Public Health and Biotechnology Perspective on BWC Verification

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U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR)

- ASPR leads the nation's medical and public health preparedness for, response to, and recovery from disasters and public health emergencies.

- ASPR collaborates with hospitals, healthcare coalitions, biotech firms, community members, state, local, tribal, and territorial governments, and other partners to improve readiness and response capabilities.

Providing Strong Leadership

Building a Regional Disaster Health Response System

Sustaining Public Health Security Capacity

Enhancing the Medical Countermeasures Enterprise

Many Areas of Biotechnology are Dual-Use

- There are diverse public and international perspectives and a lack of reliable indicators for mis-use and ill intent

Technological Advances Bring Benefits and Risks - examples -

- Manipulation of genetic material and microorganisms in order to understand the pathogenicity of specific microbes or host response
- Applications of synthetic biology intended to “redesign” organisms with desired characteristics and functionalities that are generally not found in nature
- Developments in DNA sequencing that drastically reduce the time and cost, making this process increasingly widely available
- Advances in high-capacity computing and information technology which, again, have played a major role in increasing understanding of pathogenicity
- Discoveries in the fields of immunology and molecular biology that have had an enormous impact on the identification of candidate diseases and novel approaches for generating protection or treatment

The Central Issue: Accounting for Dual-Use when Assessing Compliance

"Assessing compliance with the BTWC should focus on.. determining whether states are using their life science capabilities to build biological weapons." Hunger and Zmorzynska, 2011

Non-compliant intent and behavior can be difficult to discern even with intrusive oversight

System must therefore rely upon demonstrated behaviors that indicate full acceptance of compliance, such as development of medicines to support public health needs and global health security, promulgating institutional norms of behavior within the society at large.

Governmental, Corporate, Institutional and Personal Adherence to Culture of Responsibility

Some Ways to Promote Confidence in Peaceful Use

- Oversight and Regulatory Programs to Safeguard Use of Pathogens
  - Biological Select Agent and Toxin Programs, Biorisk Management Programs
- Advisory Committees at National Level to Enhance Biosafety and Biosecurity National Coordination
  - Federal Experts Security Advisory Panel
- Joint Development of National Biodefense Strategy
  - Inclusion of Global Health Security Agenda (GHSA) norms and objectives
- Leadership for Pandemic Potential Pathogens Oversight and Care (P3CO)
- Engagement with Industry and Academia for medical countermeasures research, capacity building and norms
  - Synthetic DNA Policy
  - Dual-Use Research of Concern (DURC) Policy
  - Novel approaches for diagnostics, drugs, therapies, devices
- Annual BWC Confidence Building Measures (CBM) report

Additional Useful Measures to Build Confidence

- Encourage adoption and alignment of national dual-use review processes
- Foster a culture of biosafety, biosecurity, and responsible conduct in the life sciences
- Develop new medical countermeasure for any type of complex threat
  - New approaches for antibiotics, rapid platforms for medical countermeasures, *in silico* and machine learning systems for test and development of products, host-pathogen based combinatorial therapies for emerging or unknown threats