

Integration of Biosafety and Bioscurity:

*With Responsibility of Researchers
in the Life Sciences*

FLASH News!!!

The New York Times | **BREAKING NEWS ALERT**

[NYTimes.com](#) | [Unsubscribe](#)

BREAKING NEWS Wednesday, October 16, 2013 8:20 PM EDT

Senate Passes Measure to End Shutdown and Raise Debt Limit

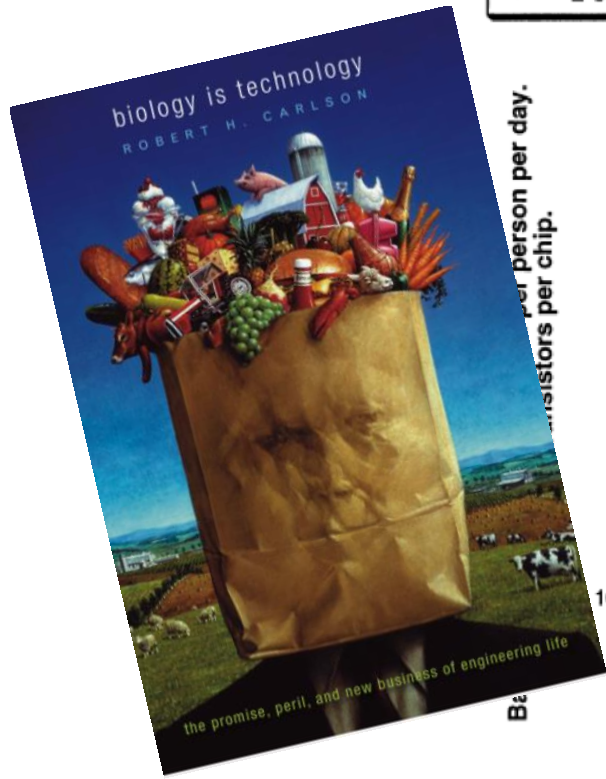
With Treasury warning it could run out of money to pay U.S. obligations within a day, the Senate voted overwhelmingly Wednesday evening 81-18 to approve a proposal hammered out by the Senate's Republican and Democratic leaders after the House on Tuesday was unable to move forward with any resolution.

The House was expected within hours to follow suit and approve the Senate plan that would fund the government through Jan. 15 and raise the debt limit through Feb. 7.

History and the Current Condition

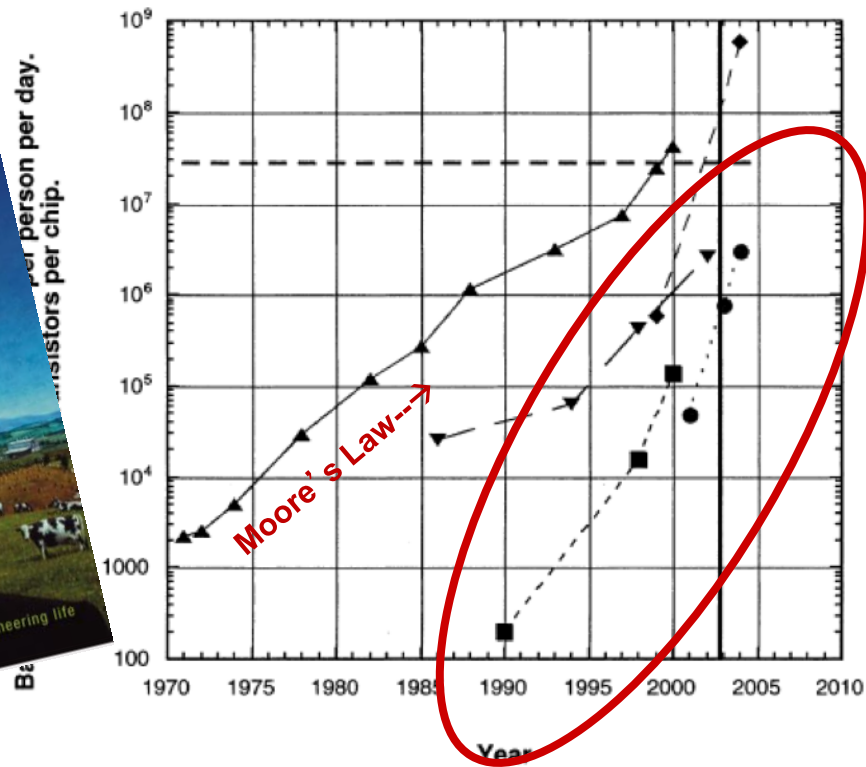
- What drove the (US) regulation?
- What regulatory scheme evolved?
- What are the [my] Concerns?
- Were there alternatives?
- How can we (scientists) make a difference?

The Biotech Revolution



- ▲ Number of transistors per chip
- ▼ ABI sequencers
- Pyrosequencing
- ABI synthesizers
- Egea GeneWriter
- E Coli DNA Polymerase III

Productivity Improvements in DNA Synthesis and Sequencing
(as of October, 2002)



Measures of progress in biotechnology

THE SCARIEST NEW
COMPUTER SCAM P. 112

THE GEEKIEST
PLACES ON EARTH P. 128

APPLE AFTER
STEVE JOBS P. 29

WIRED, Oct 2011

WIRED

CAGE FREE | OCT 2011

Scientists know how
to turn a chicken
into a dinosaur.
What could possibly
go wrong?

REVERSE EVOLUTION

Scientists know how
to turn a chicken
into a dinosaur.
What could possibly
go wrong?

+

HOW GOOGLE GOT SOCIAL NETWORKING RIGHT (FINALLY)

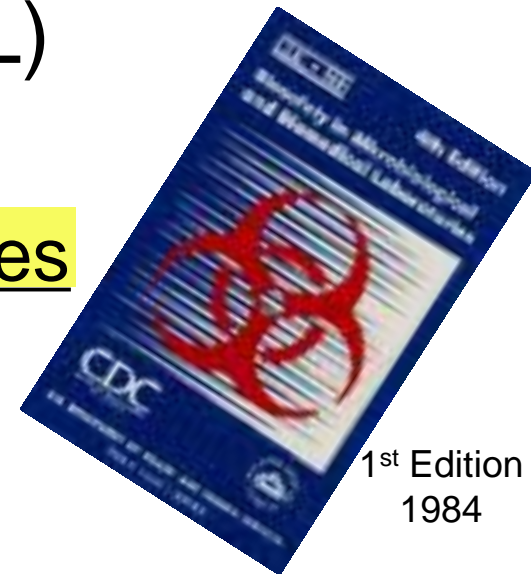
“The Revolution”

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.”

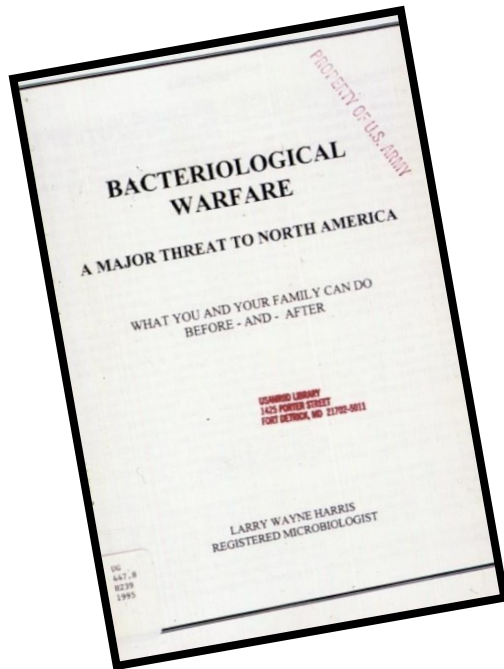


1st Edition
1984

Then in 1996...Biosecurity

“The Select Agent Rule”

Anti-Terrorism and Effective Death Penalty Act of 1996



Larry Wayne Harris

A 'bio-unabomber' ?

- Selected agents to be controlled
- **Registration of laboratories for agent transfer**



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 biowarfare 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.

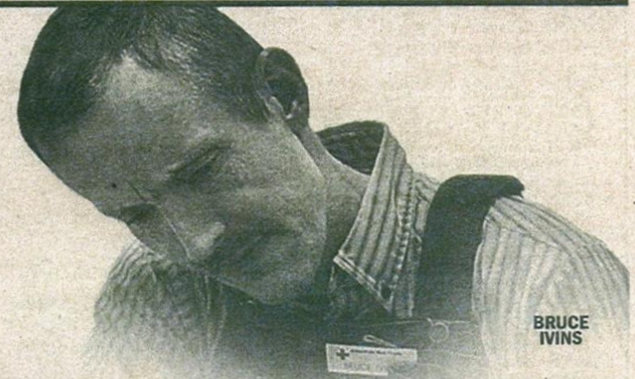
JULY 12: Testing determines *The Sun's* headquarters is free of anthrax.

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

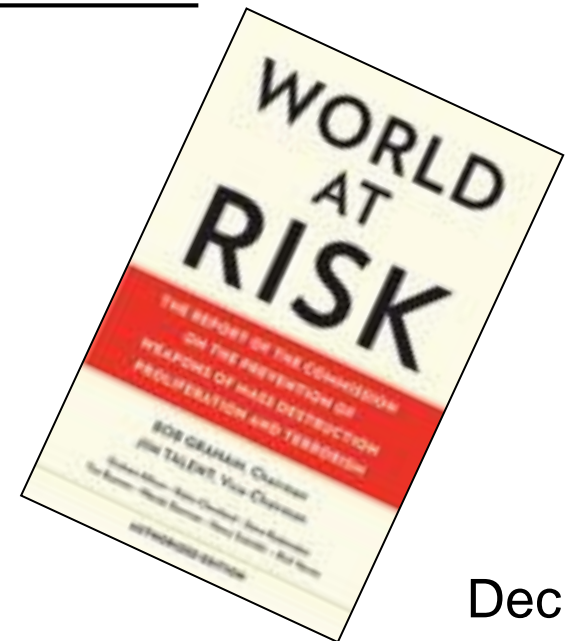
The former residence of Steven Hatfill, Ivins' colleague at Fort Detrick. Then-Attorney General John Ashcroft called Hatfill a "person of interest" in 2002. In late June, the Justice Department cleared Hatfill, who had been wrongly suspected in the anthrax case, and paid him \$5.8 million. He also sued *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.

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

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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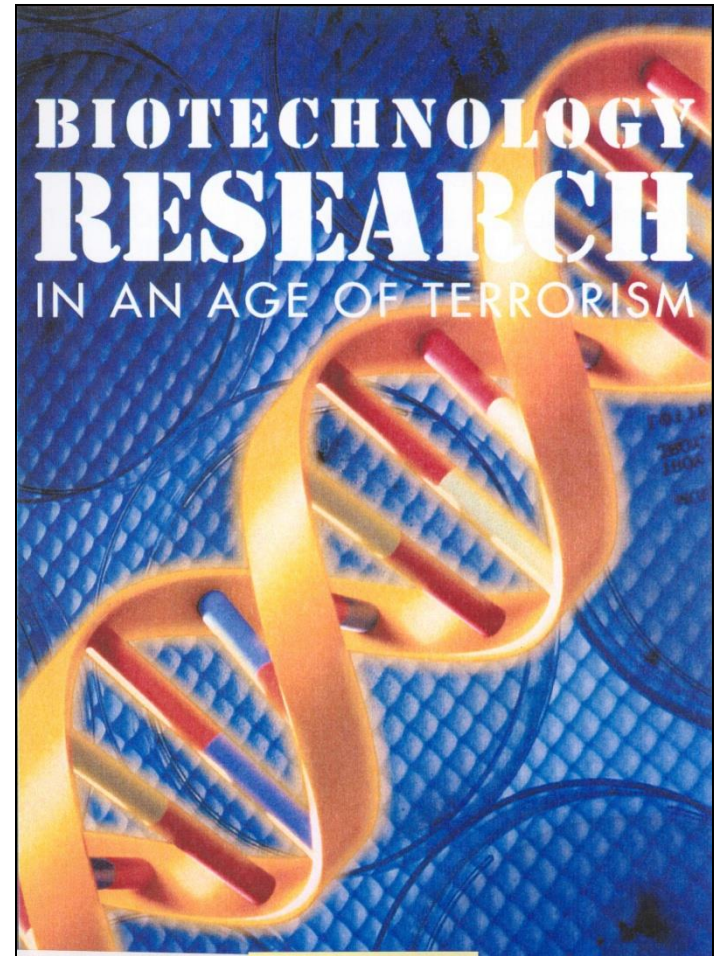
(5) **Attempting to conceal PDI [*potentially disqualifying information*]** from certifying officials

“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

The Concept of “Dual Use” Research

- Report of the National Research Council of the National Academies (2003)
- “...the same technologies can be used legitimately for human betterment and misused for bioterrorism.”



Fink Report Conclusions

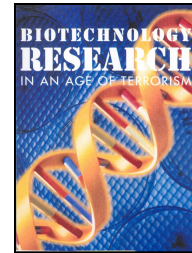
- More good than harm from biotech
- We need these technologies for good
- We must balance regulation and progress
- The playing field is international
- Education and Awareness are key...



Recommended a NSABB

“Experiments of Concern”

- (1) Demonstrating how to render a **vaccine ineffective**,
- (2) **conferring resistance** to therapeutically useful antibiotics or antiviral agents,
- (3) **enhancing the virulence** of a pathogen or rendering a non-pathogen virulent,
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- (7) **enabling the weaponisation** of a biological agent or toxin.



Mammalian Transmissible A/H5N1

Ron Fouchier & Yoshihiro Kawaoka

Funded by the US NIH
Conducted in:
Erasmus MC, Rotterdam
University of Wisconsin, Madison

NEWS & ANALYSIS

AVIAN INFLUENZA

Surprising Twist in Debate Over Lab-Made H5N1

For the past several months, the media, the public, scientific groups, and a key U.S. government advisory panel on biosecurity have wrestled with how to deal with two unpublished studies they thought described the creation of a bird flu virus capable of triggering an influenza pandemic with the potential to kill millions of people. *The New York Times* even billed it as a “doomsday virus.” But now, a researcher who created one of the H5N1 mutants and a leading U.S. health official say the threat has been blown out of proportion, offering what they said were clarifica-

among mammals could guide research on defensive measures and help derail an emerging pandemic, but many fear that the knowledge could help bioterrorists start one. To date, this debate has taken place largely in an information vacuum. Only a select group of people outside the two research groups involved have read drafts of papers describing the work, one of which was submitted to *Science* and the other to *Nature*. On 29 February, Fouchier attempted to partially fill that vacuum by offering glimpses of his group’s data at a public meeting held by the Amer-

November, calling the mutant “probably one of the most dangerous viruses you can make.”

In December, the U.S. government’s National Science Advisory Board for Biosecurity (NSABB) recommended that the researchers and the journals redact key information from the papers. The diverse panel—which includes scientists from several disciplines, veterinarians, and biosecurity experts—also questioned whether the teams should have used more stringent biocontainment measures to safeguard against these viruses escaping from the lab. An uproar followed. Some said the experiments never should have been performed. Fouchier and the researcher who led the second team, Yoshihiro Kawaoka of the University of Wisconsin, Madison, and the University of Tokyo, criticized the call for redaction and the attempts to control the free flow of scientific communication, as did many other scientists. Kawaoka also stressed in a *Nature* comment in January 2012 that his mutant did not kill ferrets and was no more dangerous than the strain that caused the relatively mild 2009 pandemic.

But the researchers and the journals agreed to follow NSABB’s recommendation, and the influenza community called for a voluntary 2-month moratorium on research with such mutant viruses. Then in February, an expert group consisting mainly of influenza researchers met with Fouchier and Kawaoka for 2 days at the World Health Organization (WHO) in Geneva and came to a conclusion that directly contradicted that of NSABB: Redaction did not make sense, they said, for both scientific and practical reasons.

At the ASM meeting, NSABB acting chair Paul Keim of Northern Arizona University in Flagstaff led the discussion with Fouchier;



Clarifying agents. Ron Fouchier (left) and Anthony Fauci urged people to rethink threat posed by engineered bird flu at a recent meeting in Washington, D.C.

Fouchier Malta Sep 11

“This is very bad news”

“..as efficiently transmitted as seasonal virus”

Science Nov 11

“Probably one of the most dangerous viruses you can make”

NSABB Review Dec 11

- 1-Recommended key information be redacted
-Available globally based on ‘need to know’
- 2-Bring in the international community
- 3-Questioned “safety issues”.
- 4-Two-month moratorium on related research

WHO Feb 12 (consensus)

- New information provided to committee
- Research should continue
- Findings contribute...surveillance/pathogenesis
- Studies highlight safety and security concerns
- Viruses stay in labs but moratorium continue
- Need communications plan BS/BS review
- Redaction and limited distribution not feasible
- Recommended further work on broader issues

NSABB Re-review Mar 12

Recommended that the revised manuscripts be communicated fully.

A Path Forward: Framework for Guiding U.S. Department of Health and Human Services Funding Decisions about Highly Pathogenic Avian Influenza H5N1 Gain-of-Function Research

I. Issue and Task at Hand

In 2011, two studies funded by the National Institutes of Health (NIH), which examined the mammalian trans...
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purpo...
funct...

**Is it possible to assess risk?
How to mitigate and manage?**

ding the...
or misuse...
search...
s key...
e...
i-of-

Box 2. Criteria for guiding HHS funding decisions for HPAI H5N1 gain-of-function research proposals

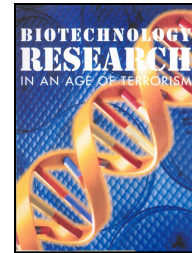
HPAI H5N1 gain-of-function research proposals are acceptable for HHS funding only if:

1. The research addresses a scientific question with high significance to public health;
2. The research does not intend, nor is reasonably anticipated to yield an HPAI H5N1 experimental virus that has increased transmissibility, pathogenicity, or expanded host range, unless there is evidence that such a virus could be produced through a natural evolutionary process in the foreseeable future;
3. There are no feasible alternative methods to address the same scientific question in a manner that poses less risk than does the proposed approach;
4. Biosafety risks to laboratory workers and the public can be sufficiently mitigated and managed;
5. Biosecurity risks can be sufficiently mitigated and managed;
6. The research information is anticipated to be broadly shared in order to realize its potential benefits to global health; and
7. The research will be supported through funding mechanisms that facilitate appropriate oversight of the conduct and communication of the research.

“Experiments of Concern”

Also Called, “7 deadly sins”

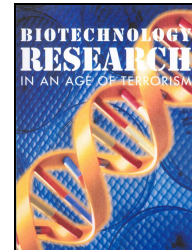
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And the Eighth...?',

Calling it **'Dual-Use RESEARCH of CONCERN...**



...rather than, 'Responsible Life-Sciences Research'

And the Eighth...?'

Calling it 'Dual-Use RESEARCH of CONCERN...'



...rather than, 'Responsible Life-Sciences Research'

Actions by a few impact many

Government(s) react to surprises...

Larry-Wayne Harris 1996



Select Agent Rule '97

Anthrax Letters 2001



USA Patriot Act 2002 (SAR)

Army Regulation 50-1 2004--2008

rH5N1 2011-12



USG Policy for Oversight of

Life-Sciences DURC Mar 2012

Aug 2013

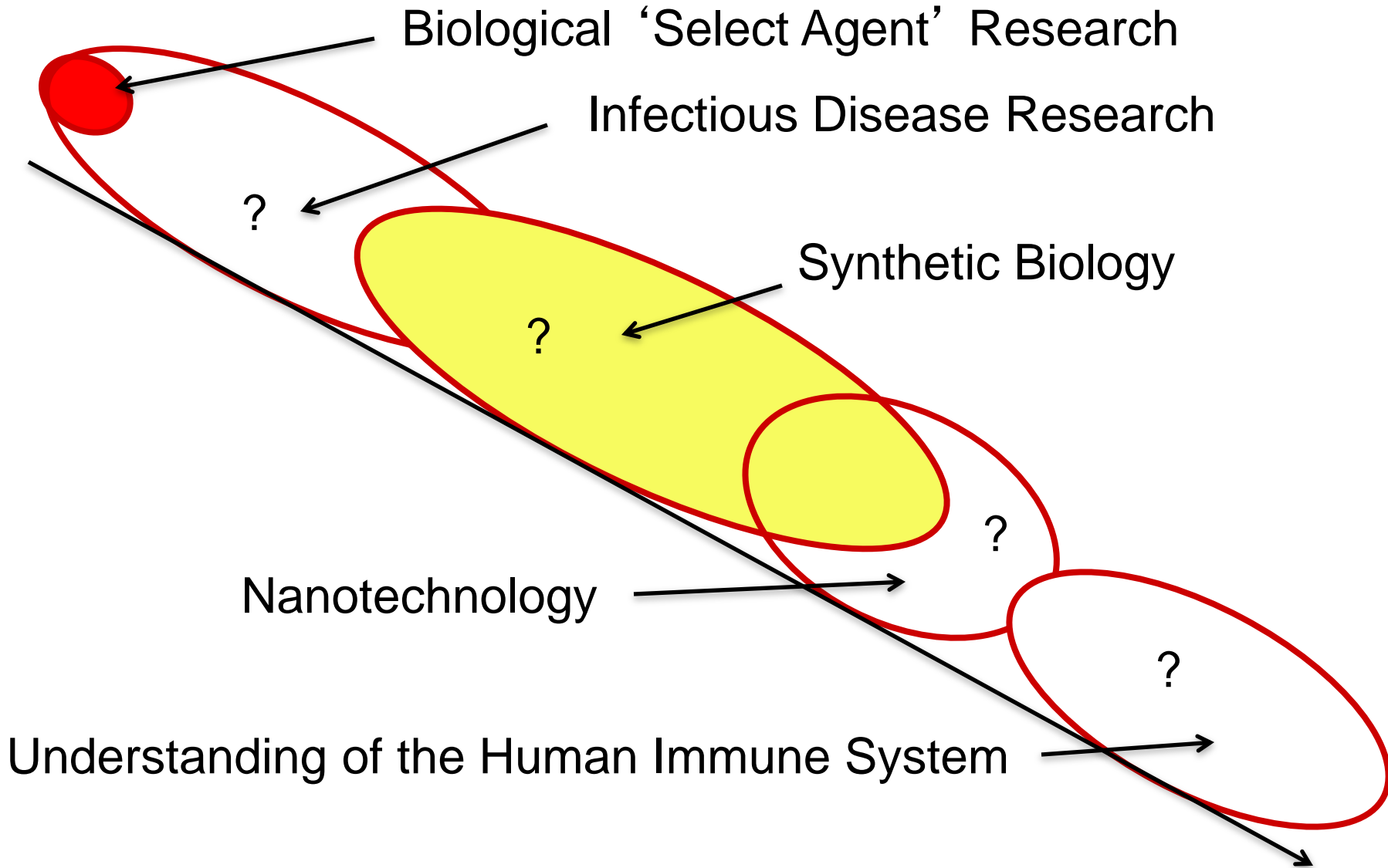
Implications of a mistake:

Over-regulation of our life-sciences research enterprise

- Our ability to provide
 - Healthcare
 - Food and agriculture
 - Energy
- Our economies
- Our ability to compete globally
- Our nations' security

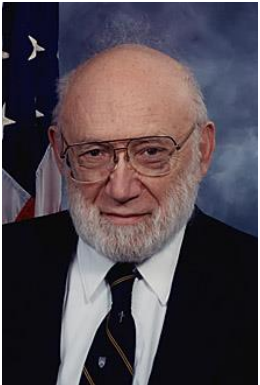
It could take 5-10 years to know that we have over-regulated...
...and 15-20 years to turn it around

Are we on a Slippery Slope?



“No technical solution...”

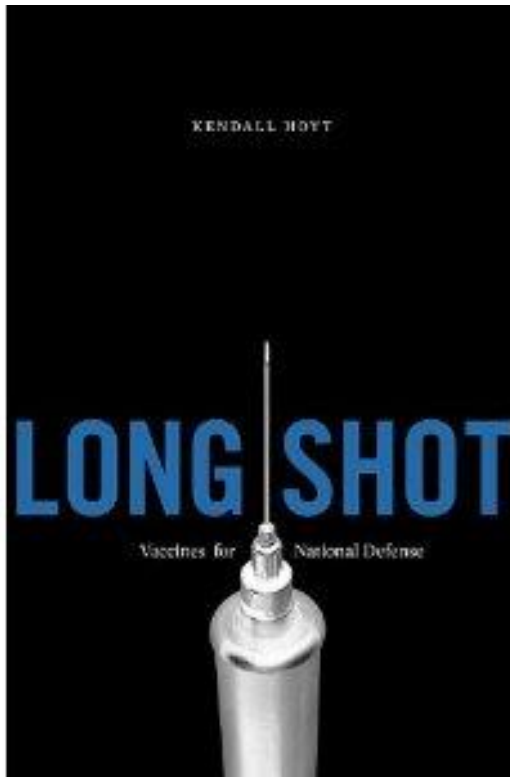
“There is no technical solution to the problem of biological weapons. It needs an ethical, human, and moral solution if it’s going to happen at all. Don’t ask me what the odds are for an ethical solution, but there is no other solution.”



<Then Dr. Lederberg paused and said,>

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

The New Yorker 1998



Long Shot:

Vaccines for National Defense



Kendall Hoyt

Success in producing countermeasures:

1. A 'champion'
2. Communities of Trust

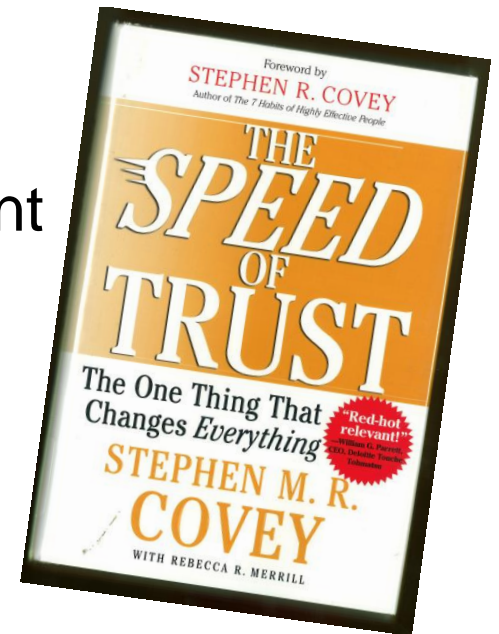
The *Value* of Trust

High Trust Organization

- Increased Value
- Accelerated Growth
- Enhanced Innovation
- Improved collaboration
- Stronger Partnering
- Better Execution
- Heightened Loyalty

Low Trust Organization

- Redundancy
- Bureaucracy
- Politics
- Disengagement
- Turnover
- Churn
- Fraud



1-Leadership can make this much difference!

2-Are we doing all we can to encourage this kind of leadership?

3-Are we doing all we can to develop and maintain high-trust organizations?

U.S. NEWS

THE OUTLOOK | By Jon Hilsenrath

How a Trust Deficit Is Hurting the Economy

ONE thing holding back the economic recovery may be a trust deficit.

Trust is an essential lubricant for economic activity. It makes investors, employers, policy makers and consumers willing to take part in transactions with each other, which in turn drives spending, investing and growth. You don't hand money or make promises to somebody unless you think that person is going to make good on his promises.

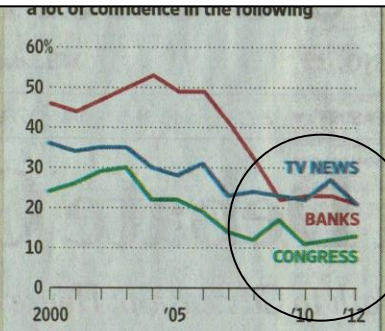
"Virtually every commercial transaction has within itself an element of trust," the Nobel-prize winning economist Kenneth Arrow wrote in a 1972 paper.

Research has shown that measures of trust in society are closely connected to economic growth and the effectiveness of government. In places where trust breaks down, economic development is damaged. In one example, researchers have found that the slave trade in Africa damaged trust in segments of society and that this held back economic growth for centuries after it ended.

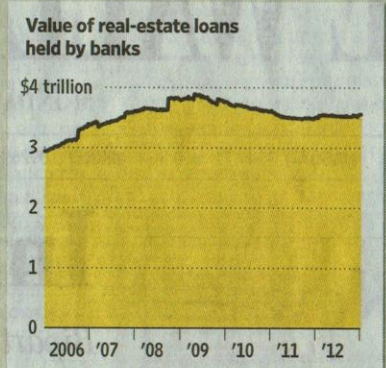
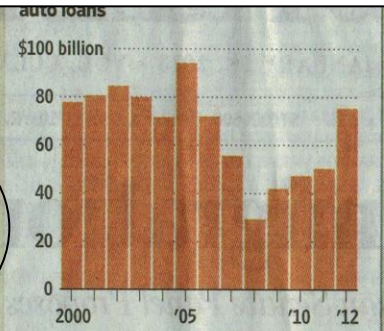
You don't have to look hard to find examples of fraying trust in American society today: Lance Armstrong admits to cheating to win seven Tour de France titles; Democrats and Republicans can't seem to work with each other; Wall Street keeps delivering new scandals.

Surveys by the University of Chicago's Booth School of Business and Northwestern's

It's not just biology...



Sources: Gallup (confidence); Dealogic (securities); Federal Reserve (real-estate loans)



The Wall Street Journal

Kellogg School of Management show that only a third of Americans trust banks, and about one in six trust the stock market or large corporations. For banks, this gauge of trust continued to fall even after the financial crisis ended. A June poll by Gallup found that only 25% of Americans had much confidence in newspapers, while only 21% trusted television news or organized labor. Congress got a vote of confidence from just 13% of the population. Trust in all these institutions has been in long-term decline, which worsened heading into the recession that began in December 2007. A September Gallup poll showed that only half of Americans trusted the government to solve do-

mestic problems. A longer-term decline of public trust in government might have been particularly damaging during the financial crisis because it prevented the government from pursuing more aggressive fiscal-stimulus programs to revive the economy, says Justin Wolfers, a University of Michigan economist. "The government's ability to fight the recession was sub-

stantially eroded the relationship between government and business in other ways. When regulators don't trust the businesses they oversee, they regulate them

more. While this is arguably necessary, it can also be an impediment to economic activity. Increased scrutiny goes beyond the banks at the center of the financial crisis. Dominic Barton, a McKinsey & Co. managing director, says executives he knows in the food industry are spending 30% more time meeting with regulators today than they did a few years ago. The regulatory trend isn't going to

be reversed. Through surveys measuring trust in important American institutions have turned dangerously down in recent years, there also are glimmers it is stabilizing. Securitization mar-

kets are one example. In these markets, Wall Street firms bundle together car loans, business loans, credit-card debt or mortgages and use the cash these loans produce to issue securities. The 2008 financial crisis severely damaged investor trust in these instruments and issuance collapsed, draining credit from the economy.

They now show signs of revival. Wall Street issued \$75.4

other example. The housing crisis left in its wake a stew of mistrust in the mortgage industry because of prolific abuses during the housing bubble. After the crisis, borrowers faced much greater scrutiny and paperwork demands by lenders. Banks feuded with Fannie Mae and Freddie Mac, the government-run mortgage-finance firms, over who holds the risk when a mortgage goes bad. However bank real-estate portfolios have quietly started to creep up; they were up 1.4% in early January from a year earlier to \$3.6 trillion, according to Federal Reserve data.

A SURVEY of 1,000 Americans by public-relations firm Edelman in November, after the election, showed big increases in measures of trust toward government, media and business compared with a year earlier.

Clearly, however, these institutions still have a long way to go after years of dismaying economic crises. A follow-up survey by Edelman in January makes that abundantly clear.

The firm suspected it might have been observing little more

How to build communities of trust?

trusted government in January, after the messy fiscal-cliff negotiations between President Barack Obama and Congressional Republicans. The survey measures dropped again.

Leaders influence culture...

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?

A call for Leadership

Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science
Volume 9, Number 3, 2011 © Mary Ann Liebert, Inc.
DOI: 10.1089/bsp.2011.0052

COMMENTARY

BALANCING OUR APPROACH TO THE INSIDER THREAT

David R. Franz and James W. LeDuc

BIOTERRORISM WAS A CONCERN of some in government even before Al Qaida-manned planes took down the World Trade Center towers. The anthrax letters greatly heightened that concern and extended it to our citizens as well. The nation responded with billions of dollars: bio-defense research and development, medical countermeasures, equipment, training first responders, and funding construction of numerous high-containment laboratories.

noted that the Department of Defense had the most stringent laboratory security regulations, recommended laboratory video cameras in labs rather than a 2-person rule (1 person to watch another scientist at work), encouraged tailoring the Personnel Reliability Programs (PRP) in biological labs to avoid having a negative impact on research, and underscored the importance of public awareness regarding risk reduction.

Thoughts on the way ahead...

- Life sciences community takes back momentum:
 - Transparency in science
 - Communicate, Educate, Recruit....LEAD
 - Demonstrate a Culture of Responsibility
 - Work to gain 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
- Work closely with international colleagues
 - ...to Strengthen Science while Reducing the Risks

We're *'Driving in the Dark'*

Richard Danzig on "prediction"

What's next???

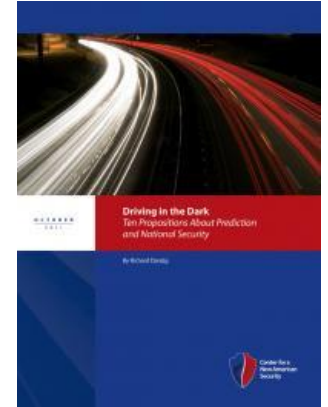
The Propensity to make Predictions - and to act on the basis of predictions - is inherently Human.

2. Requirements for Prediction Will Consistently exceed the ability to Predict.

3. The Propensity for Prediction is especially Deeply embedded in the U.S. Department of Defense.

4. The unpredictability of long-term national security Challenges will always Confound the irresistible forces That Drive Prediction.

5. Planning across a Range of scenarios is Good Practice but Will not Prevent Predictive failure.



We're 'Driving in the Dark'

Richard Danzig on "prediction"

The Propensity to make Predictions - is inherently Human

2. Requirements for Prediction

→ the ability

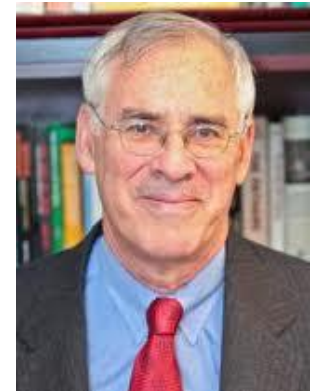
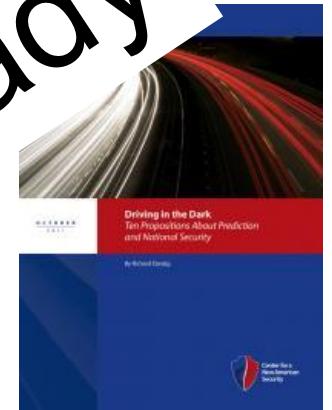
3. The Propensity to Predict

→ Deeply embedded in

4. Long-term national security Challenges with Unpredictable and Unresolvable forces That Drive Prediction.

5. Planning for a wide range of scenarios is Good Practice but Will not Prevent Catastrophic Failure.

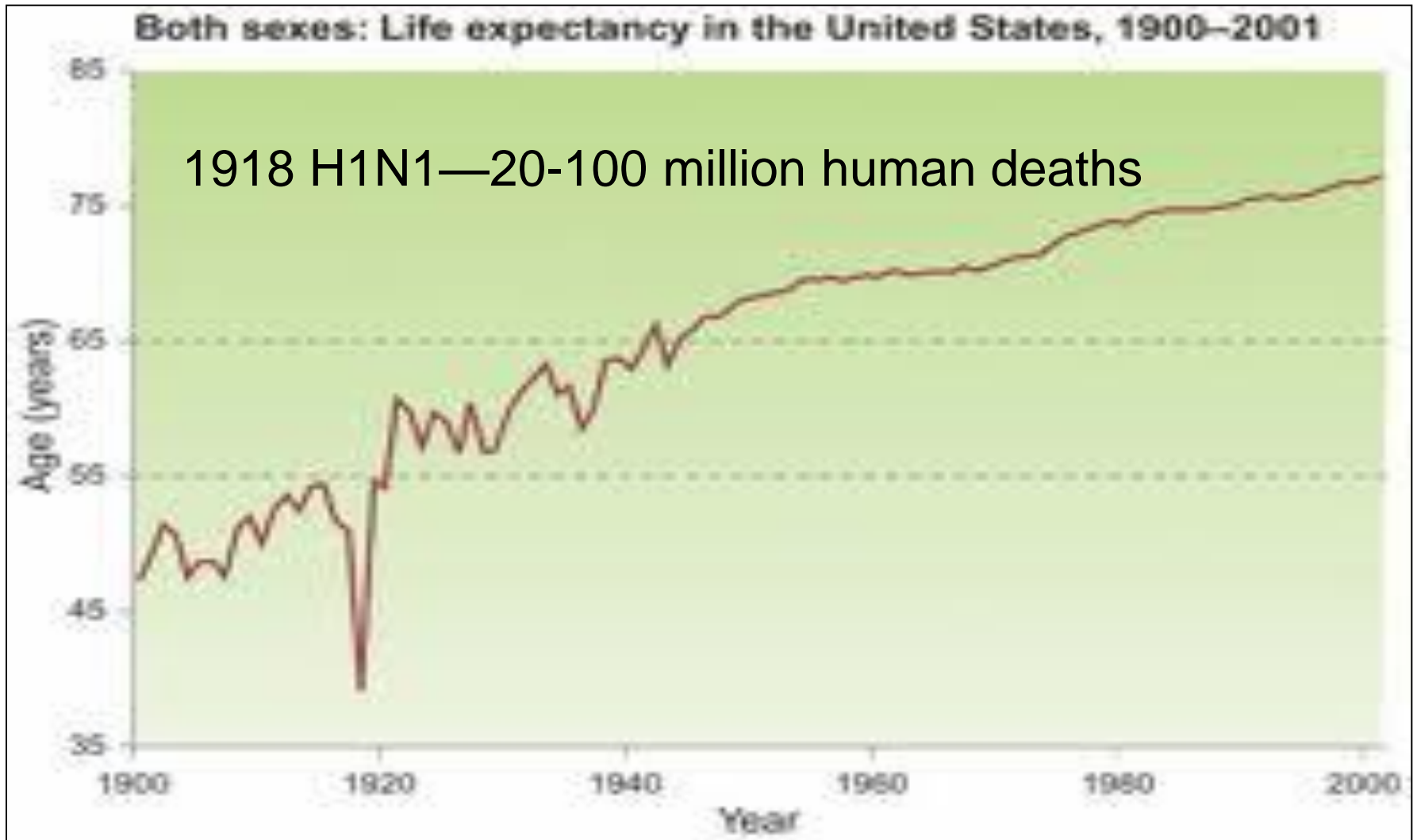
We just don't know... but we better be ready



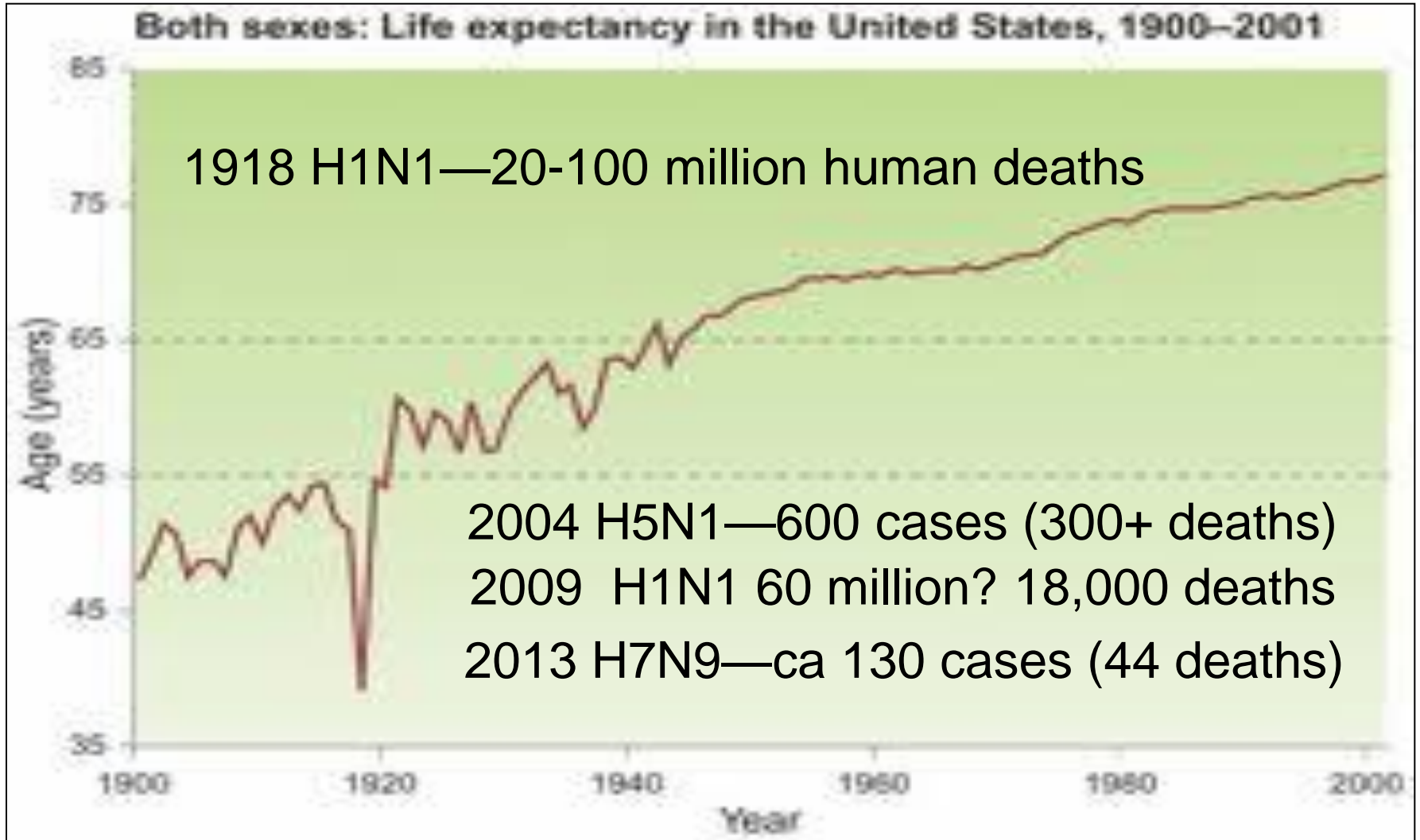
What does this graphic represent?



What does this graphic represent?



What does this graphic represent?



It's a dangerous (bio) world...



The Unknown

Emerging disease

Lab
Accident

Intentional
Misuse of Information

Bioterrorism

Chronic Disease

Communicable Disease

BioWarfare

It's a dangerous (bio) world...



A Balance of
-Enlightened Leadership
-A Culture of personal/corporate
Responsibility
-Thoughtful Regulation
-Safe/Sustainable Practices
-Freedom to Explore

PROGRESS
In the Life-Sciences

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The Unknown

Emerging disease

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BioWarfare

ZERO RISK MIGHT BE POSSIBLE

in individual laboratories like this one...



But we can't afford Zero Risk



Really good leadership from ALL of us, at all levels WILL make a difference....in our labs... in our nations...and globally.

“NGI”: each of us can be one...

“A person who strives for the betterment of society and believes in a good cause is an NGI.”



Dr. Anwar Nasim, Secretary General, Pakistan Academy of Sciences

www.anwarnasim.com