BioRisk Policy:
in a global biotech revolution

David R. Franz.
OSD (NCB)
Historically….It was **Biosafety**
1940s - 2001

- Lessons learned from USG offensive program
  - Dr. Arnold G. Wedum (Camp Detrick)
- Biosafety in Microbiological and Biomedical Laboratories (BMBL)
  - **Facilities, Equipment & Procedures**

“To further reduce the potential for laboratory-associated infections, the guidelines presented here should be considered *minimal guidance for containment*. They must be customized for each individual laboratory and can be used in conjunction with other available scientific information.”
Then in 1996....Biosecurity
“The Select Agent Rule”
Anti-Terrorism and Effective Death Penalty Act of 1996

• Selected agents to be controlled

• Registration of laboratories for agent transfer

A ‘bio-unabomber’?
The USA Patriot Act: 2001
& The Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Title II: Enhancing controls on dangerous biological agents and Toxins

Regulatory control of certain biological agents and toxins (BSAT)
Regulation of transfers of BSAT
Possession and use of BSAT
Registration (of persons) who work with BSAT
Safeguard and security requirements for registered persons
Inspections
Disclosure of information...re databases
Civil money penalty
Notification in event of release of BSAT
Reporting requirements

Not required in 1996 Act

April 2008---9,918 individuals approved to work with Select Agents
May 2008---324 entities registered with CDC (gov, corp, acad, NGOs)
USAMRIID | ANTHRAX BREACH INVESTIGATION

FEDERAL AGENTS WERE CLOSING IN, AND BRUCE IVINS KNEW IT.

The army microbiologist who was working on a vaccine for anthrax poisoning was now being grilled as a suspect in the 2001 letter attacks that killed five people and sickened 17. FBI agents were staking out his house. Ivins was a Frederick resident who worked at the U.S. Army Medical Research Institute of Infectious Diseases. He died Tuesday in an apparent suicide. Authorities were planning to charge him with mailing the toxin-laced letters, which spread national alarm just weeks after the Sept. 11, 2001, terror attacks in New York and Washington.

ANTHRAX CASE TURNS

SCIENTIST COMMITS SUICIDE AS FBI PROBE TIGHTENS

THE PLACES AND THE PLAYERS

USAMRIID

The U.S. Army Medical Research Institute of Infectious Diseases at Fort Detrick, Maryland. Bruce Ivins worked for more than 20 years as a civilian. It has been reported that USAMRIID is the lead medical research laboratory for the U.S. Biological Defense Research Program.

STEVEN HATFILL

The former resident of Steven Hatfill was classified at Fort Detrick. Then-Attorney General John Ashcroft called Hatfill a "person of interest" in 2002. In late June, then-Attorney General Alberto Gonzales cleared Hatfill, who had been wrongly suspected in the anthrax case, and paid him $5.8 million. He also sued The New York Times.

BRUCE IVINS

The house of Bruce Ivins. Federal investigators investigating the 2001 anthrax attacks were planning to raid his home in connection with anthrax mailings that killed five people, Ivins died Tuesday at Frederick Memorial Hospital, after being found unresponsive by police in his home Sunday.
USAMRIID | ANTHRAX BREACH INVESTIGATION

FEDERAL AGENTS WERE CLOSING IN, AND BRUCE IVINS KNEW IT.


JUNE: FBI rules out 30 scientists who had knowledge and opportunity to send the anthrax letters.

ALLEGATIONS: Law enforcement officials call Steven R. Hatfill, a government expert, a "person of interest."

JUNE: FBI donors in Frederick, in search of evidence of anthrax attacks.

JUNE: FBI rules out the docent as a suspect in the anthrax attacks.

AUGUST: Hatfill raises the possibility of the anthrax attacks.

AUGUST: Hatfill rules out the docent as a suspect in the anthrax attacks.

DECEMBER: Postal workers begin moving back into Washington's main post office.

FLORIDA: Orange County, a manufacturer of fertilizer, is ruled out as a suspect in the anthrax attacks.

THE PLACES AND THE PLAYERS

USAMRIID

The U.S. Army Medical Research Institute of Infectious Diseases is the lead medical research laboratory for the U.S.

STEVEN HATFILL

The former residence of Steven Hatfill, now a residence at Fort Detrick, is the lead medical research laboratory for the U.S.

BRUCE IVINS

The former residence of Bruce Ivins, now a residence at Fort Detrick, is the lead medical research laboratory for the U.S.

 odometer

Assuming the FBI is correct... The insider threat is more serious than I believed...
The President
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear Mr. President:

We write to you today about a most urgent public health and national security issue. This week the Federal Bureau of Investigations (FBI) officially made a number of serious allegations about Dr. Bruce Ivins, a former senior scientist with the U.S. Army’s Medical Research Institute for Infectious Diseases (USAMRIID) at Fort Detrick in Frederick, Maryland.

If these allegations are true, the FBI has identified serious weaknesses in the security at one of our Nation’s premier laboratories for the study of some of the most deadly pathogens in the world. Their allegations also raise equally troubling security concerns about the thousands of other scientists and technicians who work at hundreds of labs across our country with “select biological agents” such as anthrax.

In light of these recent revelations, we urge you to immediately order a Government-wide investigation into the adequacy of the physical and personnel security systems in place at all Government-run or-sponsored Biosafety Level 3 and 4 laboratories (BSL 3 and 4) in the United States. In addition, until your investigation is complete and the results of that investigation are reported to you and Congress, we urge you to order the suspension of all further design and construction of such laboratories.

Sincerely,

John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations
The Dingell – Stupak Letter

The President
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

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Subcommittee on Oversight and Investigations
2–8. Other disqualifying factors
Any of the following traits,, based on the certifying official’s informed judgment.

d. Inappropriate attitude, conduct, or behavior...
(1) Negligence or delinquency in performance of duty.
(2) … a contemptuous attitude toward the law, regulations, or other duly constituted authority…. 
(3) Poor attitude or lack of motivation… arrogance, inflexibility, suspiciousness, hostility, flippancy toward BPRP responsibilities, and extreme moods or mood swings.
(4) Aggressive/threatening behavior toward other individuals.
(5) Attempting to conceal PDI [potentially disqualifying information] from certifying officials
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“This reminds me of many scientists I know. Really smart people are often just a tiny bit weird and quirky, in case you haven’t noticed…and often irritating…”  

web blog editorial
Biological ‘Surety’ 2008

• Biological ‘Surety’
  – Biological Safety
  – Physical Security
  – Agent Accountability
  – Personnel Reliability*

* Requires that persons with access to select agents are “mentally alert, mentally and emotionally stable, trustworthy, and physically competent”.

AR 50-1
Fear the Slippery Slope

Biological ‘Select Agent’ Research

Infectious Disease Research

Synthetic Biology

Nanotechnology

Understanding of the Human Immune System
Implications of a mistake:
Over-regulation of our life-sciences research enterprise

- Our ability to provide
  - Healthcare
  - Food and agriculture
  - Energy
- Our economy
- Our ability to complete globally
- Our national security

It could take 5-10 years to know that we have over-regulated... ...and 15-20 years to turn it around
The Risk in Context

• PRPs are US-Centered
• Most BSATs are Naturally Occurring
• Tracking Individual Pathogens Impossible
• New Technologies make Lists Obsolete
• New Technologies not on “The List”

We’re in a different kind of competition over nuclear issues. It’s wide open and uncontrolled by international norms.
If we over-regulate our science...don’t assume the world will follow

But disease surveillance, Diagnostics, biosafety, biosecurity, quality research, and ethics are all accepted topics for discussion and engagement.
“Some old wisdom…”

“There is no technical solution to the problem of biological weapons. It needs an ethical, human, and moral solution if it’s going to happen at all. Don’t ask me what the odds are for an ethical solution, but there is no other solution.”

<Then Dr. Lederberg paused and said,>

“But would an ethical solution appeal to a sociopath?”

The New Yorker 1998
The ‘insider threat’

**Enlightened Leadership**
- *Lead with Science*
  - Quality Research
  - Emphasis on Safety
  - Vision
  - Education
  - Responsibility
  - Accountability
  - Honesty
  - Transparency
  - Ethics
  - *A Culture of Trust*

**Regulatory Oversight**
- *Lead with Security*
  - Guns, Gates and Guards
  - Background Checks
  - Psychological Evaluation
  - Lists & Pathogen Control
  - *A Culture of Mistrust?*

Some labs will need some of the right column, but every lab can benefit from the left…

*Which will make us safer and more productive?*
The ‘insider threat’

**Enlightened Leadership**

*Lead with Science*
- Quality Research
- Emphasis on Safety
- Vision
- Education
- Responsibility
- Accountability
- Honesty
- Transparency
- Ethics

**A Culture of Trust and Accountability**

*Lead with Security*
- Guns, Gates and Guards
- Background Checks
- Psychological Evaluation
- Lists & Pathogen Control
- A Culture of Mistrust?

Which will make us safer and more productive?
Thoughts on the way ahead...

• Life sciences community takes back momentum:
  – Transparency in science
  – Communicate, Educate, Recruit…Lead!
  – Demonstrate a Culture of Responsibility
  – Build Public Trust

• Work with “the Regulators” and concerned citizens to:
  – Carefully consider real risk
  – Carefully consider real value of all solutions
  – Consider the entire cost of all solutions
    – Real costs: Equipment, scientist time, Decreased ‘tooth-to-tail’ ratio
    – Intangible costs: Scientists move to other fields, Research offshore

• Seek solutions that limit frustration to scientists
“Zero Risk” is not an option…
We can’t afford it!

It’s a dangerous world out there. We must work through these issues together…globally.

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