James Martin Center for Nonproliferation Studies
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Chemical and Biological Weapons Nonproliferation Course for U.S. Government Personnel

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Introduction

- Long history of efforts to prevent biological agents, equipment & knowledge from resulting in destructive consequences
- Numerous governance efforts
  - Multiple levels: international, national, local, individual
  - Many forms: treaties, resolutions, policies, etc.
  - Different aspects: safety & security, controlling access, assessing & mitigating risks
- Focus today: 6 things to understand about biological problem

1. Biological technology can cause harm because of deliberate or inadvertent actions

- Pathogens to develop vaccines can escape labs
- Equipment to study pathogens can be used to make more dangerous pathogens
- Knowledge from research about extinct pathogens can be used to resurrect them

Challenge: prevent dual-use technology from being used for intentional & unintended harm

2. Biological technology requires broader governance efforts than chemical or nuclear weapons

- Nonproliferation measures
- Antiterrorism measures
- Biosafety measures

Goal: Prevent governments, terrorists, private & commercial entities from causing harm with biological technology

3. September 11 & anthrax letters watershed events for governing biological technology

USG response:

- Make it harder to acquire dangerous pathogens:
  - PATRIOT Act
  - Select agent law
  - gene synthesis guidelines
- Unprecedented increase in medical countermeasures
  - NIH grant: 33 in 1996-2000; ~500 in 2001-Jan 2005
  - NIH civilian biodef. funding: $53 million FY'01; > $6.7 billion FY'16
  - Specialized labs: 400 in 2005; ~1,500 today
  - 2014: 316 facilities & 11,000 people approved for select agent work

Undercuts attempts to limit access to select agents

4. Proliferation of research on Select Agents at time of rapid technological change

- Australian mousepox experiment
- 2003 Fink Committee report
  - dual-use biotech research could cause harm on "a catastrophic scale"; 7 experiments of concern
- 2007 NSABB proposal for review & approval of dual-use research of concern (DURC)
- Both Fink Committee & NSABB underscored international dimension of dual-use research

5. US Government response to dual-use research risks inadequate

- Initial US policy on dual-use research oversight not released till 2012:
  - Impetus: H5N1 papers: creation of avian influenza viruses spread via respiratory droplets between mammals
  - Policy narrower than NSABB recommendation: only USG funded work involving one of 15 select agents
- DURC guidelines for research institutions not released until 2014:
  - Impetus: research by US scientists to create virus similar to 1918 pandemic virus that could evade immune system
  - Slightly broader than 2012 policy: relevant research at any institution that receives USG funding for life sciences research

6. Life sciences research community more divided over ethics/risks than any time since 1970s

- Controversy over rDNA research→ US scientists to organize conference addressing risks
  - Led to NIH guidelines for conduct of rDNA research
  - Guidelines modified in response to scientific devel.
  - Major weakness: formally apply only to institutions receiving NIH funding for rDNA research
- Current controversy on "gain of function" research→ October 2014 USG announces deliberative process to develop new policy, funding pause
  - NAS and NSABB to contribute to policy process

6. Life sciences research community more divided over ethics/risks than any time since 1970s (cont'd)

- Final NSABB report recommends focusing on gain of function research of concern:
  - all relevant research in US/US companies should be subject to oversight regardless of funding source
- NSABB report weaknesses:
  - Overly narrow definition?
  - Inherent conflicts of interest
  - Lack of clarity on risk-benefit assessment
  - Absence of concrete recommendations to address international dimension

Conclusions

GOFROC policymaking process creates opportunity to address both GOF issue & weaknesses in USG DURC policies:

- Use authority from Select Agent law to make oversight requirement legally binding
- Mandate *all* relevant research be subject to oversight requirements
- Avoid real/perceived conflicts of interest
- Undertake serious effort to seek common rules and procedures internationally