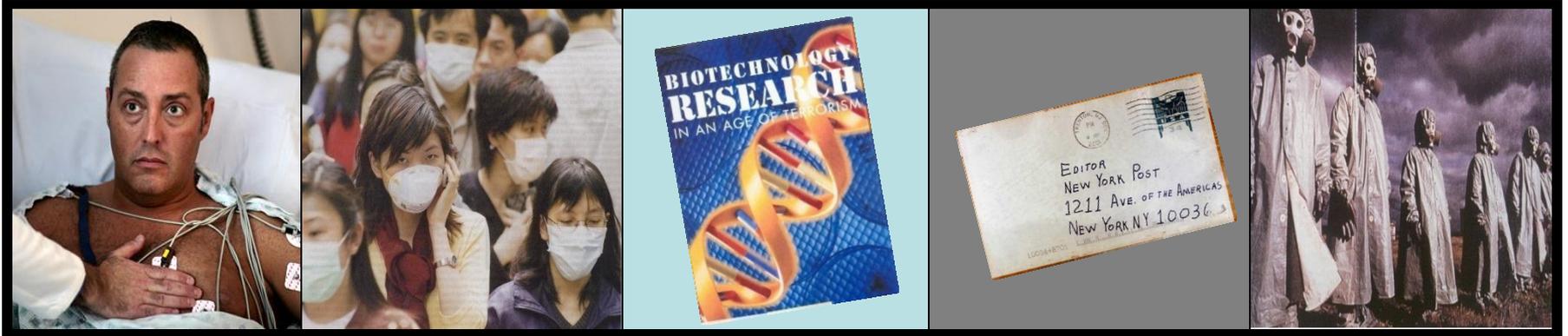


The Role of Leadership and Culture within the Laboratory

Some challenges and thoughts on how to address them...



David R. Franz
2nd World Conference on Research Integrity
Pan Pacific Hotel Singapore
21-24 July 2010

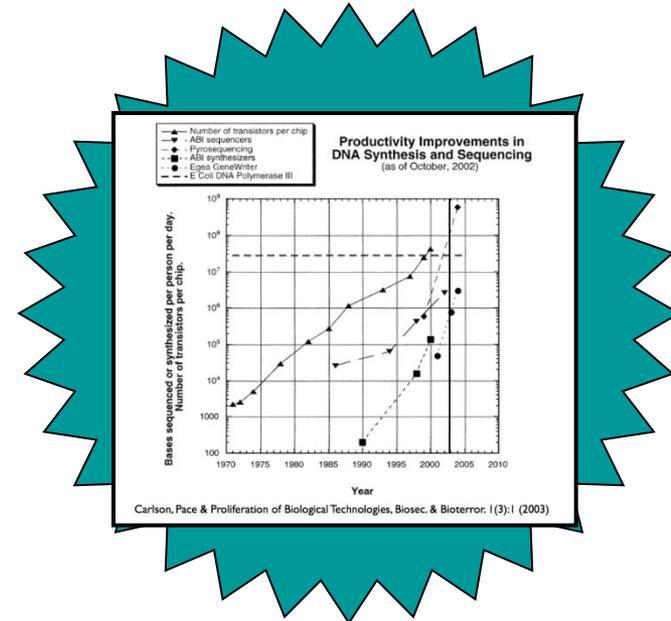
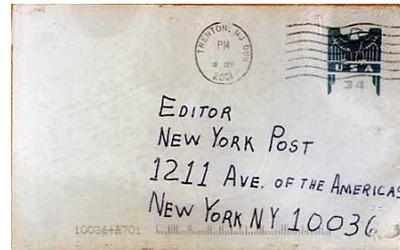
The Biodefense 'build-up' in Context

2003

2000 – Mouse pox and IL-4



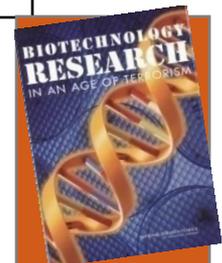
9-11-01



10-4-01

2002 – Synthesis of Poliovirus (2nd)
2002 - Smallpox "SPICE"

ca. \$6 Billion annually... **Dual-Use Research of Concern...**





TIMELINE OF KEY EVENTS

OCTOBER: Anthrax is mailed to lawmakers on Capitol Hill and news media in New York and Florida. By November, five people are dead and 17 others sickened.

JANUARY: Senate office building reopens. FBI doubles the reward to \$2.5 million.

JUNE: FBI scrutinizes 20 to 30 scientists who had knowledge and opportunity to send the anthrax letters.

AUGUST: Law enforcement officials call Steven J. Hatfill, a bio warfare expert, a "person of interest."

JUNE: FBI drains pond in Frederick, in search of anthrax-related evidence. Nothing suspicious is found.

AUGUST: Hatfill sues government officials, accusing them of using him as a scapegoat.

DECEMBER: Postal workers begin moving back into Washington's main mail center, almost two years after anthrax-laced letters killed two employees.

FEBRUARY: A white powder determined to be the deadly poison ricin is found in an office of Senate Majority Leader Bill Frist. No one is hurt and no arrests are made.

JULY 11: BioONE, a company founded by former NYC Mayor Rudolph Giuliani, begins fumigating former headquarters of *The Sun*, the Florida tabloid that was targeted first.

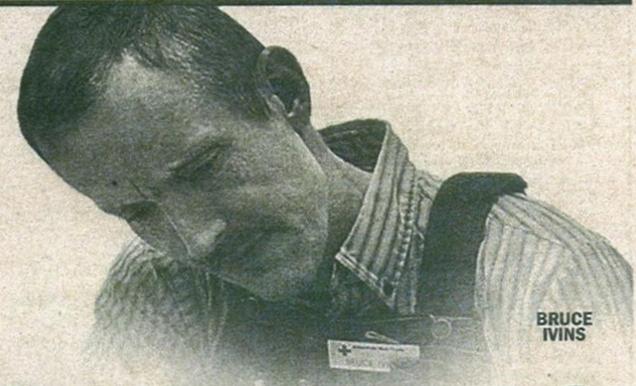
JULY 12: Testing determines *The Sun's* headquarters is free of anthrax.

JULY 13: Hatfill sues *The New York Times* for

USAMRIID | ANTHRAX BREACH INVESTIGATION

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

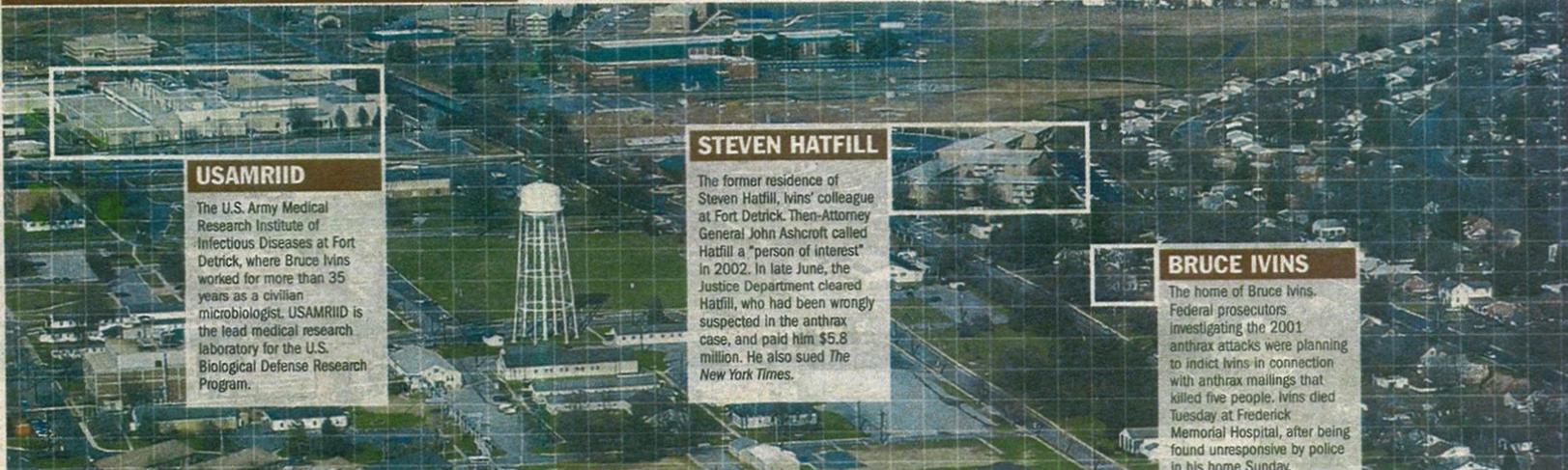
THE ARMY MICROBIOLOGIST WHO WAS WORKING ON A VACCINE FOR ANTHRAX POISONING WAS NOW BEING GRILLED AS A SUSPECT IN THE 2001 LETTER ATTACKS THAT KILLED FIVE PEOPLE AND SICKENED 17. FBI AGENTS WERE STAKING OUT HIS HOUSE. IVINS WAS A FREDERICK RESIDENT WHO WORKED AT THE U.S. ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES. HE DIED TUESDAY IN AN APPARENT SUICIDE. AUTHORITIES WERE PLANNING TO CHARGE HIM WITH MAILING THE TOXIN-LACED LETTERS, WHICH SPREAD NATIONWIDE ALARM JUST WEEKS AFTER THE SEPT. 11, 2001, TERROR ATTACKS IN NEW YORK AND WASHINGTON.



BRUCE IVINS

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, where Bruce Ivins worked for more than 35 years as a civilian microbiologist. USAMRIID is the lead medical research laboratory for the U.S. Biological Defense Research Program.

STEVEN HATFILL

The former residence of Steven Hatfill, Ivins' colleague at Fort Detrick. Then-Attorney General John Ashcroft called Hatfill a "person of interest" in 2002. In late June, the Justice Department 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 home of Bruce Ivins. Federal prosecutors investigating the 2001 anthrax attacks were planning to indict Ivins 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.

The Dingell – Stupak Letter

HENRY A. WAXMANN, CALIFORNIA
EDWARD J. MARKEY, MASSACHUSETTS
BOB BYRNE, VIRGINIA
EDOUARD B. CLAY, NEW YORK
FRANK RALPH JONES, NEW JERSEY
BART GORDON, TENNESSEE
ROBERT L. RUBEN, ALABAMA
ANNA G. ESCOBAR, CALIFORNIA
BART STUPAK, MICHIGAN
ELIOT L. ENGEL, NEW YORK
BENNY GREEN, TEXAS
DANNA ROZETT, CALIFORNIA
VICI D'AMMARI
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JOHN BARROW, GEORGIA
BARRY P. HILL, INDIANA
DORIS O. MATSUDA, CALIFORNIA

ONE HUNDRED TENTH CONGRESS
U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515-6115

JOHN D. DINGELL, MICHIGAN
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MARTIN BLANCHARD, TENNESSEE

August 8, 2008

DENNIS O. FITZGERALD, CHIEF OF STAFF
DORIS A. McFARLAND, DEPUTY CHIEF OF STAFF
AND CHIEF COUNSEL

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

Dear Mr. President:

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.

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,

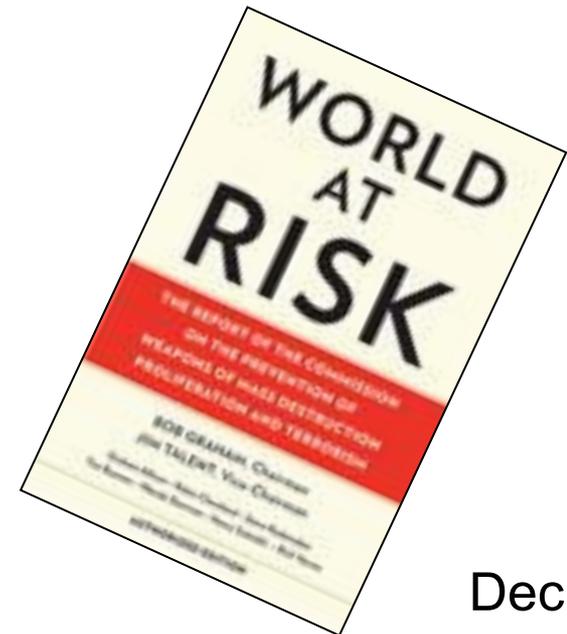


John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

WMD Commission of 2008

"The United States should be less concerned that terrorists will become biologists and far more concerned that biologists will become terrorists."



Dec '08

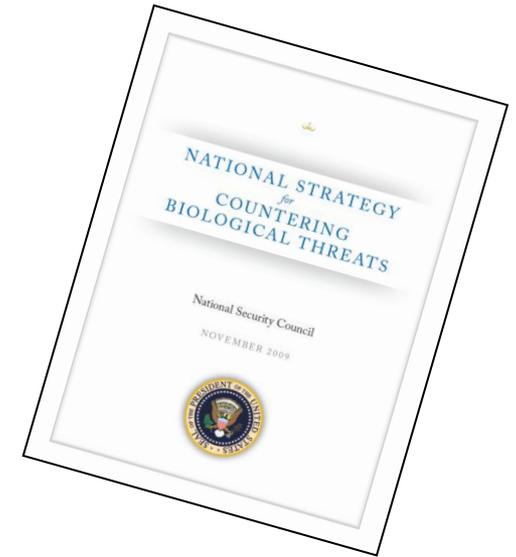
New Committee Reports since 28 July 08

1. DoD/DSB Study---Feb 09

2. NSABB Study---May 09

3. Trans Federal Task Force--- Jul 09

4. National Academies Study---Sep 09



Dec 09

...and in July 2010, an Executive Order

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”**.

Personnel Reliability: AR 50-1

28 July 08. ...AR 50-X since 2004

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](#)

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

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?

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Psychological Evaluation

Lists & Pathogen Control

A Culture of Mistrust?

Which will make us safer and more productive?

Seeking Balance

Security, Safety and Productivity

Biosafety: *Necessary, understood and very important.*

Biosecurity: *Necessary, not always understood and can be overdone.*

Enlightened Leadership: *Necessary, sometimes under-appreciated and more is usually better.*

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!

There are many risks out there, but we can't stop working toward the good that can come from biotechnologies and knowledge...



www.biosecurityboard.gov

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ADVISORY
BOARD FOR
BIOSECURITY

DOES YOUR RESEARCH RAISE SECURITY CONCERNS?

STRATEGIES FOR PROMOTING RESPONSIBLE RESEARCH IN THE LIFE SCIENCES

An Interactive Webcast

September 22, 2010, 8:00 AM - 10:30 AM (Eastern Daylight Time)

(1200 – 1430 GMT)

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an effective
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Institut Pasteur