GSC 598 WEEK 4 NOVEMBER 2020

# 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

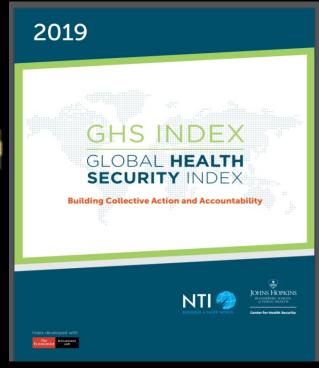
## Global Oversight and International Cooperation in Biosecurity

Natural Infections and Global Public Health

**Chemical and Biological Weapons** 



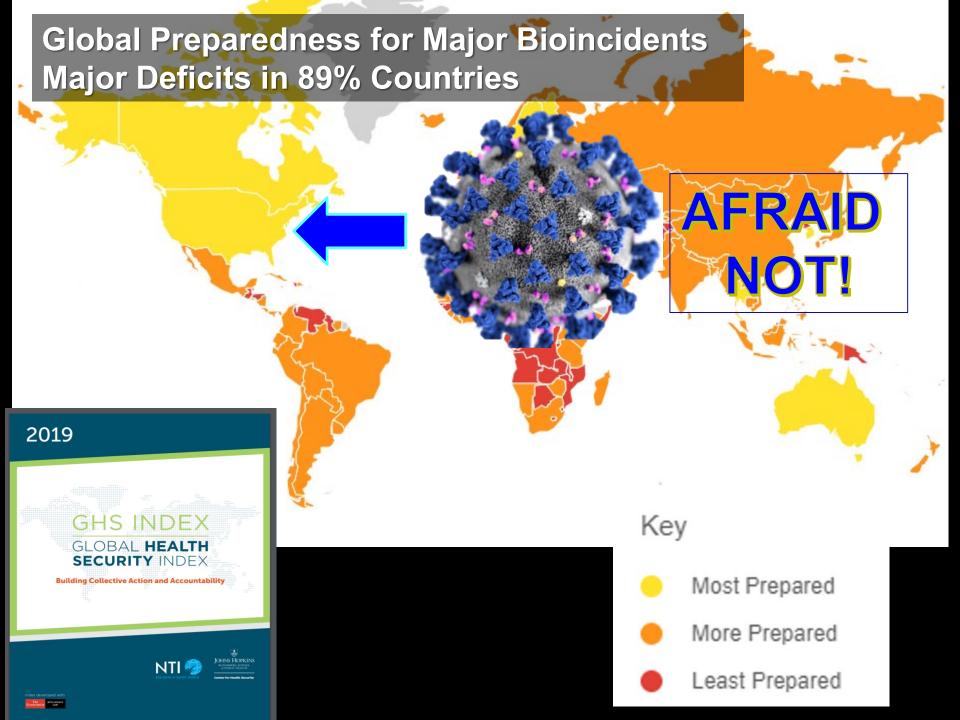
Global Health Security Agenda





## 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



## **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

CRS REPORT
Prepared for Members an



#### 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 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
- manufactured to military, or unusually high, specifications
- Unusually favourable, or non-standard payment terms
   Unusual requests regarding the shipment route, or

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

#### WHAT NOW?

labelling of the goods

s of industry who have information id identify a suspicious enquiry or a are encouraged to contact

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
R1-1-A038. Russell Offices

For further information on DECO's Privac Policy click on the link to the 'Reporting A

#### 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





# 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













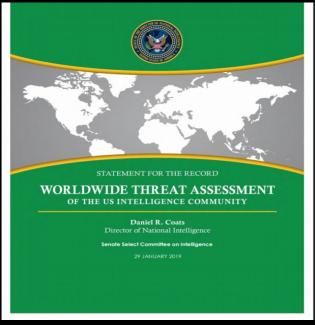


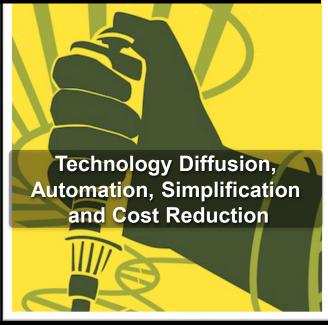


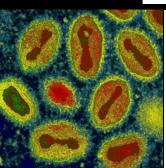




### Dual-Use Applications of Synthetic Biology Misuse, Error or Accident







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

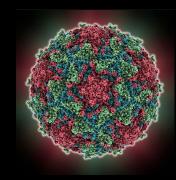
Ryan S. Noyce<sup>1</sup>, Seth Lederman<sup>2</sup>, David H. Evans<sup>1</sup>\*

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

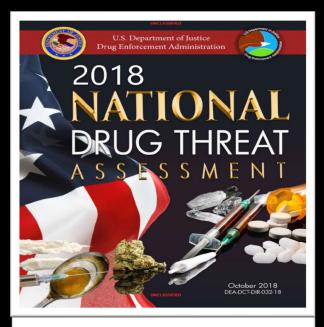
Jeronimo Cello, Aniko V. Paul, Eckard Wimmer\*



# 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



U.S.-China Economic and Security Review Commission



February 1, 2017

#### Fentanyl: China's Deadly Export to the United States

Sean O'Connor, Policy Analyst, Economics and Trade

Acknowledgments: The author thanks Bart Carfagno, Research Fellow, Economics and Trade, for his research sestimate. The author tasks hash self-cities at the U.S. Dung Enforcement Administration and U.S. Department of Justice for their helpful insights. Their assistance does not imply any endorsement of his report's contents, and any errors should be attributed solely to the author.

Dickinsser: This paper is the product of professional research performed by stiff of the US-China Economic and Security Reviews website is intended to protome general policic understanding of the times addressed by the Commission is in sugging assessment of US-China economic relations and their implications for US-security, as mandated by Public Law 100-199 and Public Law 101-199. However, China economic relations and their implications for US-security, as mandated by Public Law 100-199 and Public Law 101-199. However, Commission's public professional stiff of the views or contains expressed in this start fresearch report

#### U.S.-China Economic and Security Review Commission



Issue Brief

November 26, 2018

#### Fentanyl Flows from China: An Update since 2017

Sean O'Connor, Policy Analyst, Economics and Trade

Acknowledgments: The author thanks Jeffrey James Higgins and officials at the U.S. Drug Enforcement Administration for their helpful insights. Their assistance does not imply any endorsement of this report's contents, and any errors should be attributed solely to the author.

#### **Key Findings**

- China remains the largest source of Illicit feature) and feature). His substances in the United States: Since the publication of the Commission's 2017 saft report on featurely flows from China, there has en no substantive cutralinear of featurely flows from China to the United States. In large part, these flows persist does to weak regulations governing pharmaceutical and chemical production in China.
- U.S. and Chinese government negotiations for increased counternarcetic cooperation are engoing: Chinese officials have shown a williaguese to work with their U.S. counterparts, controlling 39 new substances since February 2017 and assisting with U.S. law enforcement investigations into alleged Chinese drug traffickers.
- Beijing's scheduling procedures remain slow and ineffective: Because the Chinese government schedules chemicals one by one, flicit immunifictures; reset new substance faster than they can be controlled. U.S. officials have proposed strategies for Beijing to systematically control all fentanyl substances, but the changes have not been approved by the Chinese government.
- U.S. law enforcement agencies are taking legal actions against known Chinese drug traffickers: Efforts to sanction or indict known Chinese drug traffickers represent a new approach to create greater pressure on Chinese counternarcotic officials.

#### Overview of Chinese Fentanyl and Other Illicit Synthetic Opioid Flows to the United States

In February 2017, the Commission published a staff report titled Fentanyl: China's Deadly Export to the United States, which detailed how illicit flows of fentanyl and other new psychoactive substances (NFS) from China are flueling an opioid crisis in the United States. The 2017 report's conclusions remain accurate, including that

- China remains the largest source of illicit fentanyl and fentanyl-like substances in the United States
   Fentanyl, a synthetically produced opioid, is shipped from China either directly to the United States or to
- \*For more on fentanyl flows from China to the United States, see Sean O'Connor, "Fentanyl: China's Deadily Export to the United States,"

  \*U.S.-China Zenomic and Security Review Commission,

  \*U.S.-China's ZE-States Commission,

  \*Commission Pelevany 1, 2017.

  \*China's ZE-States Commission, 12 (China's ZE-States Co. 2017. pt. 2017.

  \*China's ZE-States Co. 2017. pt.

U.S.-China Economic and Security Review Commission

Testimony

#### Evolution of the U.S. Overdose Crisis

Understanding China's Role in the Production and Supply of Synthetic Opioids

Bryce Pardo

CT-497

Testimony presented before the House Foreign Affairs Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations on September 6, 2018.



#### Department of Austice

#### STATEMENT OF

PAUL E. KNIERIM
DEPUTY CHIEF OF OPERATIONS
OFFICE OF GLOBAL ENPORCEMENT
DRUG ENFORCEMENT ADMINISTRATION
U.S. DEPARTMENT OF JUSTICE

#### BEFORE THE

SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH, GLOBAL HUMAN RIGHTS AND INTERNATIONAL ORGANIZATIONS COMMITTEE ON FOREIGN AFFAIRS U.S. HOUSE OF REPRESENTATIVES

FOR A HEARING ENTITLED

"TACKLING FENTANYL: THE CHINA CONNECTION"

PRESENTED

SEPTEMBER 6, 2018

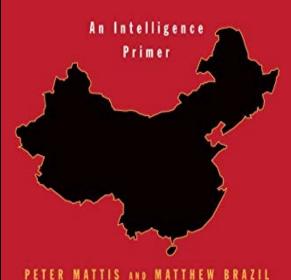
2018/12/02



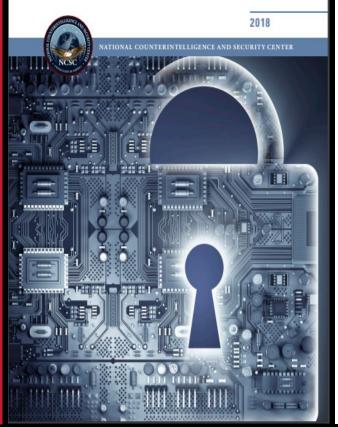


# C H I N E S E C O M M U N I S T

ESPIONAGE



Foreign Economic Espionage in Cyberspace



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**

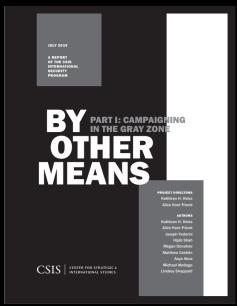
**An Emerging Dimension of Hybrid Warfare** 

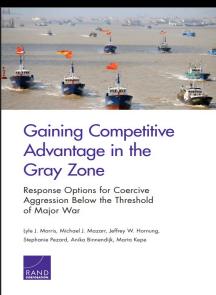
New Risks in the Gray Zone Between Peace and Major Conflict

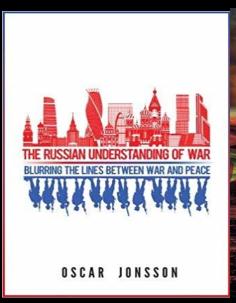
**Implications for Biosecurity** 

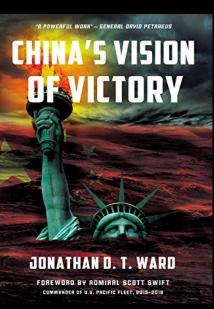
### Darker Shades of Gray: The Emerging Dimension of Hybrid Warfare

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





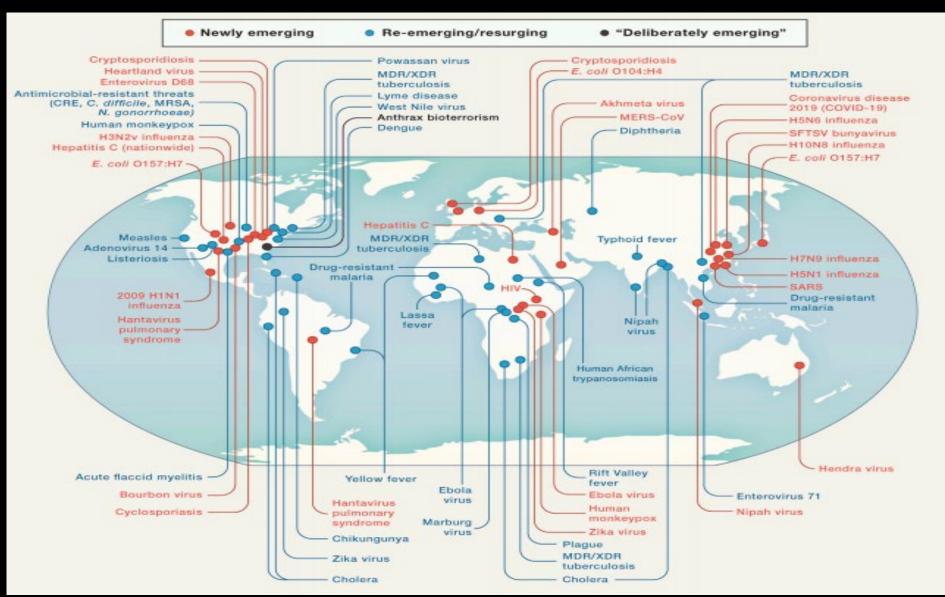




## Gray Zone Tweets and Biosecurity: Russian Trolls and Twitter Bots

- 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 Novochok 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**

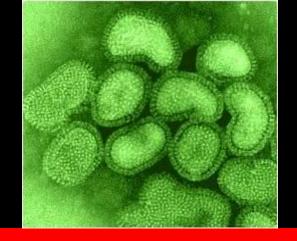


# The Need for International Cooperation in International Public Health Has Never Been Greater

- 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

Science and Technology Public
Health
and
Healthcare
Systems

Intelligence, Foreign Policy and Military Strategies

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