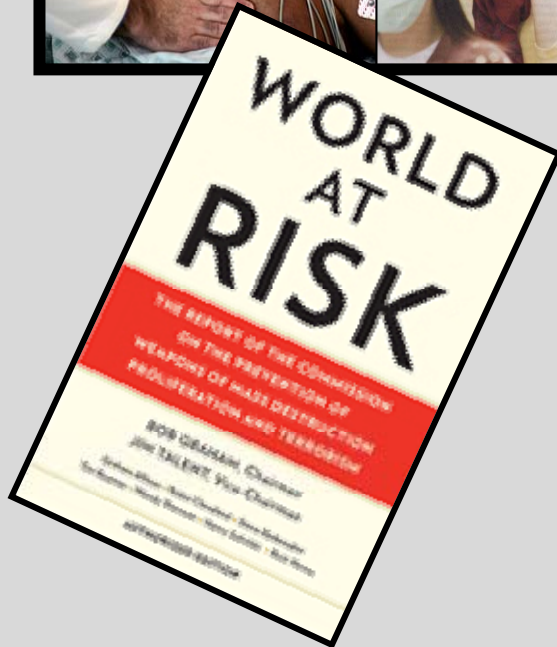
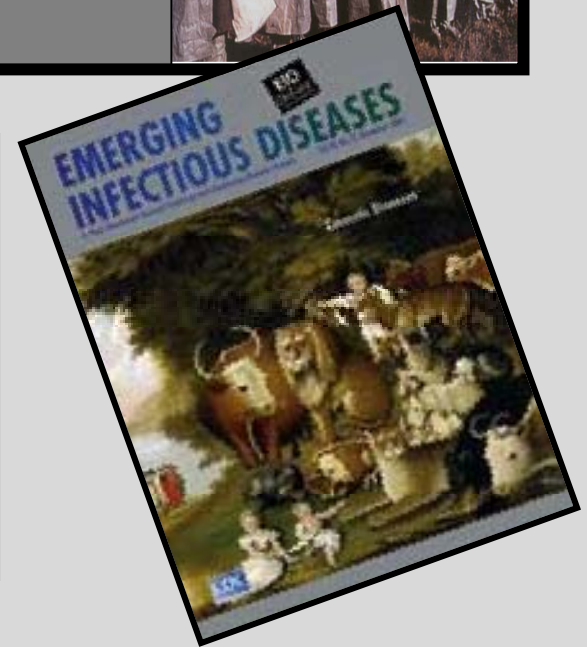


BioRisk Policy: in a global biotech revolution



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

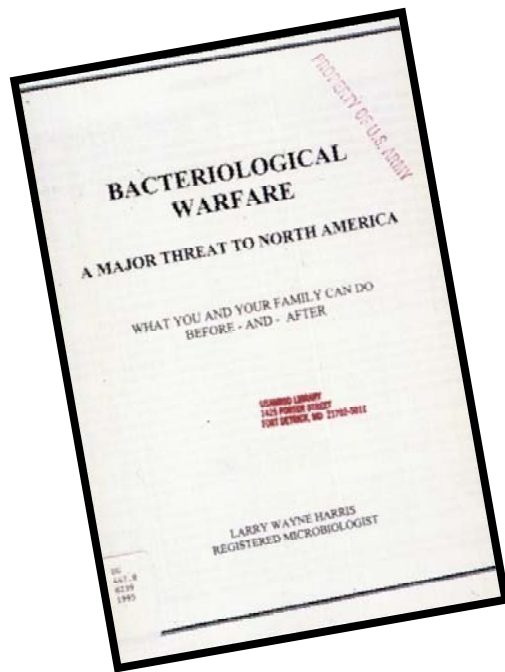
“To further reduce the potential for laboratory-associated infections, the guidelines presented here should be considered minimal guidance for containment. They must be customized for each individual laboratory and can be used in conjunction with other available scientific information.”



Then in 1996...Biosecurity

“The Select Agent Rule”

Anti-Terrorism and Effective Death Penalty Act of 1996



Larry Wayne Harris

- 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

Not required in 1996 Act



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

April 2008---9,918 individuals approved to work with Select Agents

May 2008---324 entities registered with CDC (gov, corp, acad, NGOs)



© 2008 Randall Family, LLC

SATURDAY

AUGUST 2, 2008

fredericknewspost.com | Vol. 125 | No. 293 | 4 Sections | Press Run: 43,268 | FINAL

50¢

MELINE 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 blowfare 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.



© 2008 Randall Family, LLC

SATURDAY

AUGUST 2, 2008

fredericknewspost.com | Vol. 125 | No. 293 | 4 Sections | Press Run: 43,268 | FINAL

50¢

TIMELINE OF KEY EVENTS

OCTOBER: Anthrax letters mailed to lawmakers on Capitol Hill and news media in New York and Florida. By November, five people are killed and 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 MICROBIOLOGIST WHO WAS WORKING ON A VACCINE FOR ANTHRAX POISONING WAS NAMED AS A SUSPECT IN THE 2001 LETTER ATTACKS THAT KILLED FIVE PEOPLE AND INJURED 12. FEDERAL 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 WAS NAMED AS A SUSPECT. AUTHORITIES WERE PLANNING TO CHARGE HIM WITH SPREADING ANTHRAX TO SPREAD NATIONWIDE ALARM JUST WEEKS AFTER THE ATTACKS IN NEW YORK AND WASHINGTON.



BRUCE IVINS

ANTHRAX CASE TURNS SCIENTIST COMMITS SUICIDE PROBE TIGHTENS

Assuming the FBI is correct....
The insider threat is more difficult
serious than I believed...

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

<small>HENRY A. WAXMANN, CALIFORNIA EDWARD J. MARKEY, MASSACHUSETTS BOB BAKER, VIRGINIA EDOUARD B. BOURNE, NEW YORK FRANK PALLONE, JR., NEW JERSEY BART GORDON, TENNESSEE BOBBY L. LUNDGREN, ILLINOIS KERRY B. BENNETT, CALIFORNIA BART STUPAK, MICHIGAN ELIOT L. ENGEL, NEW YORK BENNY L. RAY, TEXAS DAN Rostenkowski, ILLINOIS VIC FOXX, CALIFORNIA LEO CARR, CALIFORNIA MIKE DOYLE, PENNSYLVANIA JOE HANCOCK, CALIFORNIA TOM ALTO, MARYLAND JIM SCHROEDER, ILLINOIS WILSON L. GOODE, CALIFORNIA CHARLES A. GONZALEZ, TEXAS JAY INGLE, WASHINGTON TAMMY BALDWIN, WISCONSIN BOB ROSEN, ARIZONA ANTHONY D. MARTINO, NEW YORK JIM RAHALL, OREGON D. K. BILTEFELD, NORTH CAROLINA CHARLIE MELANCON, LOUISIANA JOHN BARON, GEORGIA BARRY P. HILL, NEVADA DORIS O. MATSUDA, CALIFORNIA</small>	<small>ONE HUNDRED TENTH CONGRESS</small> U.S. House of Representatives Committee on Energy and Commerce Washington, DC 20515-6115 JOHN D. DINGELL, MICHIGAN CHAIRMAN	<small>JOE BARTON, TEXAS JAMROG ALMEIDA RALPH H. HALL, TEXAS FIELD LITTON, MICHIGAN GUY STEARNS, FLORIDA NATHAN DEAL, GEORGIA ED WHITFIELD, KENTUCKY BARBARA CLERK, WYOMING JOHN SHAWNEE, ILLINOIS KATHY WALSH, NEW MEXICO JOHN S. SHARDES, ARIZONA CHARLES W. STAFFORD, MISSISSIPPI WTO FORESTILL, NEW YORK BOB BYRNE, IOWA STEVE BUYER, INDIANA GEORGE BODANOVICH, CALIFORNIA JOSEPH R. PITTS, PENNSYLVANIA MARTY ROSEN, CALIFORNIA SING AUCTION, OREGON LEE TRIPP, MISSISSIPPI MIKE FORZANO, NEW JERSEY MIKE ROGERS, MICHIGAN DIE WELCHER, NORTH CAROLINA JOHN SULLIVAN, OKLAHOMA TIM MURPHY, PENNSYLVANIA MICHAEL C. BURGESS, TEXAS MARSHA BLACKBURN, TENNESSEE</small>
August 8, 2008		
<small>DENNIS O. FITZGERALD, CHIEF OF STAFF DRESS A. MCNEIL, DEPUTY CHIEF OF STAFF AND CHIEF COUNSEL</small>		
<p>The President The White House 1600 Pennsylvania Avenue, N.W. Washington, D.C. 20500</p> <p>Dear Mr. President:</p> <p>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.</p> <p>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.</p> <p>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.</p>		
Sincerely,		
 		
<small>John D. Dingell Chairman</small>	<small>Bart Stupak Chairman Subcommittee on Oversight and Investigations</small>	

The Dingell – Stupak Letter

HENRY A. WAXMAN, CALIFORNIA
 EDWARD J. MARKEY, MASSACHUSETTS
 BOB BAKER, VERMONT
 ED PAUL TORRES, NEW YORK
 FRANK PALLONE, JR., NEW JERSEY
 BART GORDON, TENNESSEE
 BOBBY L. LUND, ILLINOIS
 KRISTEN G. BRADY, CALIFORNIA
 BART STUPAK, MICHIGAN
 ELIOT L. ENGEL, NEW YORK
 BENE GARDIN, TEXAS
 DANIA CRUJEIRA, COLORADO
 VICE CHAIRMAN
 LEO CAPPY, CALIFORNIA
 MIKE DOYLE, PENNSYLVANIA
 JOHN HANCOCK, CALIFORNIA
 TOM ALTMAN, FLORIDA
 JIM BROWNSTOCK, ILLINOIS
 MELBA L. SOLOS, CALIFORNIA
 CHARLES A. GONZALEZ, TEXAS
 JAY BYRNE, WASHINGTON
 TAMMY BALDWIN, WISCONSIN
 MIKE ROSS, ARIZONA
 SARAHINE HOOVER, OREGON
 ANTHONY D. MARTINO, NEW YORK
 JIM MATTHESEN, UTAH
 G. K. BUTTERFIELD, NORTH CAROLINA
 CHARLIE MELANCON, LOUISIANA
 JOHN BARON, GEORGIA
 BARRY P. HILL, NEVADA
 DORIS O. MATSUI, CALIFORNIA
 DENNIS O. FITZGERALD, CHIEF OF STAFF
 GREGG A. MCNEIL, DEPUTY CHIEF OF STAFF
 AND CHIEF COUNSEL

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

JOHN D. DINGELL, MICHIGAN
 CHAIRMAN

August 8, 2008

JOE BARTON, TEXAS
 JAMROG ALMEIDA
 RALPH H. HALL, TEXAS
 FRED LUTON, MICHIGAN
 GUY STEARNS, FLORIDA
 MATTHEW DEAR, GEORGIA
 ED WHITFIELD, KENTUCKY
 BARBARA CLERK, INDIANA
 JOHN SHAWNEE, ILLINOIS
 KATHERINE WALTON, NEW MEXICO
 JOHN B. SHARDES, ARIZONA
 CHARLES W. "CHIP" PICKERING, MISSISSIPPI
 WED FORDWELL, NEW YORK
 BOB BLYDEN, MISSOURI
 STEVE BURER, INDIANA
 GEORGE BODANOVICH, CALIFORNIA
 JOSEPH E. RTTIS, PENNSYLVANIA
 MARY ROSSO MACK, CALIFORNIA
 SING ANJOUN, OREGON
 LEE TRIPP, NEVADA
 MIKE FORZANO, NEW JERSEY
 MIKE ROGERS, MICHIGAN
 DUE WELLES BRIDCE, NORTH CAROLINA
 JOHN SULLIVAN, OKLAHOMA
 TIM MURPHY, PENNSYLVANIA
 MICHAEL C. BURGESS, TEXAS
 MARIAN BLANCHARD, TENNESSEE



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

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

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

“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](#)

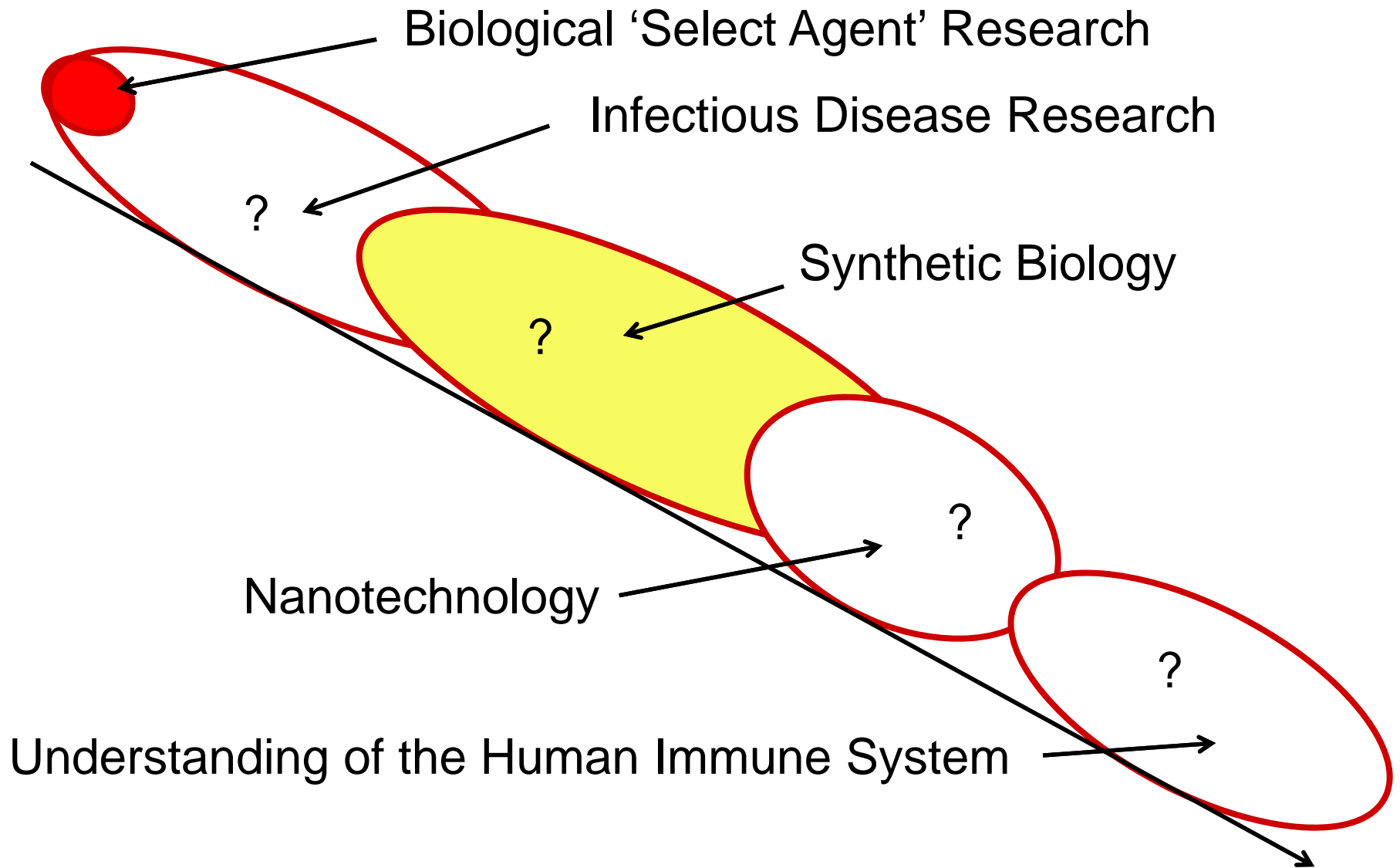
Biological 'Surety' 2008

- 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”**.

Fear the Slippery Slope



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 compete 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...
over nuclear issues...
open and... wide
controlled
— by international norms.

Proliferation is over...

If we over-regulate our science...don't assume the world will follow

Monday, July 20, 2009

THE WALL STREET JOURNAL.

India Rebuffs U.S. Push for Binding Pollution Limits



Associated Press

Indian Environment Minister Jairam Ramesh dismissed U.S. Secretary of State Hillary Clinton's suggestions that India accept binding limits on carbon emissions, saying it had among the lowest per capita emissions. A7

*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

Regulatory Oversight

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.

dfranz@mriresearch.org