The Good, the Bad, and the Unjust: The Past, Present, and Future of the HHS Select Agent Program

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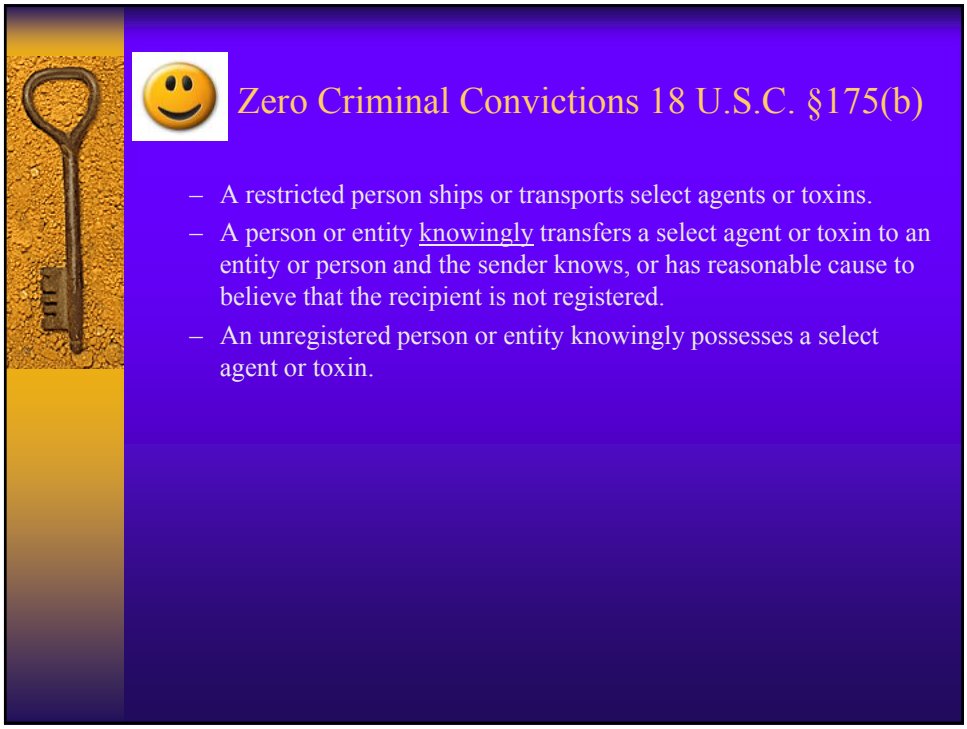
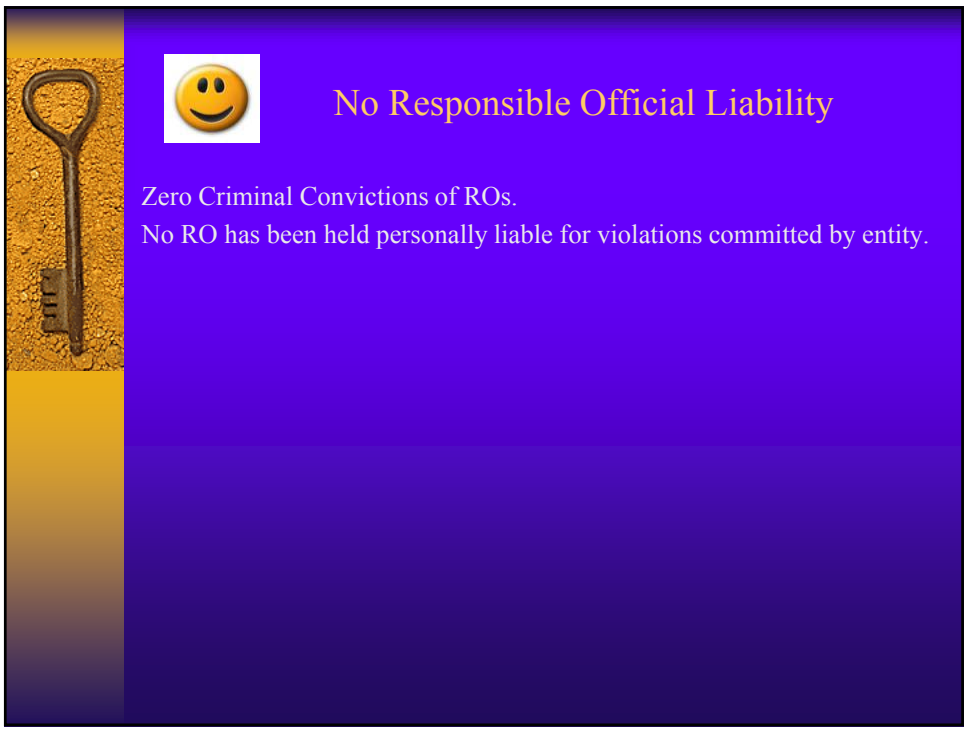
2003 - 2009: The Good Old Days?


Zero Criminal Convictions 18 U.S.C. §175(b)
– A restricted person ships or transports select agents or toxins.
– A person or entity knowingly transfers a select agent or toxin to an entity or person and the sender knows, or has reasonable cause to believe that the recipient is not registered.
– An unregistered person or entity knowingly possesses a select agent or toxin.


No Responsible Official Liability
Zero Criminal Convictions of ROs.
No RO has been held personally liable for violations committed by entity.


Reasonable Civil Penalties
CMPs assessed since 2003
Boston University.....$0
Protatek International.....$12,000
Meridian Bioscience.....$50,000
Wako Chemical.....$50,000
SRI.....$100,000
Missouri Company.....$110,000
Lawrence Livermore.....$450,000
Texas A & M.....$1,000,000


The not so good: 2003 - 2009
►Inconsistent HHS inspections.
►Coordination between HHS, USDA, NIH, and local governments could be better.
►Questions on gray areas in regulations have been addressed on an ad-hoc basis by inspectors and/or DSAT.

The Bad: 2003 - 2009

- How much time did we spend complying?
- How much did compliance cost us?
- Are we way beyond the Interim Final Rule 42 CFR Part 73 (December 13, 2002) estimates?:
  - "The median annualized cost (of compliance with the rule) is estimated to range from $9,300 to $201,000."
  - "The estimated first year cost of the rule ranges from $23,400 for a small commercial entity with a BSL 3 lab to $730,400 for a medium university with a BSL 2-3 lab."

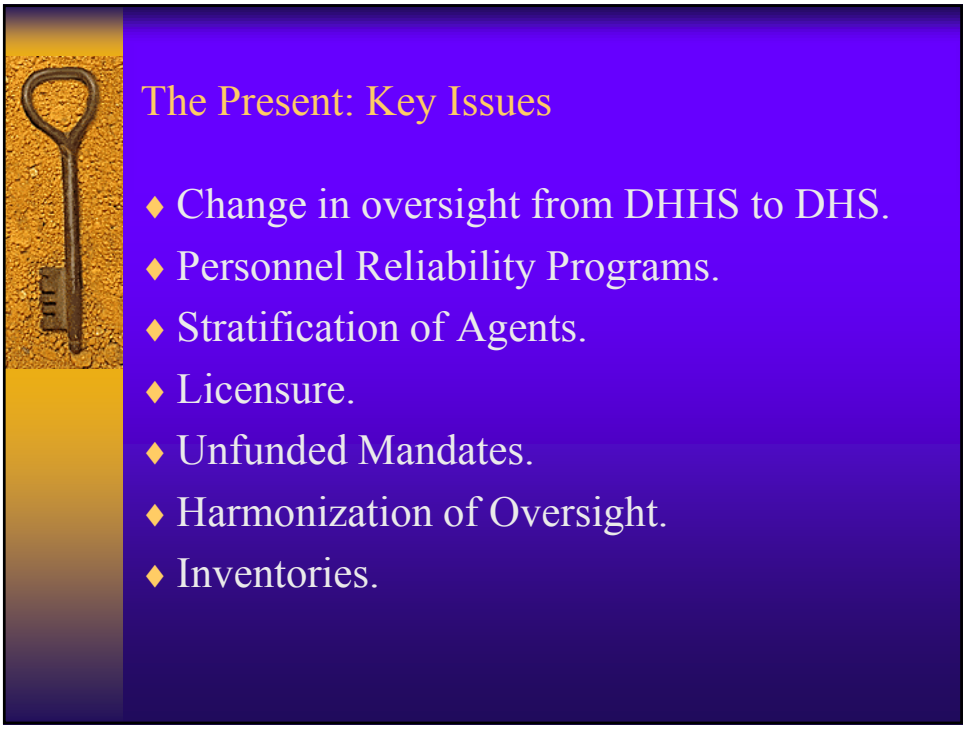
The Present Legislative Environment: Back to the Future

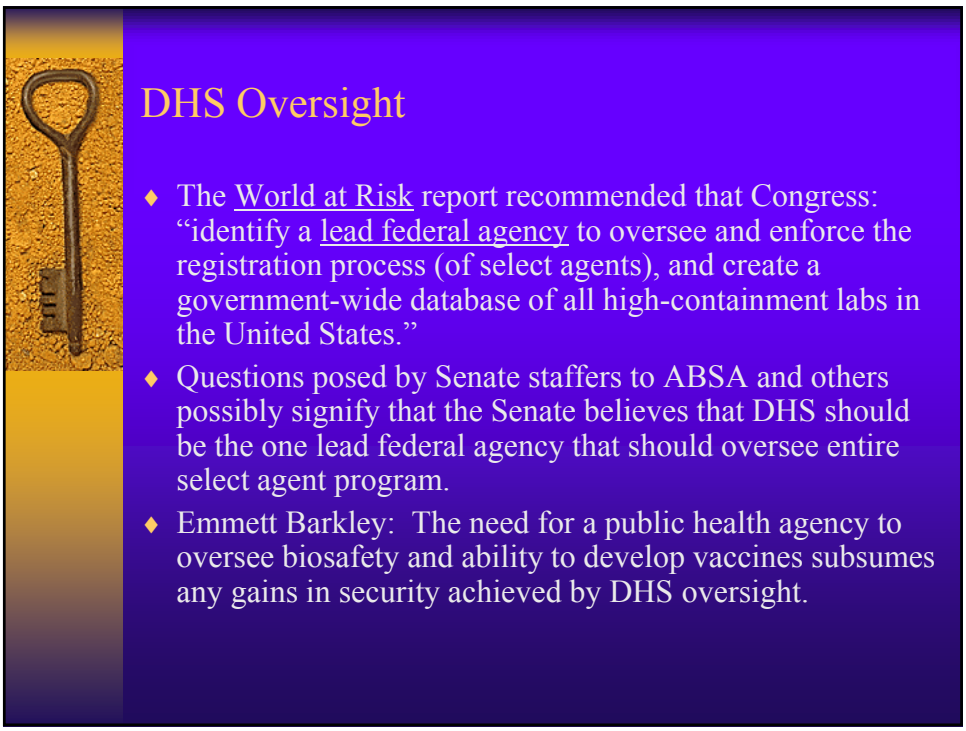
- Senate Bill 485, known as the Select Agent Program and Biosafety Improvement Act of 2009.
- House Bill 1225 known as the Select Agent Program and Biosafety Improvement Act of 2009.
- Legislation from Senators Lieberman and Collins which may be introduced during the summer of 2009.
- Executive Order 13486 (1/9/2009), titled "Strengthening Laboratory Biosecurity in the United States."

What a Mess!

The Legislative Landscape

- The GAO Report on High Containment Biosafety Laboratories (10/4/2007),
- The Commission of the Prevention of WMD Proliferation and Terrorism's World at Risk report (12/2/08),
- The Congressional Research Service Report on Oversight of High-Containment Laboratories (3/5/09),
- The National Scientific Advisory Board (NSABB) report on Enhancing Personnel Reliability Among Individuals with access to Select Agents,
- The American Association for the Advancement of the Science's (AAAS) workshop report on Biological Safety Training Programs as a Component of Personnel Reliability,
- The UPMC Center for Biosecurity Letter to Representatives Jane Harman and Mike Rogers,
- Report of the Defense Science Board Task Force on Department of Defense Biological Safety and Security Program (May 2009),
- Reports coming soon: • Trans-federal Task Force on Optimizing Biosafety and Biocontainment Oversight • the Executive Order Working Group (EOWG) on Strengthening the Biosecurity of the United States, • the National Scientific Advisory Board on Biosecurity (NSABB), • the National Academy of Sciences (NAS).


The Present: Key Issues
♦ Change in oversight from DHHS to DHS.
♦ Personnel Reliability Programs.
♦ Stratification of Agents.
♦ Licensure.
♦ Unfunded Mandates.
♦ Harmonization of Oversight.
♦ Inventories.


DHS Oversight
♦ The World at Risk report recommended that Congress: "identify a lead federal agency to oversee and enforce the registration process (of select agents), and create a government-wide database of all high-containment labs in the United States."
♦ Questions posed by Senate staffers to ABSA and others possibly signify that the Senate believes that DHS should be the one lead federal agency that should oversee entire select agent program.
♦ Emmett Barkley: The need for a public health agency to oversee biosafety and ability to develop vaccines subsumes any gains in security achieved by DHS oversight.

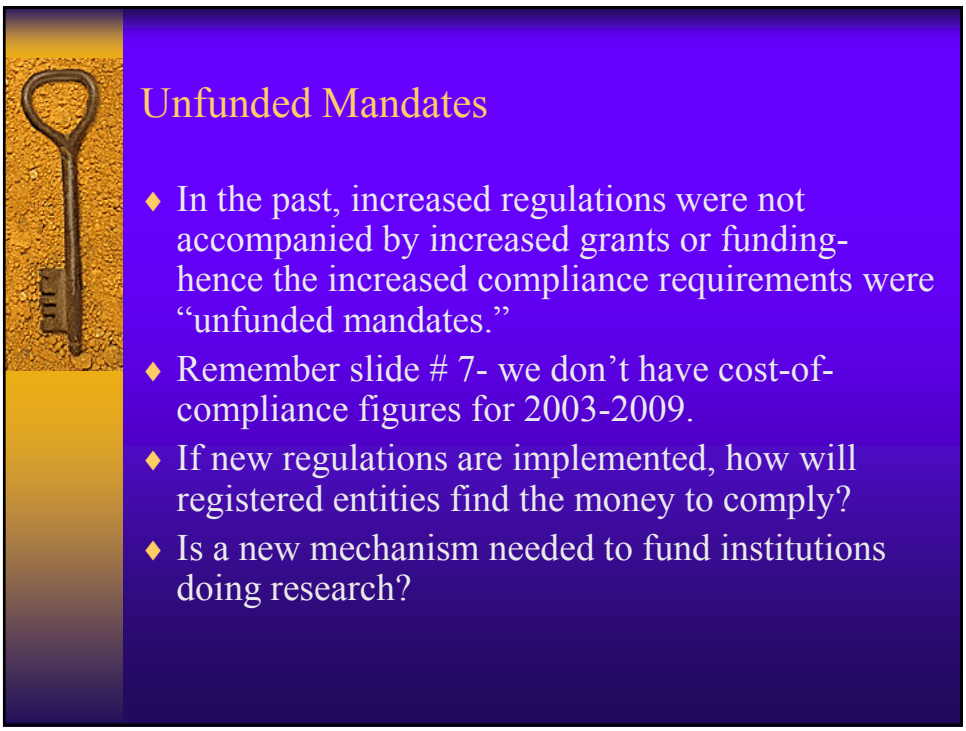
Personnel Reliability Programs (PRPs)

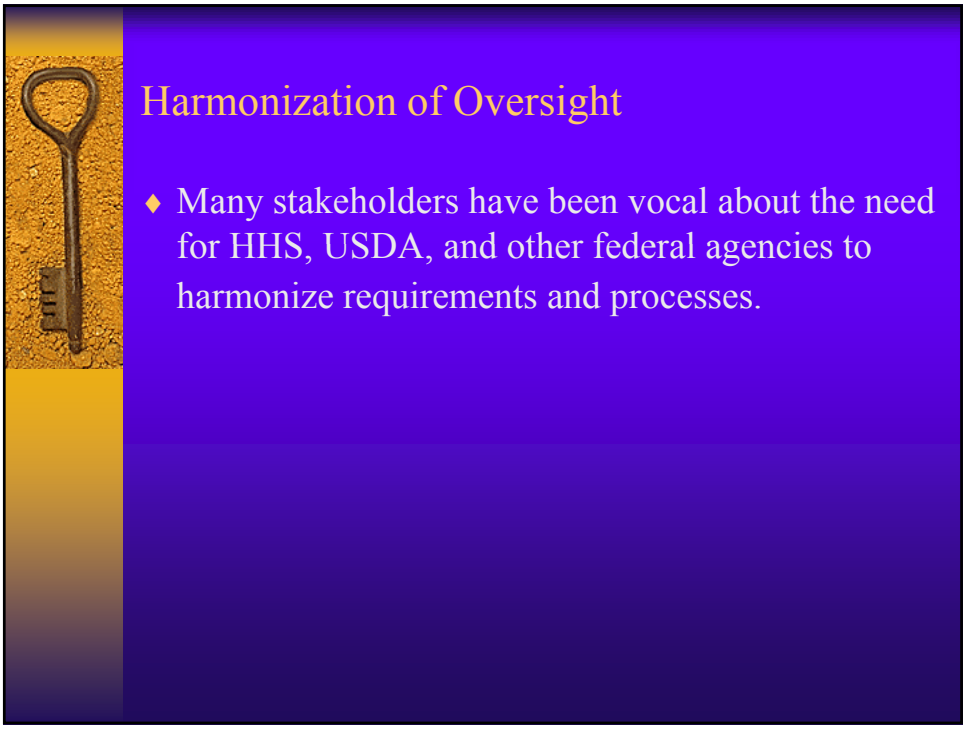
- PRPs exist in nuclear regulatory environment and DOD.
- PRP programs *can* include: background investigations, security clearances, medical examinations, psychological evaluations, polygraph testing, drug and alcohol screening, credit checks, and ongoing monitoring.
- The National Scientific Advisory Board (NSABB) report on Enhancing Personnel Reliability Among Individuals with access to Select Agents stated: "(there is) insufficient evidence of the effectiveness of PRP measures towards mitigating the risk of an insider threat to warrant the additional, significant burden on research institutions."

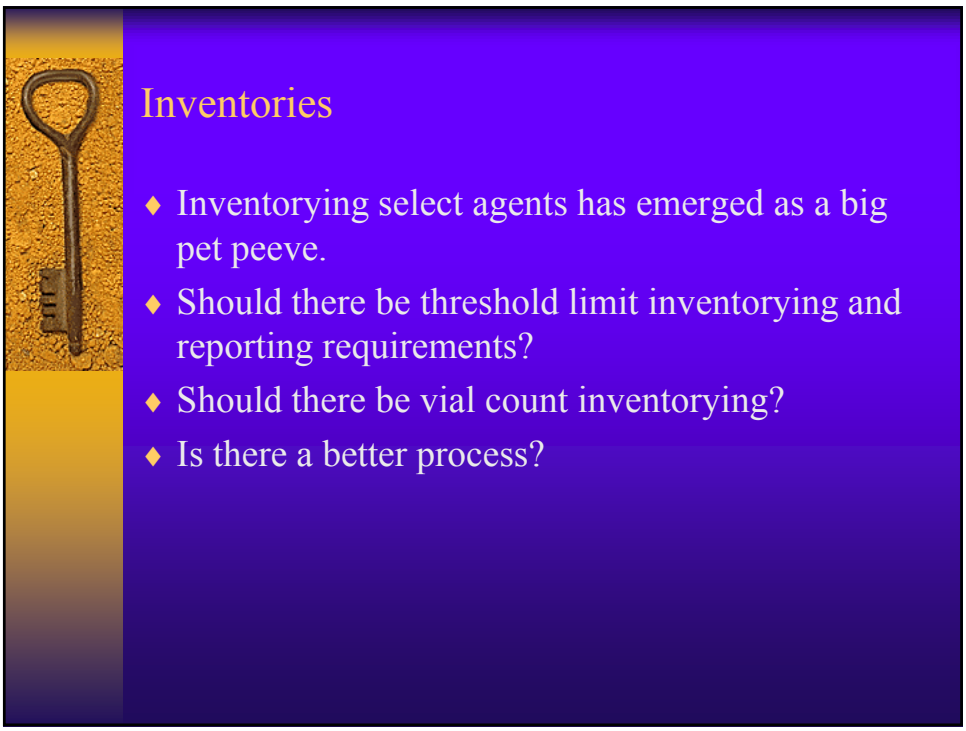
Stratification of Agents

- The NSABB Enhancing Personnel Reliability Among Individuals with access to Select Agents report recommended removing some select agents from list or stratifying the list.
- Security standards for less lethal agents might be relaxed, while standards for more lethal agents might be bolstered.
- Security Risk Assessments are the cornerstone of biosafety.
- An inflexible, stratified list could be an administrative nightmare for ROs who oversee many agents.


Licensure
The World at Risk report recommended that, "all biosafety officers should be tested and certified by a competent government authority."
This opinion has garnered support from only a minority of fringe groups.


Unfunded Mandates
In the past, increased regulations were not accompanied by increased grants or funding- hence the increased compliance requirements were "unfunded mandates."
Remember slide # 7- we don't have cost-of-compliance figures for 2003-2009.
If new regulations are implemented, how will registered entities find the money to comply?
Is a new mechanism needed to fund institutions doing research?


Harmonization of Oversight
Many stakeholders have been vocal about the need for HHS, USDA, and other federal agencies to harmonize requirements and processes.


Inventories
Inventorying select agents has emerged as a big pet peeve.
Should there be threshold limit inventorying and reporting requirements?
Should there be vial count inventorying?
Is there a better process?

The Future

Don’t get legislated out of the game!

Things you can do

- Contact your legislators:
  - https://writerep.house.gov/writerep/welcome.shtml
  - http://www.senate.gov/general/contact_information/senators_cfm.cfm
- If you work at a university or college, contact your public affairs or communications department.
- Contact the National Academy of Sciences:
  - www.national-acadamies.org
- Contact the EOWG:
  - biosecuity.workgroup@hhs.gov .

New Regulations

- Doubtful they will be perfect.
- HHS Office of General Counsel should be required to issue Advisory Opinions, not Industry Guidance.
- Advisory Opinions are: "binding and may legally be relied upon only by the requestor."

Conclusion

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