Regulating Biological Agents: Balancing Security and Bio-Medical Research

Charles Vidich, Harvard School of Public Health
cvidich@hsph.harvard.edu
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Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std Z39-18
Overview

• Why Congress tightened bio-agent rules
• Key legislation
• Who’s in charge of bio-agent regulation
• Criteria for bio-agent controls
• Impacts on academic & public health labs
• Impacts on public health priorities
• Conclusions
• Policy alternatives and recommendations
Why Have Biological Agents Become a Big Deal?

• **1996 mail order plague** – Larry Wayne Harris
  – “Do it Yourself” approach to plague research
  – Led to new law on transfer/use of bio-agents

• **2001 anthrax mailed to politicians & media**
  – Triggered massive ongoing investigation
  – Led to new laws on possession of bio-agents
  – Military labs implicated as possible source for agents
Legislation – Biological-agents

• **Antiterrorism & Effective Death Penalty Act of 1996**
  – Governs transfer and use of bio-agents

• **USA PATRIOT Act of 2001**
  – Prohibits restricted persons from lab work

• **Public Health Security & Bio-terrorism Preparedness Response Act of 2002**
  – Governs bio-agent possession, lab security, bio-safety, training, inspections and notifications.
Why Did Congress Increase Regulation of Biological Agents?

• **Assumption 1:** Increased lab security will reduce improper use of bio-agents for terrorism.

• **Assumption 2:** Increased inventory controls will allow for rapid tracking of misused bio-agents.

• **Assumption 3:** Security clearances for lab workers handling bio-agents minimizes risks of their misuse.
Were The Assumptions Congress Made Correct?

- **Alternative Hypothesis 1**: Increased lab security may have no impact on improper use of bio-agents for terrorism.

- **Alt. Hypothesis 2**: Increased inventory controls of reproducible bio-agents doesn’t guarantee misused bio-agents can be tracked.

- **Alt. Hypothesis 3**: Security clearances for lab workers may discourage legitimate scientists from pursuing bio-agent work.
Who’s in Charge of Select Biological Agent Work?

- Responsibility depends on the Issue
- Who’s in charge varies by issue.
- Multiple federal Laws govern laboratory work.
Select Agent Regulatory Issues: Who Governs What?

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<th>ICE</th>
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= Pre 2001

= Post 2001
Who’s Affected by the Rules?

1,653 labs admit possessing select agents
But only 817 are expected to register

- Public health labs – 98 in Laboratory Response Network (LRN)
- Academic/non-profit labs – 344 affected.
- Commercial labs – 375 affected.

Will illicit labs register??
What will the new Rule Cost?

• CDC grossly underestimates fiscal impacts
  – Anticipates annualized costs of $40 million
• True costs are 3 to 5 times more expensive
  – CDC estimates called “low ball” numbers
• Rule doesn’t consider:
  – Lost lab productivity
  – Increased capital investment costs
  – Lost opportunity costs
  – Lost students and researchers
“It isn’t the number of people killed. It is the potential of people getting killed.”

– Dr. Anthony Fauci, HHS, February 5, 2002

» Explaining why the Bush administration is providing an overwhelming increase in funds for bio-terrorism prevention.
Step 1: Selecting Select Agents

Threshold Selection Criteria

- Vulnerable population
- Health Effects
- Treatment Options
- Degree of Contagion
Step 2: Selecting Select Agents

Applying Selection Criteria

- No cure or limited vaccine
- Lethal
- Contagious
- Population susceptibility

Selection criteria Filter

CDC Select Agents
Step 2: Are Select Agents of Equal risk?

**Risks vary by agent**

1. **Public Health Impacts** - Defined by high Morbidity and Mortality
2. **Dissemination Potential** – Defined by person to person transmissibility and potential for widespread production and distribution
3. **Special Public Health Preparation** - Such as stockpiling of vaccines, public education or surveillance and rapid diagnostic lab analysis
4. **Public Perception** – Agents that could cause mass fear and civil disruption.
Step 3: Priority Select Agents:
Categorizing Agents - some worse than others

Number = Agents

- Cat. A: 6
- Category B: 10
- CDC Agents: 23
- USDA Agents: 41
- Uncategorization Biological Agents: 1
- Uncategorization Animal & plant Agents: 1
Bio-Medical Research: Who in Government Controls this Work?

- CDC
- USDA

Coordination

Policy

Select Agent Rule

DOJ

Need to Know

DHS
Select Agent Rule: Are Lab Requirements Excessive?

1. Registration for possession, use/transfer
   – Will labs admit possession?
2. Security Risk Assessment
   – Does it stop criminals? Will honest lab workers accept scrutiny?
3. Designation of a Responsible Person
   – Who will accept liability of being in charge?
4. Inventory Tracking and Controls
   – Bio-agents aren’t pencils - can’t be counted
Select Agent Rule: Are Lab Requirements Excessive? (Continued)

6. Training and Inspections
   – What standards will be expected?
7. Notification of theft, loss or release
   – How can you tell if a theft has occurred?
8. Safety & Security Plans
   – Who decides if bio-safety and security is met?
9. Emergency Response Plan
   – Will community accept lab activities?
Do Lab Regulations Eliminate Link to Bio-Terrorism?

Would regulation have prevented earlier incidents? How long is arm of Patriot Act? Does it impact foreign labs?
What Other Sources Exist?

- **Natural Reservoirs**
  - For some easy access
- **Black Market Sources**
  - Terrorist group issues
- **Foreign Labs**
  - Not under Convention
- **Bio-weapon Producers**
  - Rogue nations
- **Genetic Engineering**
  - Limited controls exist
Do Lab Regulations Eliminate Link to Bio-Terrorism?
Impacts on Public Health Priorities: Competing Forces

- Increased Oversight
- More $$ for BW Research
- Loss of Lab workers
- More Personal Liability
When Will Select Agent Rule Impacts Be Felt?

Compliance timetable for 2003:
- Prohibitions, notices effective: 2/7/2003
- Applications due: 3/12/2003
- Security Risk Approval: 5/12/2003
- Security plan: 6/12/2003
- Security plan/training active: 9/12/2003
- Registration compliance on: 11/12/2003
New Lab Bio-Security Considerations
Risk Assessment Principles

Public Perception Factors
Community Factors

Security Factors

Threat Assessment

Contagious
Lethal
Gruesome
Conclusions
Getting the Balance Right

• **Priorities:** Bio-medical research priorities affected by focus on BW agents.
• **Regulations:** Controls not commensurate with risks posed by academic/commercial labs
• **Funding:** Increased budgeting for security related public health measures.
Policy Recommendations

• **Minimize Burdens on Research**
  – Provide training support for academic labs
  – Adopt Performance based security concept

• **Involve Scientists in Decision making**
  – Create Select Agent research advisory committee

• **Minimize Individual Liabilities**
  – Provide due process protections
  – Establish an “Innocent researcher” defense
  – Don’t burden honest researcher