological effects on exposed societies**

Latent, Activatable Agents

- **‘silent’ integration into host genome**
 - **targeted insertion in specific organs/cell types**
- **co-infection and co-insertion of activation trigger (gene enhancers)**
- **activation on demand by exposure to enhancer triggers**
 - **from targeted effects on individuals/groups to widespread population effects**
 - **silent insertion into germ line (sperm, eggs) and trans-generational vulnerabilities**

Synthetic Biology and DURC: Thinking 'Beyond Bugs'



- **precision medicine is mapping the molecular networks
- (circuit diagrams) of every cell type in the body and
circuit disruptions in disease**
- **roadmap for next-generation chemical warfare agents to
target specific molecular circuits**

Mapping Biological Information Pathways and New Dual-Use Threats

- **identification of genetic coding (information) and molecular pathways (wiring circuits) for every cell type in the human body**
- **disease-induced circuit changes**
 - improved diagnosis and treatment (precision medicine)
- **same information provides ‘targets’ for disruption by biological (infectious) and chemical (non-infectious) agents**
 - direct targeting
 - indirect effect by targeting the target’s control system(s)
- **epigenetic ‘gene silencing’**
 - turning silent genes on and active genes off



“Armies of the future will need weapons based on new physical principles, including genetic and psychophysical science.”

**President Vladimir Putin
Essay, Rossiyskaya Gazeta, 2012**



Dual-Use Implications of Advances in Brain Science

Mapping Sensory, Motor and Cognitive Functions



BRAIN RESEARCH THROUGH ADVANCING
INNOVATIVE NEUROTECHNOLOGIES

BRAIN INITIATIVE



DARPA Next-Generation Non-Surgical Neurotechnology (N³)

Chemical or Electronic Modulation of Specific Neural Circuitry: New Warfare Capabilities and Societal Vulnerabilities

- fear, depression, suicidal ideation
 - aggression
- disruption of sleep patterns
 - memory modulation
- lethargy ● addiction



**U.S. ARMY COMBAT CAPABILITIES DEVELOPMENT COMMAND
CHEMICAL BIOLOGICAL CENTER**

ABERDEEN PROVING GROUND, MD 21010-5424

CCDC CBC-TR-1599

**Cyborg Soldier 2050: Human/Machine Fusion and
the Implications for the Future of the DOD**

**Peter Emanuel
RESEARCH AND TECHNOLOGY DIRECTORATE**

**Scott Walper
NAVAL RESEARCH LABORATORY
Washington, DC 20375-0001**

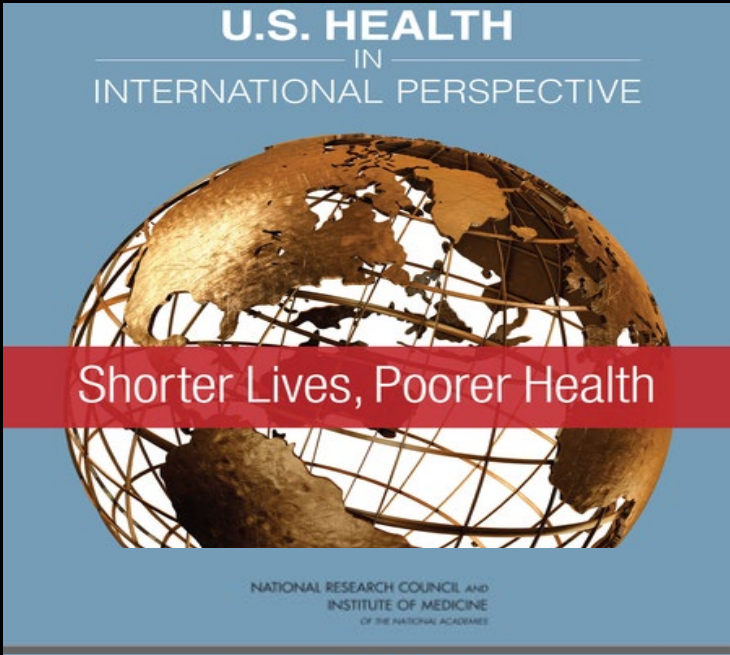
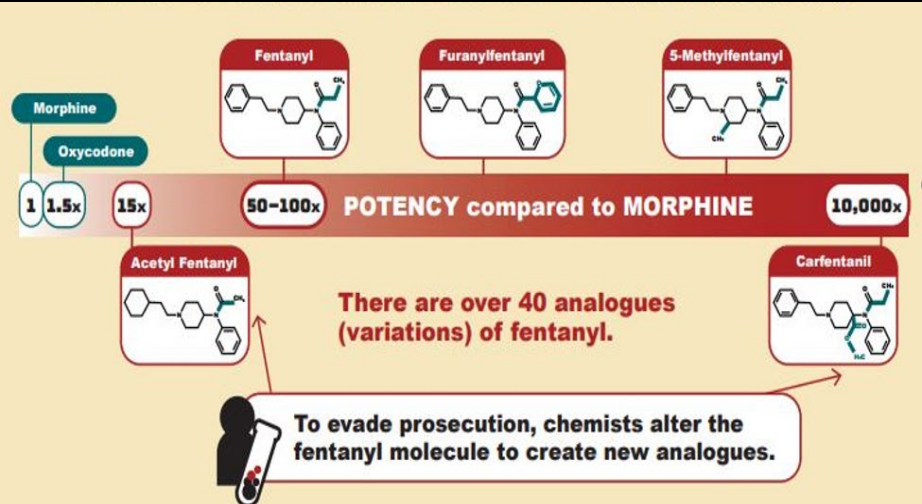
**Diane DiEuliis
NATIONAL DEFENSE UNIVERSITY
Washington, DC 20319-5066**

**Natalie Klein
U.S. ARMY MEDICAL RESEARCH and DEVELOPMENT COMMAND
Fort Detrick, MD 21702-5000**

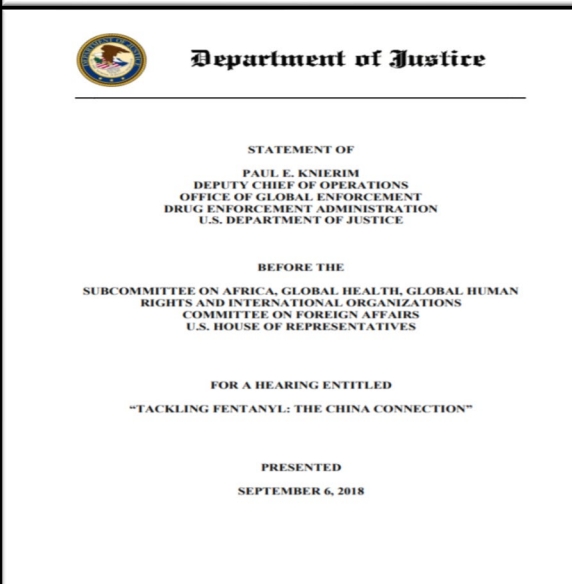
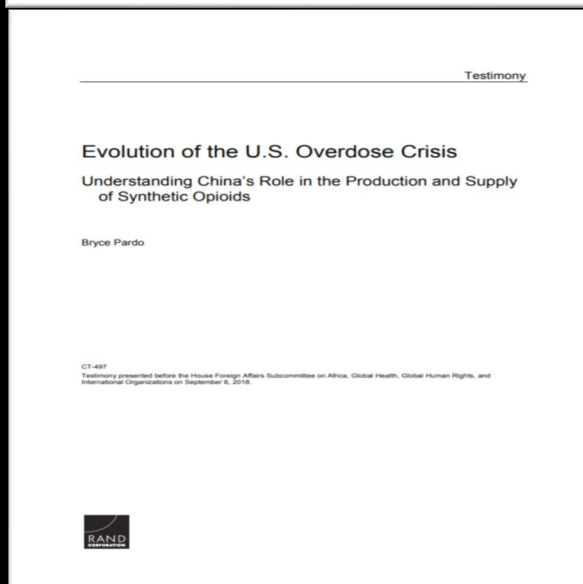
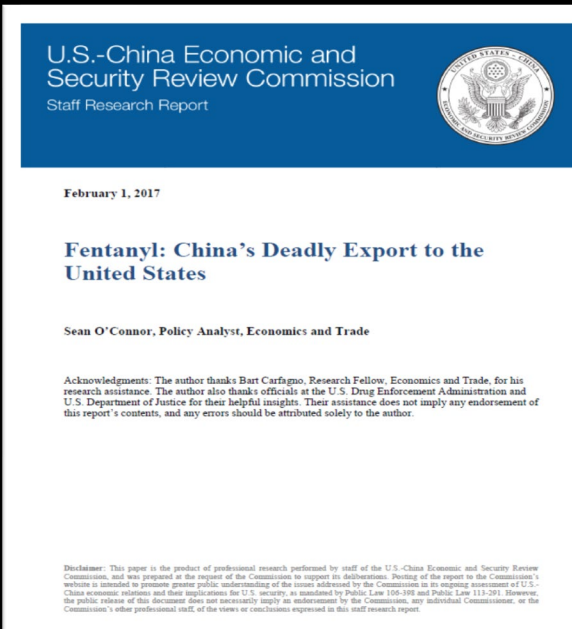
**James B. Petro
OFFICE OF THE UNDER SECRETARY OF DEFENSE
FOR RESEARCH and ENGINEERING
Alexandria, VA 22350-0002**

**James Giordano
GEORGETOWN UNIVERSITY
Washington, DC 20057-1409**

Purposeful Societal and Economic Disruptions Via Rapid Design of Ever-Changing Addiction Drugs Generated by Synthetic Biology



China's Export of Fentanyl and Derivatives: A New Biosecurity Threat



China Has Withheld Samples of a Dangerous Flu Virus

Despite an international agreement, U.S. health authorities still have not received H7N9 avian flu specimens from their Chinese counterparts.

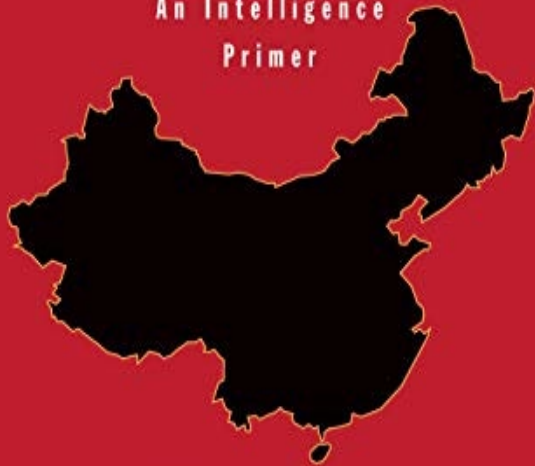


Health workers attending to an H7N9 avian flu patient in Wuhan, China, in 2017.

Agence France-Presse -- Getty Images

CHINESE COMMUNIST ESPIONAGE

An Intelligence
Primer



PETER MATTIS AND MATTHEW BRAZIL

Foreign Economic Espionage in Cyberspace

2018



NATIONAL COUNTERINTELLIGENCE AND SECURITY CENTER



United States Senate
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
Committee on Homeland Security and Governmental Affairs

Rob Portman, Chairman
Tom Carper, Ranking Member

Threats to the U.S. Research Enterprise: China's Talent Recruitment Plans

STAFF REPORT

PERMANENT SUBCOMMITTEE ON
INVESTIGATIONS

UNITED STATES SENATE

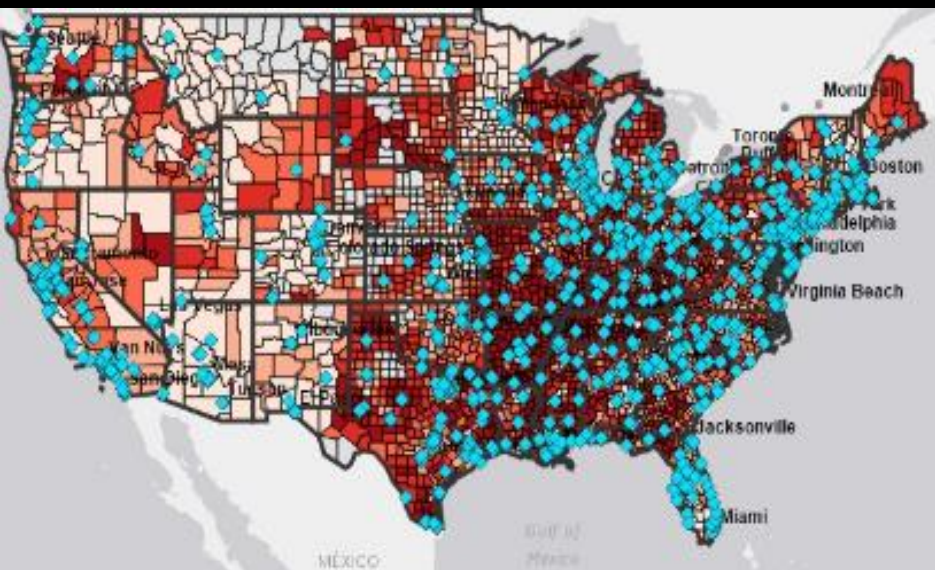




- **major R.& D. investments and sophisticated biotechnology/computing expertise**
- **purposeful creation of large diaspora for training in US/EU universities**
- **relentless industrial espionage and relentless cyber- exfiltration efforts**
- **mapping the genetic diversity of human populations**

National Security Implications of Genome Data on Populations

Population Databanks



Individual Profiles



Foreign Access to Data



华大基因
BGI

Data Security





OFFICE OF THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-1000

DEC 20 2019

MEMORANDUM FOR: SEE DISTRIBUTION

SUBJECT: Direct-to-Consumer Genetic Testing Advisory for Military Members

It has come to the attention of the DoD that some direct-to-consumer (DTC) genetic testing companies are encouraging DoD personnel to purchase genetic ancestry and health information through the offering of military discounts or other incentives. These DTC genetic tests are largely unregulated and could expose personal and genetic information, and potentially create unintended security consequences and increased risk to the joint force and mission.

Exposing sensitive genetic information to outside parties poses personal and operational risks to Service members. DTC genetic tests that provide health information have varying levels of validity, and many are not reviewed by the Food and Drug Administration before they are offered, meaning they may be sold without independent analysis to verify the claims of the seller. Possible inaccuracies pose more risk to DoD military personnel than the public due to Service member requirements to disclose medical information that affects readiness (see DoD Instruction 6025.19, "Individual Medical Readiness"). Testing outside the Military Health System is unlikely to include a clear description of this risk.

Moreover, there is increased concern in the scientific community that outside parties are exploiting the use of genetic data for questionable purposes, including mass surveillance and the ability to track individuals without their authorization or awareness.

Until notified otherwise, DoD military personnel are advised to refrain from the purchase and/or use of DTC genetic services.

Joseph D. Kernan
Under Secretary of Defense for Intelligence

James N. Stewart
Assistant Secretary of Defense for Manpower
and Reserve Affairs, Performing the Duties
of the Under Secretary of Defense for
Personnel and Readiness

Editing the Human Germ Line: No Longer An Abstract Question



- **editing humanity: moral and legal constraints or hubris and irresistible inevitability?**
- **long standing science fiction scenarios and philosophical, religious, ethical, legal debates on the societal implications**
- **no longer a theoretical debate**

The Governance and Oversight of Synthetic Biology

**Growing Gap Between Technological Acceleration
and Timely Development of National Policies
and International Harmonization**

US Policy Landscape for Bioweapons and Bioterrorism

- **Biological and Toxin Weapons Convention**
- **Biological Weapons Anti-Terrorism Act (Public Law 101-298, 1990)**
- **Antiterrorism and Effective Death Penalty Act (Public Laws 104-132, 1996)**
- **USA Patriot Act (Public Law 107-56, 2001)**
- **Public Health and Bioterrorism Preparedness and Response Act (Public Law 107-188, 2002)**
- **federal and institutional policies for oversight of dual-use research of concern (White House, 2012, 2015)**

Export Controls on Technologies for WMD Threats and CBW Weaponization



The U.S. Export Control System and the Export Control Reform Initiative

Ian F. Fergusson
Specialist in International Trade and Finance

Paul K. Kerr
Specialist in Nonproliferation

August 9, 2018

Congressional Research Service
7-5700
www.crs.gov
R41916

CRS REPORT
Prepared for Members and
Committees of Congress



Dual-Use Technologies and Export Control in the Post-Cold War Era

Documents from a Joint Program of the
National Academy of Sciences and the
Russian Academy of Sciences

National Research Council



DETECTING SUSPICIOUS PROCUREMENT ATTEMPTS

Regrettably, not all buyers approach Australian industries with a legitimate commercial purpose. The following information is designed to assist industry identify activities that may indicate an attempt to illegally acquire conventional arms or procure goods, services and technologies for weapon of mass destruction (WMD) programs.

Illicit WMD programs and proliferation of conventional arms pose significant threats to the safety of all Australians, and to regional and global security. It is in Australia's interest to ensure would-be proliferators are denied access to conventional weapons and items that may contribute to WMD activities are appropriately controlled.

The Defence Export Control Office works closely with other government agencies to prevent the proliferation of WMD and conventional weapons and, in turn, protect Australia's reputation as a responsible member of the global exporting community.

To this end, industry should ensure that all exports are compliant with all statutory and regulatory requirements. Applications to export regulated defence and dual-use goods, and goods and services that could contribute to a WMD program, must be lodged with DECO.

Australian industry can help prevent the proliferation of WMD and conventional weapons by reporting all suspicious approaches to DECO.

IDENTIFYING SUSPICIOUS APPROACHES

There are certain 'red flags' that can indicate an attempt to proliferate. These include:

- Approaches from persons or entities on the Department of Foreign Affairs and Trade's Consolidated List
- Approaches from countries subject to sanctions, or with a WMD program
- Unusual or inappropriate requests for goods to be manufactured to military, or unusually high, specifications
- Unusually favourable, or non-standard payment terms
- Unusual requests regarding the shipment route, or labelling of the goods

If you have encountered any of these red flags, you may have had a suspicious approach. More red flags can be found over the page.

WHAT NOW?

Members of industry who have information that could identify a suspicious enquiry or purchase are encouraged to contact DECO via:

Phone - 1800 66 10 66

Online - access our 'Reporting A Suspicious Approach' form at www.defence.gov.au/strategy/deco

Mail - mark all letters 'In Confidence'

and post to:

Defence Export Control Office
Department of Defence
R11-AUS, Russell Offices
CANBERRA ACT 2600

For further information on DECO's Privacy Policy click on the link to the 'Reporting A Suspicious Approach' form above.

Australia Group Common Control List Handbook

Volume I: Chemical Weapons-Related Common Control Lists



Australia Group Common Control List Handbook

Volume II: Biological Weapons-Related Common Control Lists



The Voice for
Australia's exporters

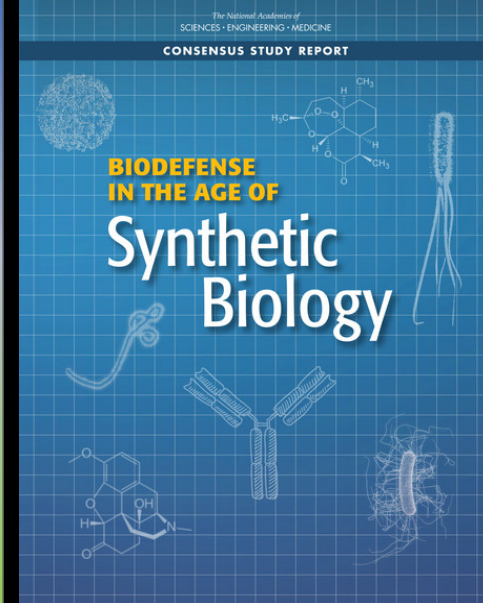
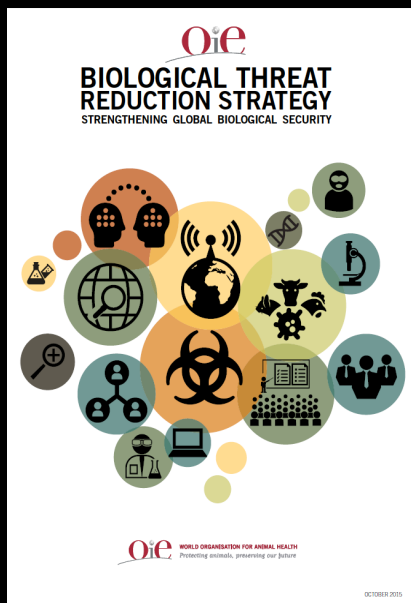
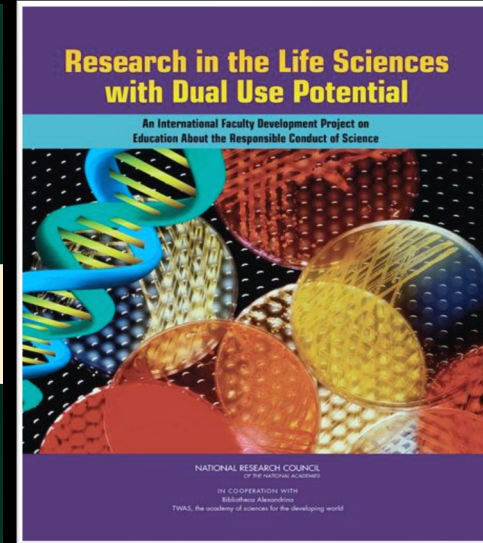
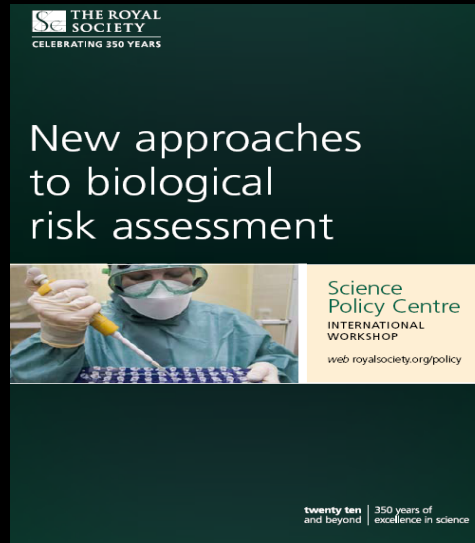
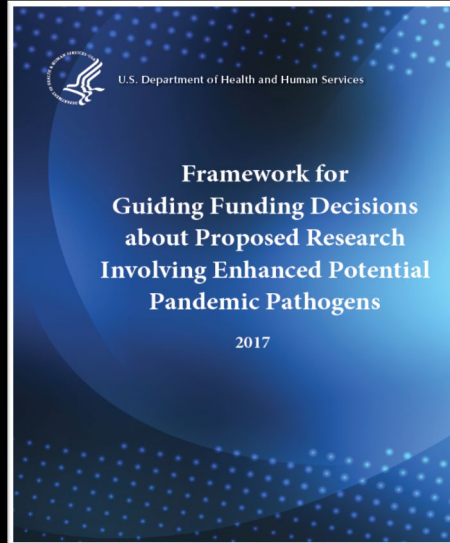
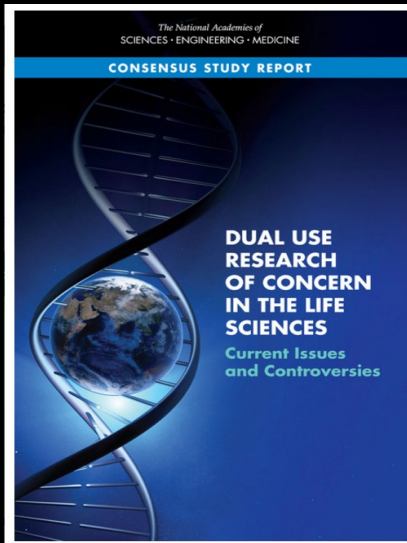


Intergovernmental Agreement on Biosecurity Review

July 2016

Submission by the Export Council of Australia

Policy Frameworks for Dual-Use Research of Concern (DURC): Primary Focus on Pathogenic Microorganisms



Current Regulatory and Oversight Frameworks are Outdated

- **historical narrow focus on small list of select pathogens**
- **major gaps in USG experience, knowledge and agility to interpret and regulate emerging industrial ecosystems**
 - **inter-agency communication and decision authorities**
 - **monitoring global supply chains and multiple intermediaries**
 - **internet crime**
 - **digital biology and data security**
- **poor coupling and integration of global public, health frameworks (natural infections) and biodefence efforts (nefarious assaults)**

Screening of

Gene Sequences of Concern



- screening orders to synthesize potentially dangerous sequences
 - focus on select agents
- likely increasing irrelevance as a biosafety/surveillance tool
 - low cost of synthesis machines
 - digital genome computer codes bypass screening and surveillance tools
 - new gene editing tools makes any gene a target

Insight Report

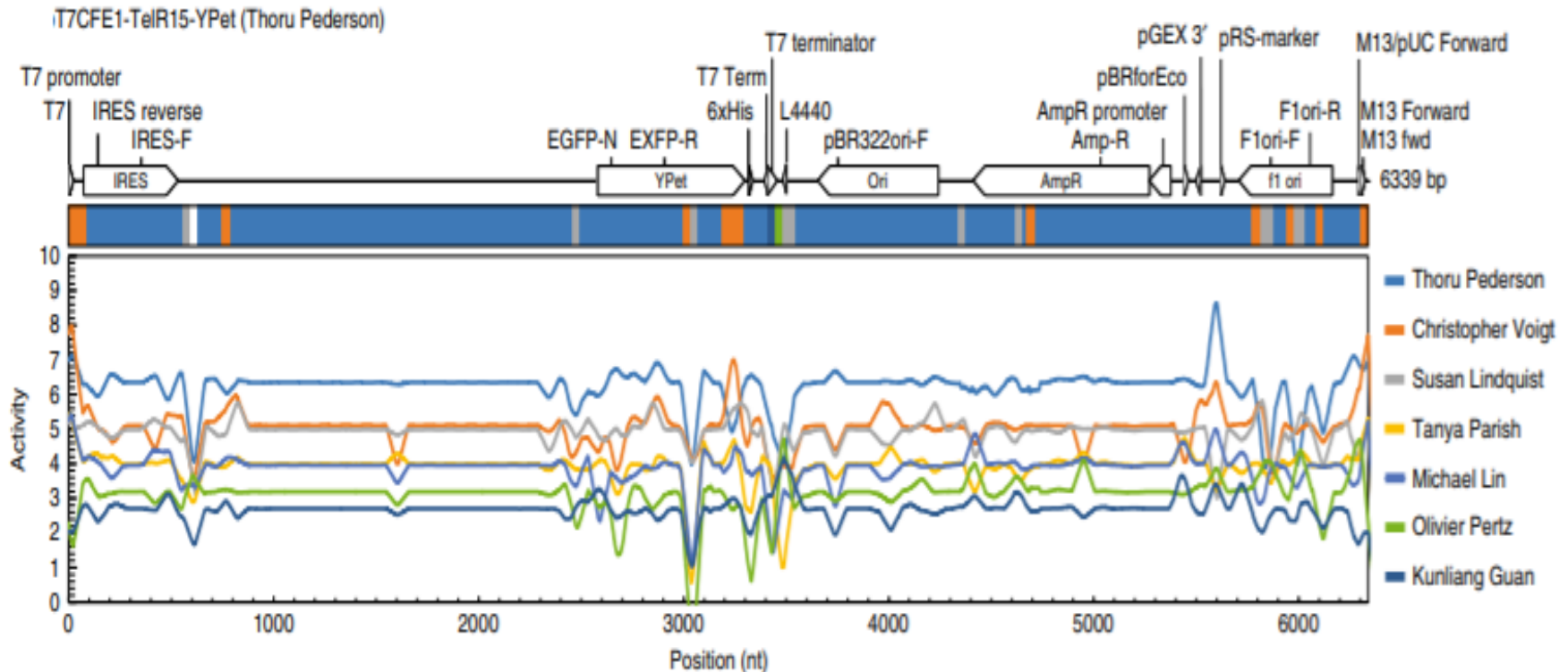
Biosecurity Innovation and Risk Reduction: A Global Framework for Accessible, Safe and Secure DNA Synthesis

In collaboration with the Nuclear Threat Initiative (NTI)

January 2020



Deep Learning Convolutional Neural Networks Profiling of Plasmids and 'Lab-Specific Drift' Patterns



new class of potential signatures to predict
lab-of-origin in engineered DNA sequences

Automated Remote Monitoring of Bioprocess Equipment to Ensure Integrity of Synthetic Program as Declared



Gray Zone Threats

An Emerging Dimension of Hybrid Warfare

**New Risks in the Gray Zone Between
Peace and Major Conflict**

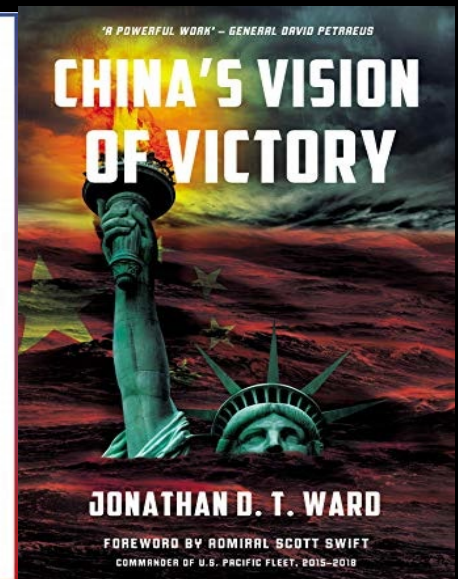
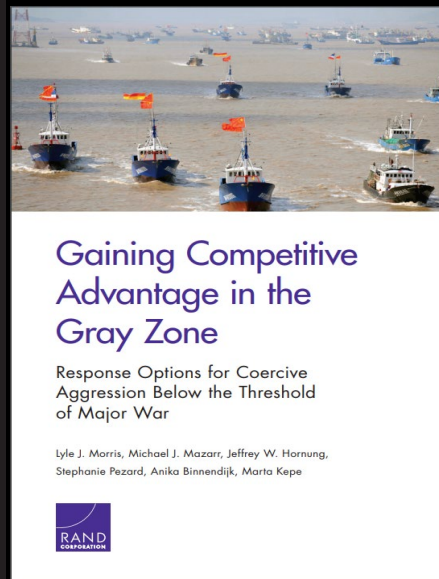
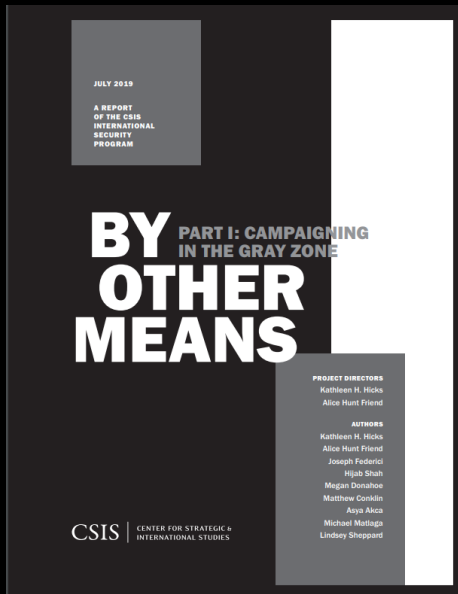
Implications for Biosecurity

Gray Zone Threats

- **between peace (zero) and major military conflicts between nations (five)**
- **are we already facing level one/two – level escalation ?**

Darker Shades of Gray: The Emerging Dimension of Hybrid Warfare

- deception, disinformation and propaganda
- weaponized narratives (“fake news”)
- lawfare; exploiting loopholes and seeding ambiguity
- plausible deniability
- exploit Western public reluctance for military deployments



Gray Zone Tweets and Biosecurity: Russian Trolls and Twitter Bots

- **weaponized health communications**
 - **anti-vaxxer campaigns**
 - **anti-GMO movements**
- **compromise health care computer systems and or other critical computing capabilities in bioincidents**
- **Novochok chemical attack UK 2018**
 - **Salisbury UK hospital computers hacked**
 - **thwarted hack of Organization for Prohibition of Chemical Weapons (The Hague) conducting forensic analysis of incident samples**

New Technologies and Public Trust

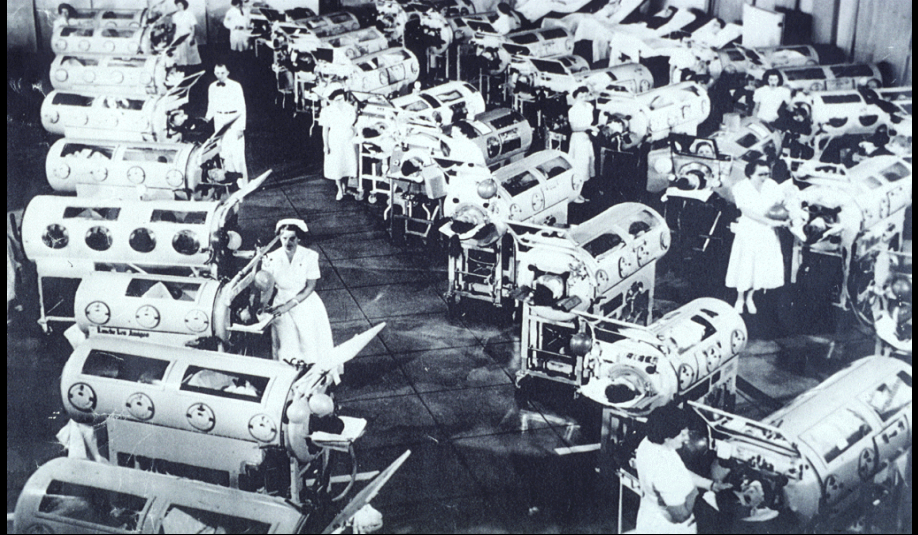
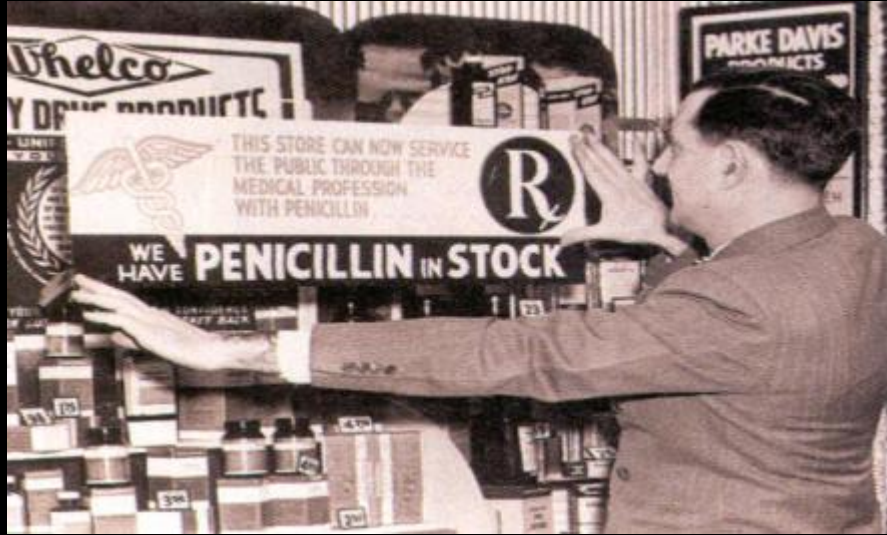
- **“techlash”**
 - **fast and loose approach of Silicon Valley to consumer data protection and privacy**
- **‘anti-science’ suspicion and resentment of elitism**
- **“fake news”**
- **autonomous vehicles/smart robots**
- **gene editing/synthetic biology**
- **machine learning/artificial intelligence**

Out of Sight: Out of Mind!

**The Cocoon of Protection: How Quickly We
Forget Past Epidemics and Their Toll**

**Reduced Investment in Public Health and Biosecurity:
Myopic and Flawed Policy**

Comfort and Complacency: The Enemies of Vigilance and Preparedness



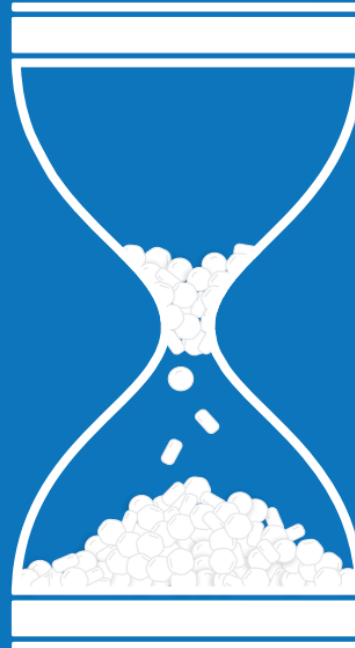


HM Government

Tackling antimicrobial resistance 2019–2024

The UK's five-year national action plan

Published 24 January 2019



NO TIME TO WAIT:
SECURING THE FUTURE
FROM DRUG-RESISTANT
INFECTIONS

**REPORT TO THE
SECRETARY-GENERAL
OF THE UNITED NATIONS**

APRIL 2019

Encouraging Vaccine Innovation: Promoting the Development of Vaccines that Minimize the Burden of Infectious Diseases in the 21st Century

Report to Congress

December 2017



**Vaccine Platforms:
State of the Field and Looming Challenges**



U.S. Department of Health and Human Services



JOHNS HOPKINS
BLOOMBERG SCHOOL
of PUBLIC HEALTH

Center for
Health Security

“Fits and Starts: Reactionary Biodefense”

October 2018

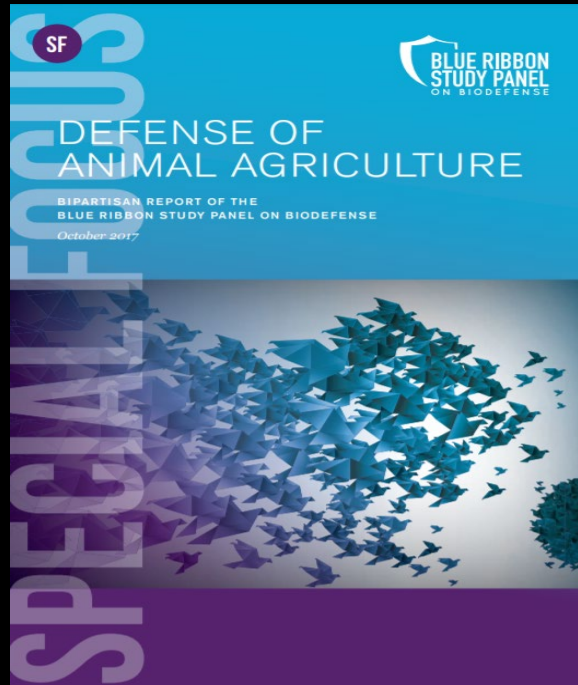


A NATIONAL BLUEPRINT FOR BIODEFENSE:

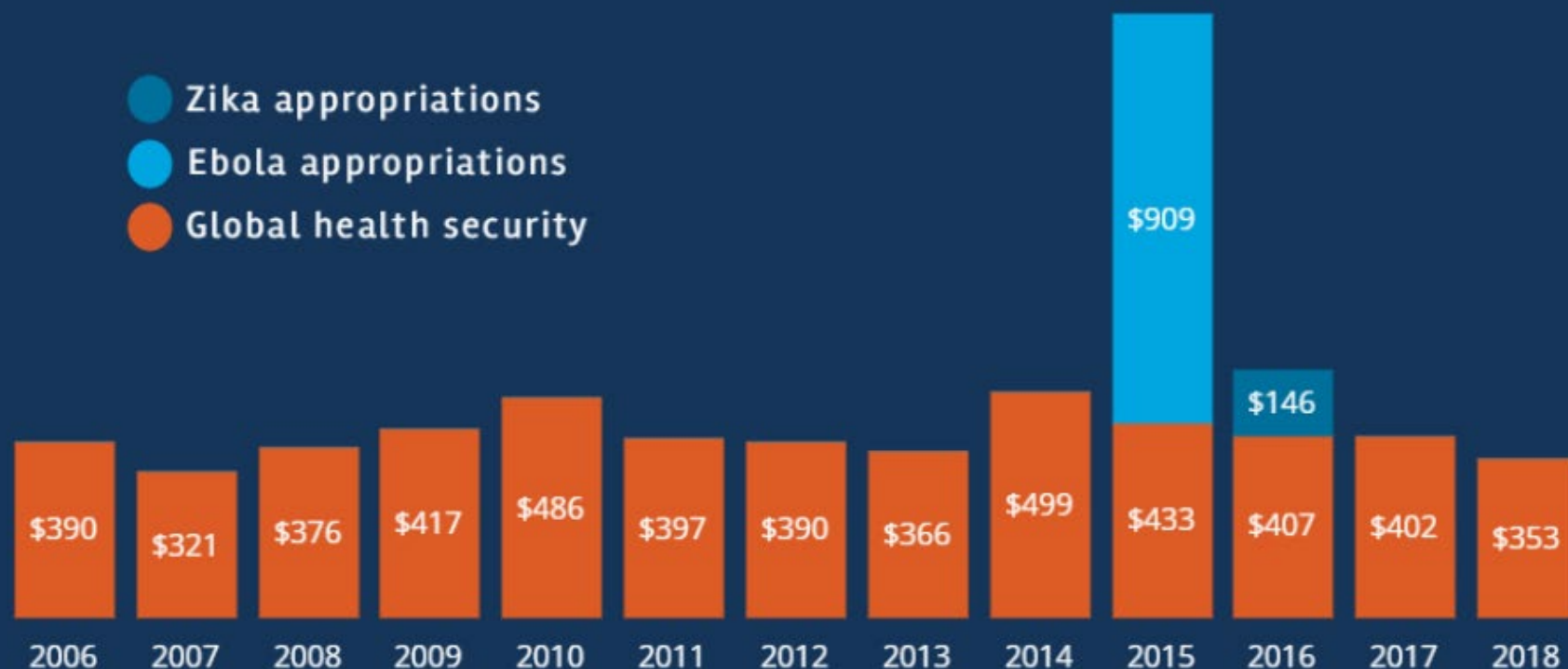
LEADERSHIP AND MAJOR REFORM
NEEDED TO OPTIMIZE EFFORTS



BIPARTISAN REPORT OF THE BLUE RIBBON
STUDY PANEL ON BIODEFENSE
October 2015



U.S. Funding for Global Health Security



SOURCE: KFF brief on U.S. Government and Global Health Security.

KFF.org

The Joint External Evaluation Exercise (JEE): January 2016*

- **major deficits in 89% of the 55 countries evaluated to date**
- **surveillance for highly antibiotic resistant pathogens and antimicrobial stewardship**
- **biosecurity and surveillance for zoonotic diseases, food poisoning and water-borne illness**
- **insufficient personnel and training**
- **investment levels**
- **major risks to cross-border disease spread**

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

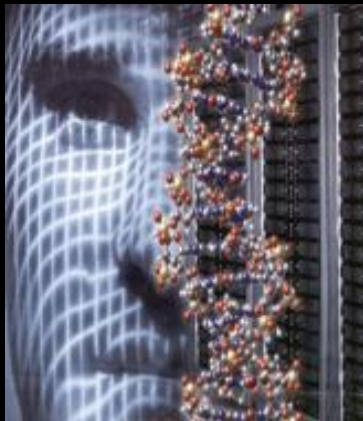
- **false comfort and complacency**
 - **society increasingly “cocooned” from complexity and risk**
- **pervasive and dangerous scientific illiteracy among legislative and policy makers about biosecurity**
- **“quick fixes” unidimensional, short term policies that**
 - **do not address long term, multidimensional complexity**
- **public policy defined increasingly by length of legislative terms**
- **influence of media in shaping public policy priorities and potential compromise of operational preparedness**

The Imperative for Proactive Actions for Robust Biosecurity

- **need for higher priority of biosecurity in national security strategy and international engagement**
- **development of more sophisticated threat assessment capabilities**
- **strengthen surveillance, analysis deterrence capabilities in national security, IC, law enforcement**
- **greater investment in robust threat mitigation capabilities**
 - **obligate private sector engagement**
 - **logistics and operational integration (and training) for complex bioincident management**
- **agile oversight mechanisms and international harmonization**

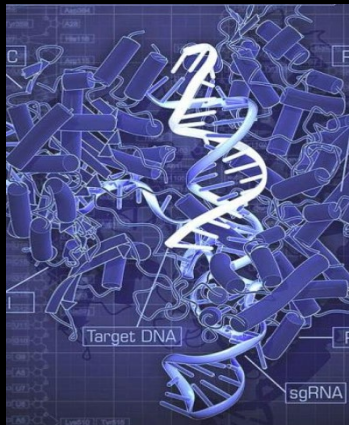
Escalating Complexities in Biosecurity

**All Hazards
Analysis**



**“Threat
Space”**

**Synthetic
Biology,
Digital Biology**



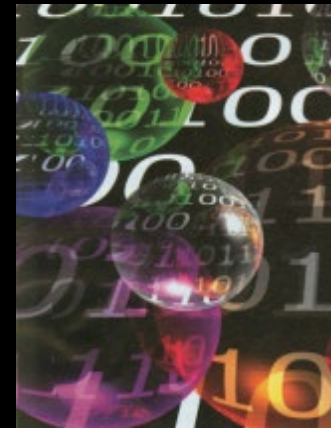
**“Design
Space”**

**Biosurveillance
and
Diagnostics**



**“Detection
Space”**

**Meta-Data,
Advanced
Computing,
AI**



**“Analysis
Space”**

**Agent X and
Proliferation
of Dual-Use
Risks**



**“Preparedness
Space”**

**“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 @ <https://casi.asu.edu/presentations/>

