

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

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Biosecurity: Domestic and International Institutions

Biosecurity: Domestic and International Institutions

- **evolution over the last 150 years**
- **integrate new scientific, clinical, public health, legal and military/counter-terrorism perspectives of risk assessment and management**
- **desired but still elusive consensus on scope and nature of international cooperation**
- **diverse regulation, legislation, conventions, treaties and access controls**
- **rapid pace of new technology-driven risks render many current oversight approaches anachronistic**

Biosecurity: Domestic and International Institutions Different Objectives and Scope of Authority

- **public health versus warfare/terrorism**
- **human populations, livestock, crops and environmental resources**
 - **‘one health’ concept gaining momentum**
- **food and water security**
- **refugee migration and care obligations**
- **disease surveillance, detection, mitigation and recovery measures**
- **transparent, prompt information exchange and international coordination (International Health Regulations: IHRs)**

Biosecurity: Domestic and International Institutions Different Objectives and Scope of Authority

- legal and ethical frameworks for bioincident mitigation
- mandatory non-consented use of diagnostics and Emergency Use Authorization (EUA) countermeasures
- forced quarantines and other 'lock-down' vehicles
- track and trace systems and protection of individual privacy
- triage criteria for rationed care
- USG diversion of private sector resources for critical supply needs and distribution logistics
- law enforcement responsibilities and forensic evidence collection in case of suspected bioterrorism

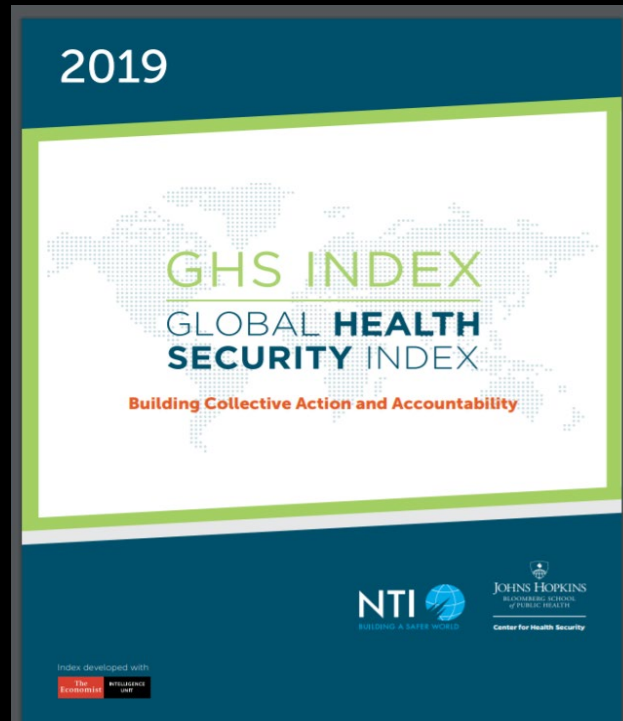
Global Oversight and International Cooperation in Biosecurity

Natural Infections and
Global Public Health

Chemical and
Biological Weapons



Global Health
Security Agenda

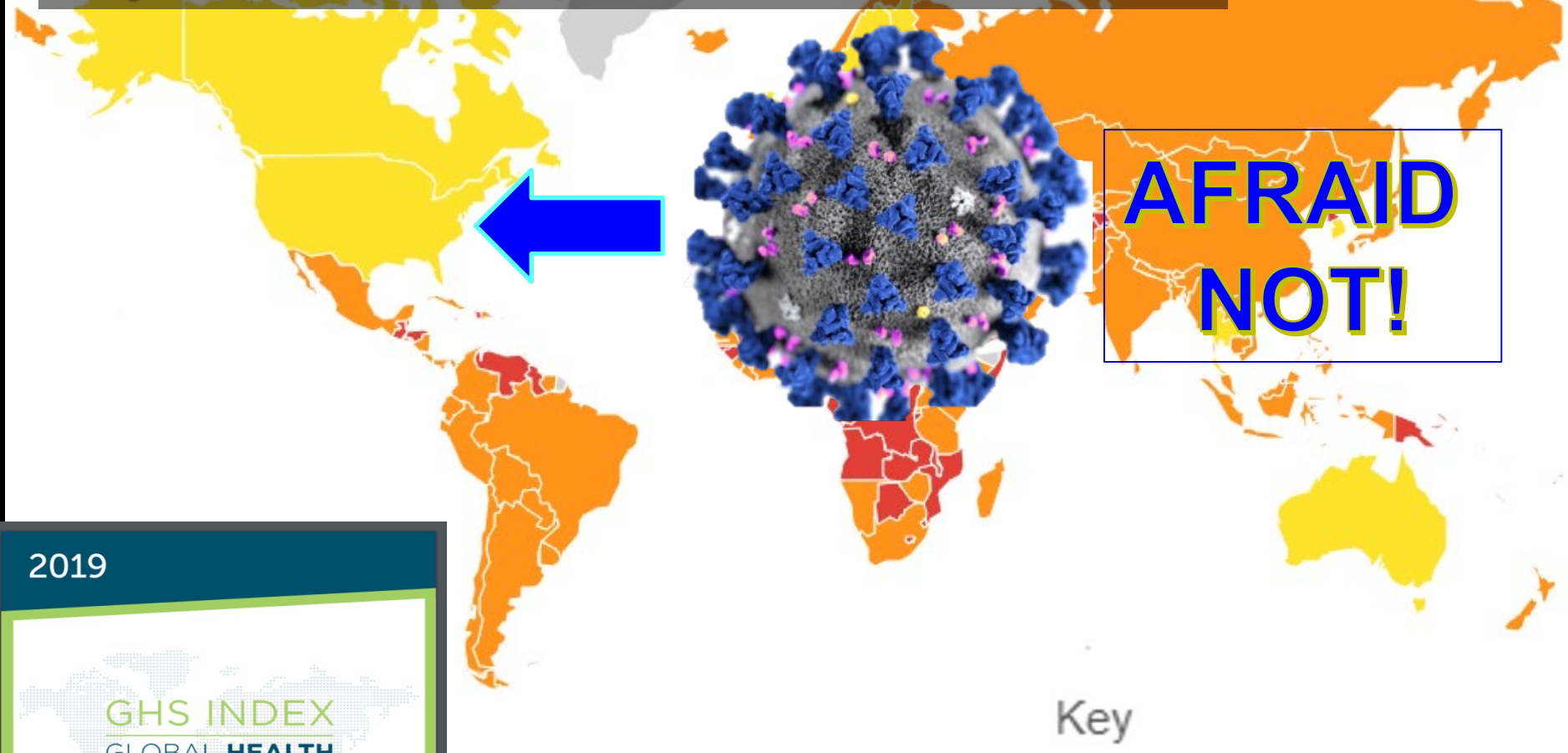


National Sovereignty and Global Policies for Infectious Disease Control

- **IHRs (and most international policies) based on principles of legal and Westphalian sovereignty**
- **autonomy of the state and its ability to exercise power (policy) without interference from external forces**
- **IHRs cannot force state-parties to act in accordance with global health interests or accept international assistance**
- **risk of economic disincentives to outbreak reporting**

Global Preparedness for Major Bioincidents

Major Deficits in 89% Countries



2019

GHS INDEX
GLOBAL HEALTH
SECURITY INDEX

Building Collective Action and Accountability



Index developed with
The Economist

Key

● Most Prepared

● More Prepared

● Least Prepared

US Policy Landscape for Bioweapons and Bioterrorism

- **Biological and Toxin Weapons Convention (1972, 1975)**
- **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)**

Biological (and Toxin) Weapons Convention (BWC)

- **Article I**
 - acquisition, retention and stockpiling of BW and delivery equipment for hostile purposes
- **Article II**
 - destroy existing BW stocks
- **Article III**
 - transfer, assist, encourage or induce third parties to acquire/retain BW
- **Article IV**
 - national compliance measures
- **Article V**
 - multilateral participation in problem in resolution
- **Article VI**
 - engage UN Security Council to investigate breaches
- **Article VII**
 - assist States exposed to danger by violations
- **Article VIII**
 - encourage peaceful uses of biological science and technology

Biological (and Toxin) Weapons Convention (BWC)

- **no formal verification mechanism to monitor compliance**
- **lack of enforcement mechanisms**
- **members ‘encouraged’ to abide by confidence-building measures (CBMs) defined at the five-year review conferences**

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 Consultation 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
R11-1-A038, 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



Intergovernmental Agreement on Biosecurity Review

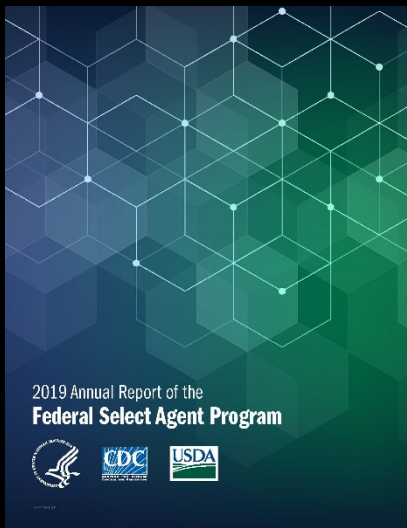
July 2016

Submission by the Export Council of Australia

History of Biosecurity Threats: Pandemics and Plagues 2000 Onwards

- 9/11/2001 attack on USA and formation of US Department of Homeland Security
- increased concern about potential use of biological agents by terrorist groups, substate actors and nation states
- expanded 'homeland security' strategic requirements added to mission of multiple USG agencies, notably DOD and the Intelligence Community (IC)





Federal Select Agent Program

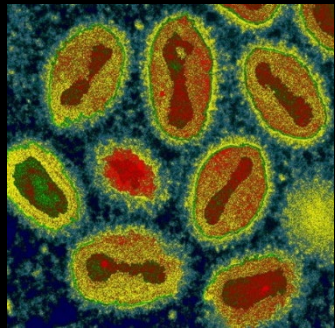
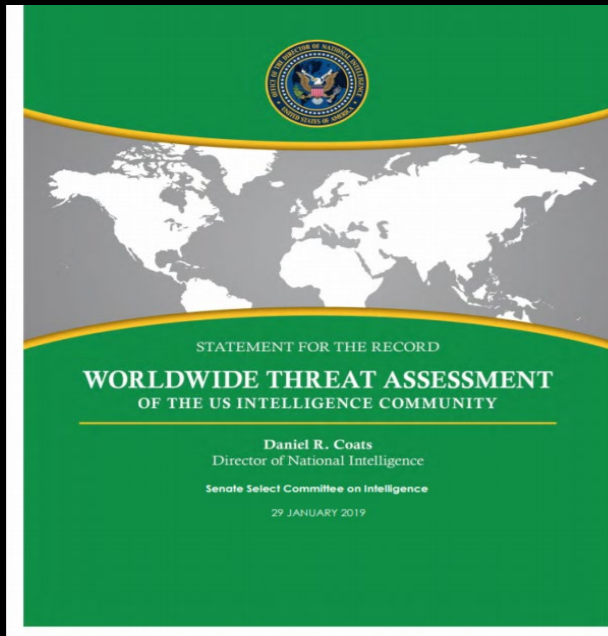
<http://www.selectagents.gov/publications.html>

- managed jointly by HHS, CDC and USDA
- registered entities
- compliance
- report detection of select agents or toxins
- transfer, theft, loss or inadvertent
- security risk assessment and inspection

2019		
247 entities	8,360 approved individuals	189 inspections



Dual-Use Applications of Synthetic Biology Misuse, Error or Accident



Construction of an infectious horsepox virus vaccine from chemically synthesized DNA fragments
PLOS ONE January 19, 2018

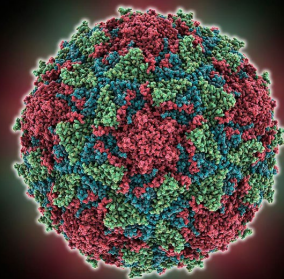
Ryan S. Noyce¹, Seth Lederman², David H. Evans^{1*}

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

Science (2002) 297, 1016

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

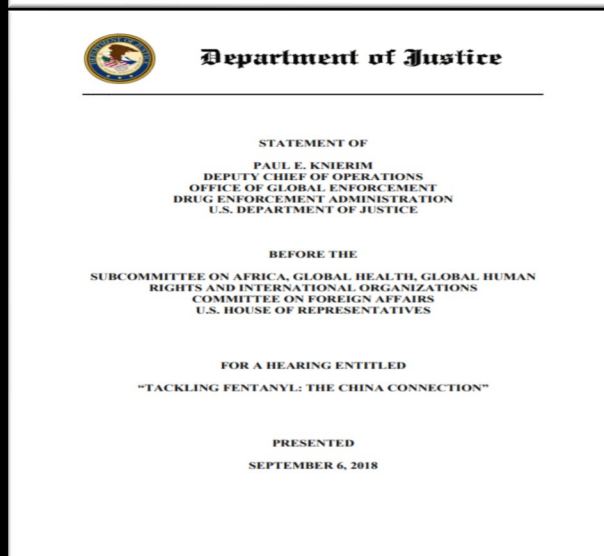
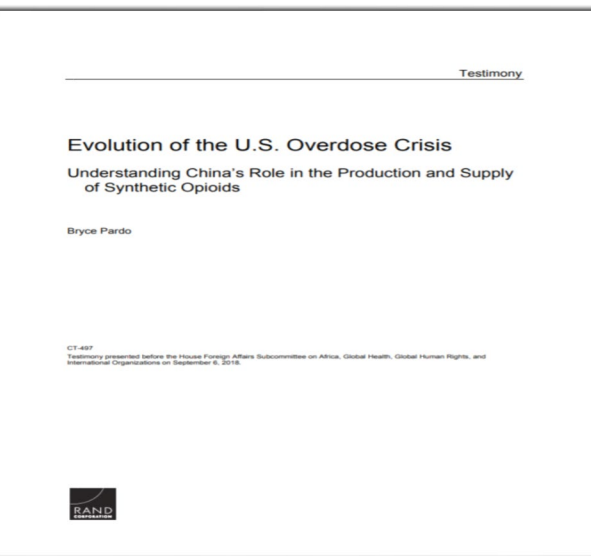
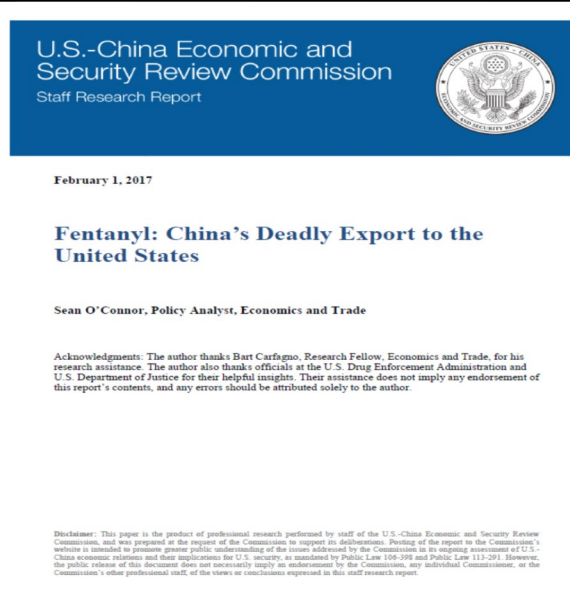
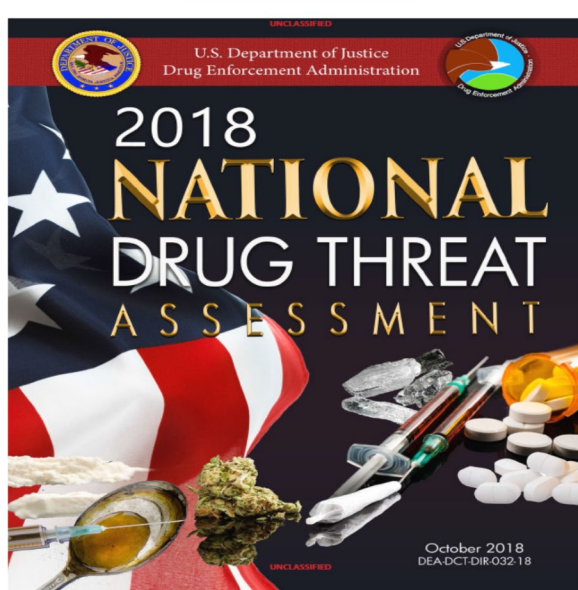
Jerónimo Cello, Aniko V. Paul, Eckard Wimmer*



Biodefense in an Era of Synthetic Biology and Precision Gene Editing

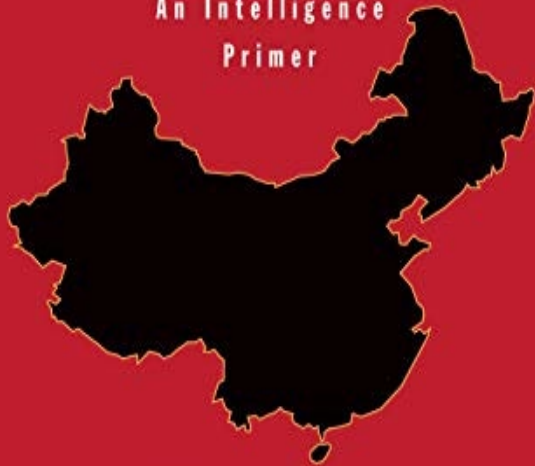
- **what are the implications for the future biothreat spectrum?**
- **what are the timeframes that particular novel threat categories are likely to evolve?**
- **what new surveillance and counter-measures will be needed?**
- **how do current international agreements regarding WMD/CBW need to be updated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

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



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



Gray Zone Threats

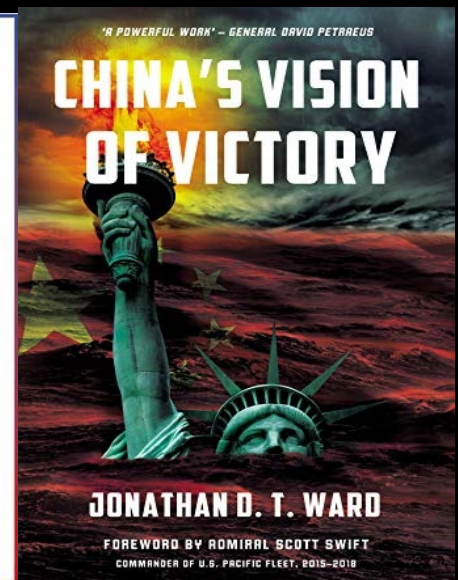
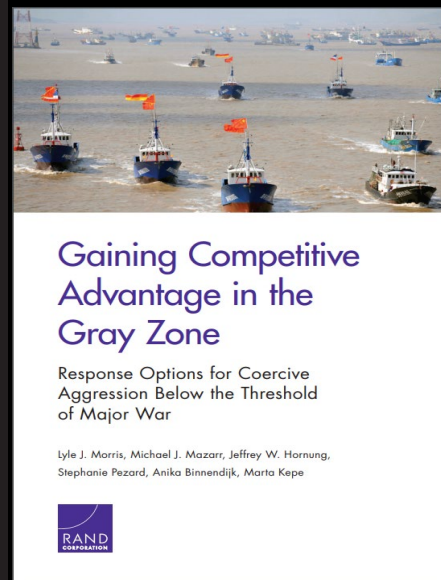
An Emerging Dimension of Hybrid Warfare

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

Implications for Biosecurity

Darker Shades of Gray: The Emerging Dimension of Hybrid Warfare

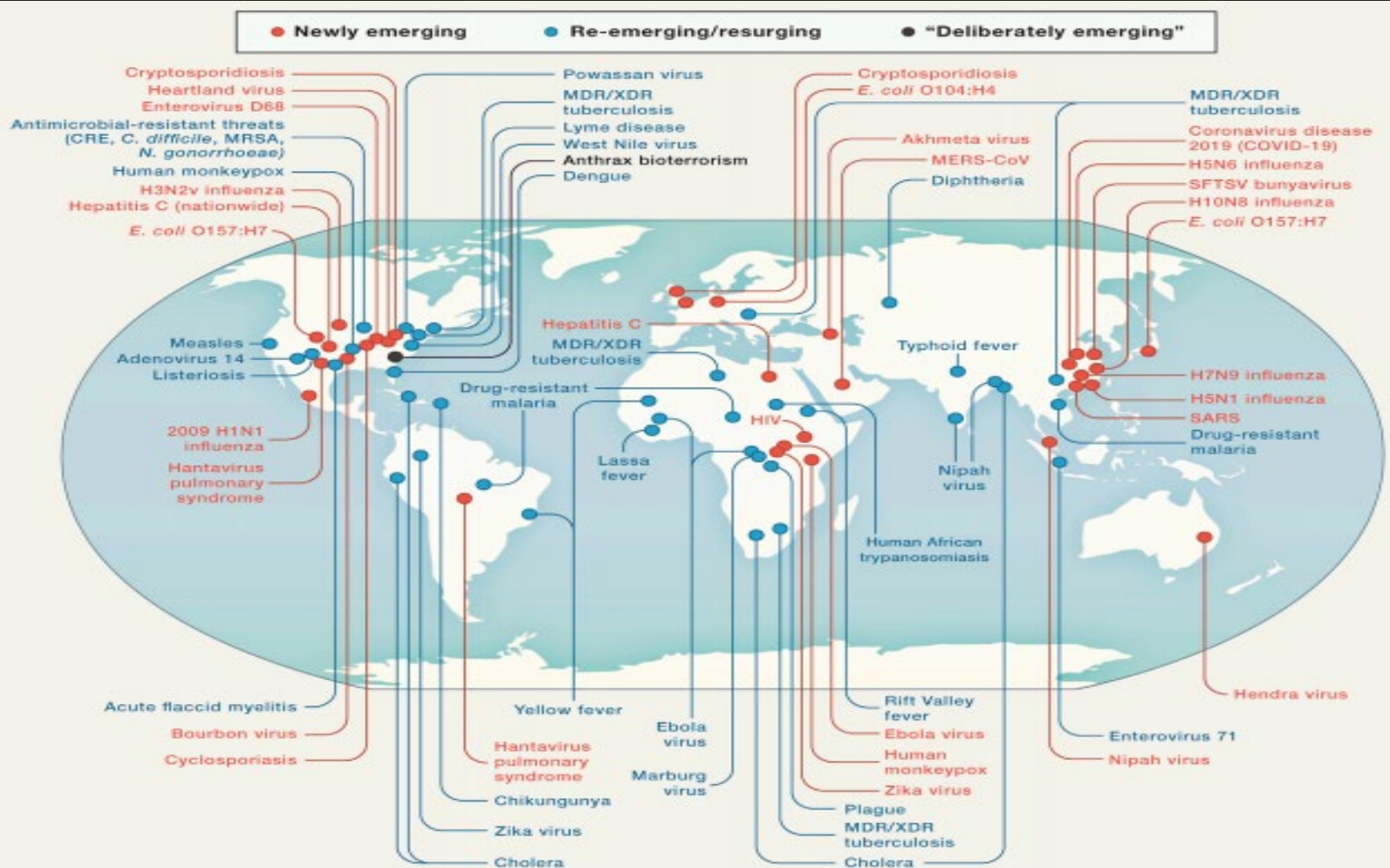
- deception, disinformation and propaganda
- weaponized narratives (“fake news”)
- lawfare; exploiting loopholes and seeding ambiguity
- plausible deniability
- exploit Western public reluctance for military deployments



Gray Zone Tweets and Biosecurity: Russian Trolls and Twitter Bots

- **purposeful social media disinformation**
- **weaponized health communications disinformation**
 - **anti-vaccination campaigns**
 - **anti-GMO movements**
 - **exploit health disparities and racial tensions**
- **compromise health care computer systems and or other critical computing capabilities in bioincidents**
- **Russian FSB Novochock chemical attack on Sergei and Yulia Skripal in UK (3/4/2018)**
 - **Salisbury UK hospital computers hacked**
 - **thwarted hack of Organization for Prohibition of Chemical Weapons (The Hague) conducting forensic analysis of incident samples**

Recent Emerging Infection Diseases



The Need for International Cooperation in International Public Health Has Never Been Greater

- **COVID-19 and economic effects on LDCs on infection detection/control programs**
- **COVID-19 Global vaccine logistics**
- **US withdrawal from WHO (5/2020) effective 7/6/2021**

The Need for International Cooperation in International Public Health Has Never Been Greater

- **COVID-19 and economic effects on LDCs on future infection detection/control programs**
 - **COVID-19 global vaccine distribution logistics**
 - **US withdrawal from WHO (5/2020) effective 7/6/2021**
- **major investment and reinvigoration of large-scale global programs**
 - **biosurveillance**
 - **PPE and related clinical stockpiles**
 - **inter-operative data systems**
 - **incentives for proactive engagement of private sector**



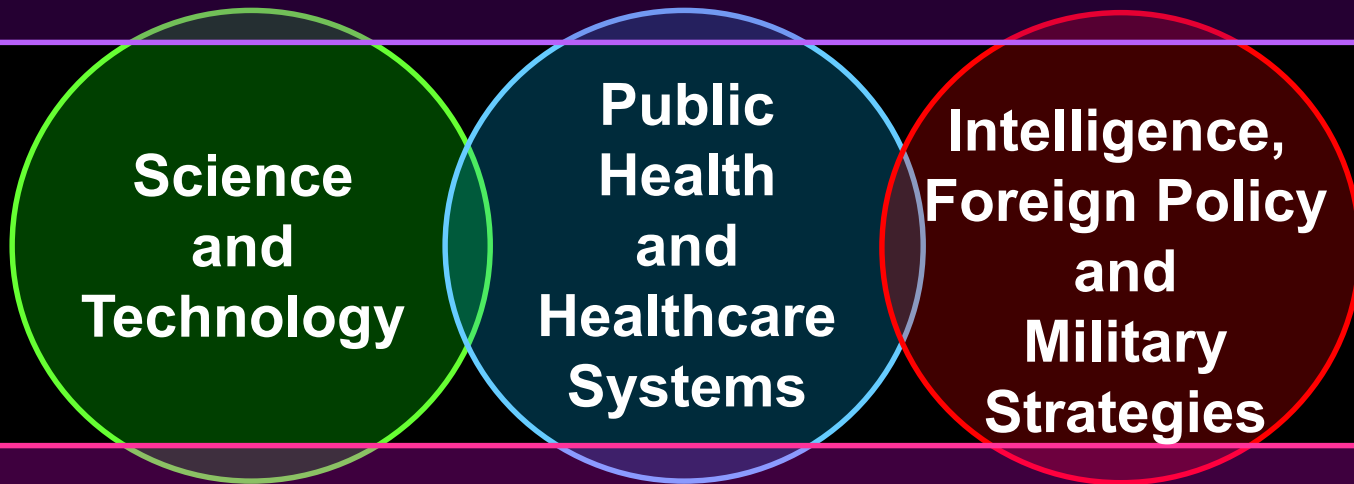
The Threat from Pandemic Influenza Remains!



Biosecurity:

A Classic Complex System of Systems Challenge

- global perspectives
- biological, socio-economic, and political ecosystems



- societal priorities and cost of biosecurity
- proactive preparedness
- conflicting political ideologies, intents and capabilities (global and national)