Laboratory Biosafety: The Leader's Role

It's about the 'people'

Thank You for this honor!

GEORGETOWN UNIVERSITY
Georgetown University Medical Center

ERG
Safer Together

Mentors: Our Guideposts

- A high-school biology teacher
- A college chemistry teacher
- An experienced clinician in vet school
- A practicing small-animal veterinarian 10 years my senior
- A British MD, PhD on my PhD committee
- The last General Officer Clinician-Scientist the US Army will produce
- Another General Officer who trusted me completely

Mentors: Our Guideposts

- A high-school biology teacher
- A college chemistry teacher

Shared their *Enthusiasm, Interests or Expertise*

Gave me *Opportunity*

Gave me *Freedom and Responsibility*

- The last General Officer Clinician-Scientist the US Army will produce
- Another General Officer who trusted me completely

The US Army Medical Research Institute of Infectious Diseases

-Freedom
-Responsibility

Opportunity

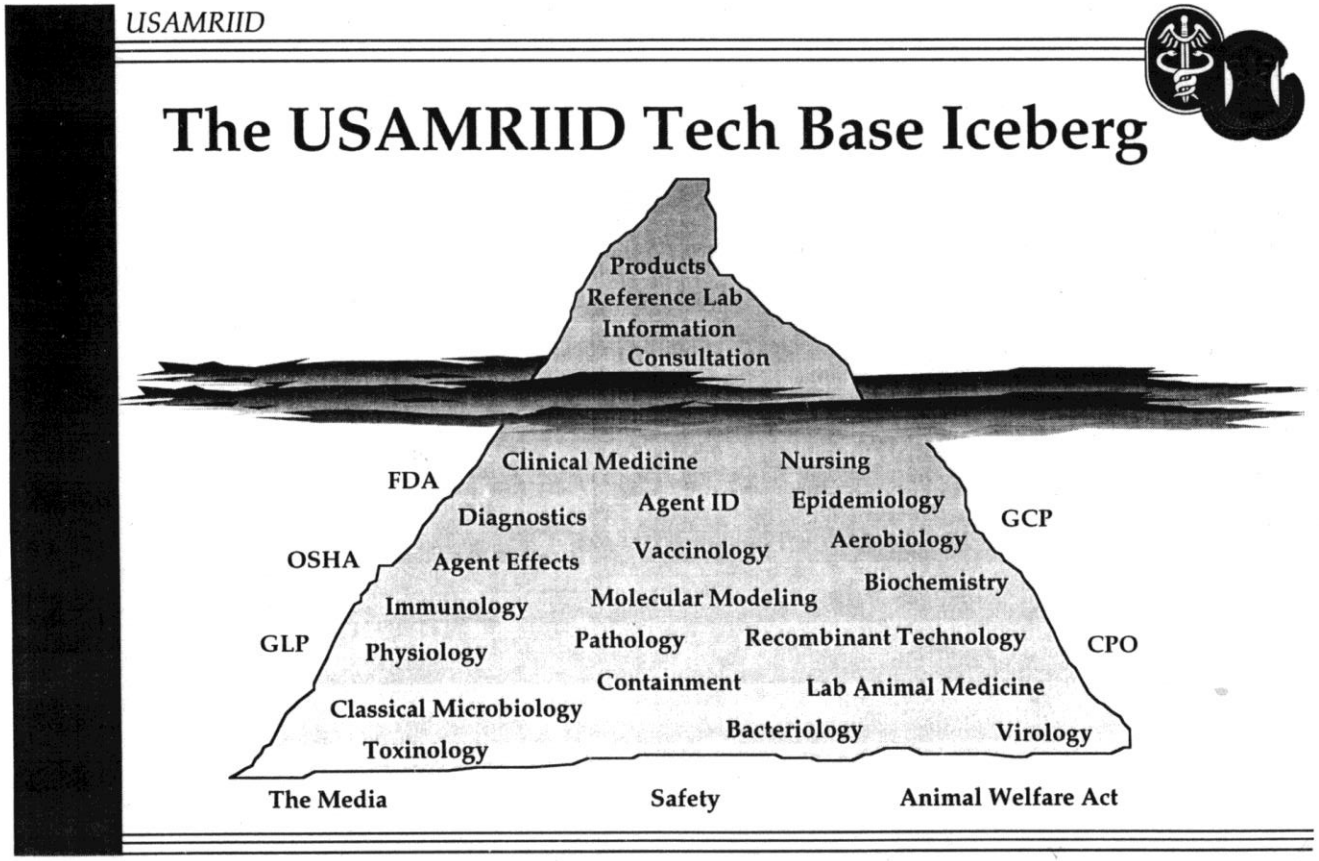
Accepting command
Of the Institute in 1995

Eventually assigned to USAMRIID

1987 – 1998

Simple Priorities!!

Leaders provide ”Beans and Bullets for the troops.”



The **important people** in the lab are back in the ‘trenches’ 1995

Subject Matter Experts

Our Nation's most important asset

- Understanding New Technologies
- Understanding Pathogenesis
- Understanding the Immunology
- Understanding the Pharmacology
- Understanding Advanced Development
- Understanding Public Education
- Understanding the Value of Trust
- Understanding Enlightened Leadership
- Understanding Laboratory Safety

Subject Matter Experts

Our Nation's most important asset

- Understanding New Technologies
- Understanding Pathogenesis
- Understanding the Immunology
- Understanding the Pharmacology
- Understanding Advanced Development
- Understanding Public Education
- Understanding Value of Trust
- Understanding Enlightened Leadership
- Understanding Laboratory Safety

A leader values and supports SMEs

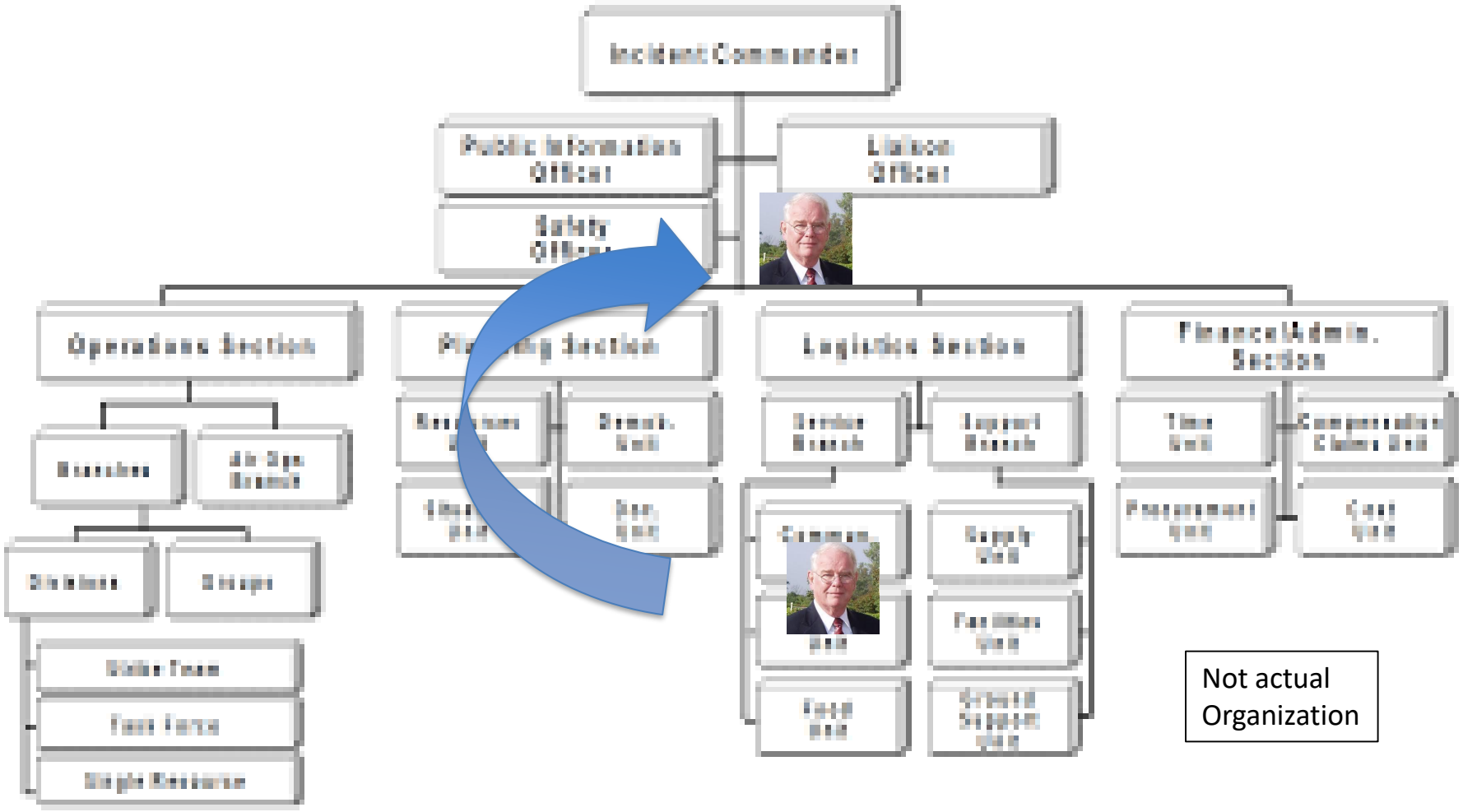
A leader is comfortable not being the 'smartest' person in the organization.

So I randomly picked someone as ‘a Biosafety Officer’

-Smart dresser
-Handsome
-Military bearing
-Good with people
-Seemed like a nice guy…

Let’s call him “Bob”

And I was JUST smart enough to know that <u>I really needed Bob’s help</u>!



1st, we assured Bob had access to the boss…

2nd, I let everyone know…

TOURS"R"US

After that my job was easy:

1. Trust Bob
2. Support Bob
3. Talk about Safety as a Priority
4. Let Bob do his work

Dave

Bob

After that my job was easy:

1. Trust Bob
2. Support Bob
3. Talk about Safety as a Priority
4. Let Bob do his work

And Bob built relationships of trust with scientists

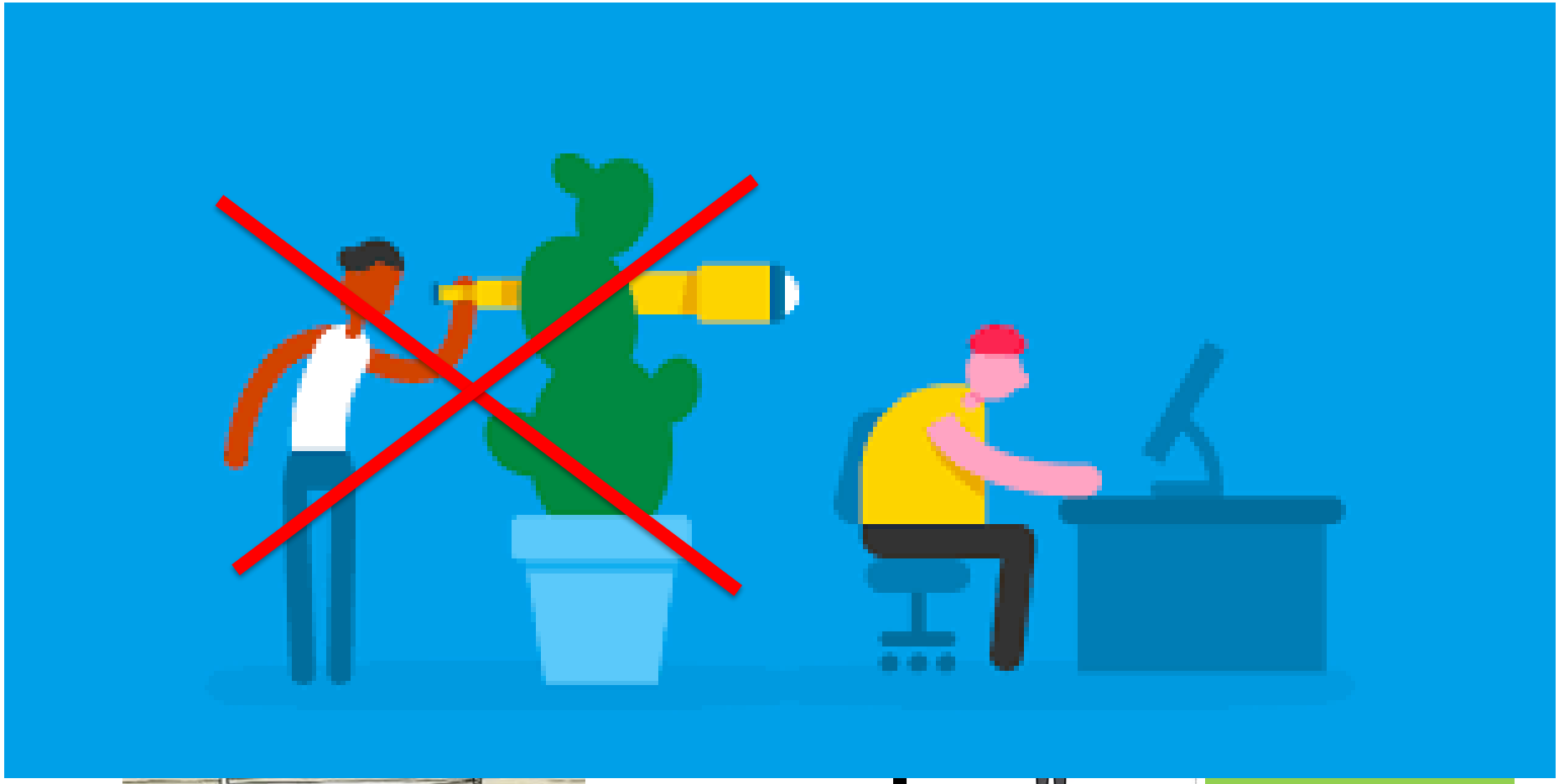
Bob was there for scientists. Always willing to help.

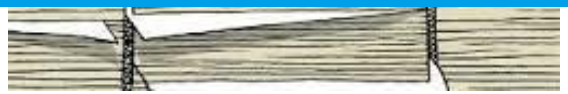
Bob protected scientists from excessive paperwork.

Happy Scientists

Safer
More Confident
More Productive

Bob was <u>not</u> a micromanager!

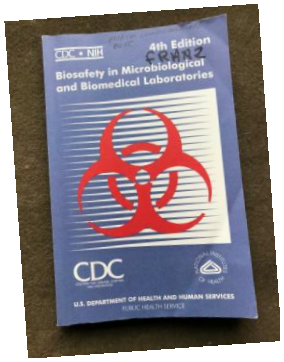




More Confident
More Productive

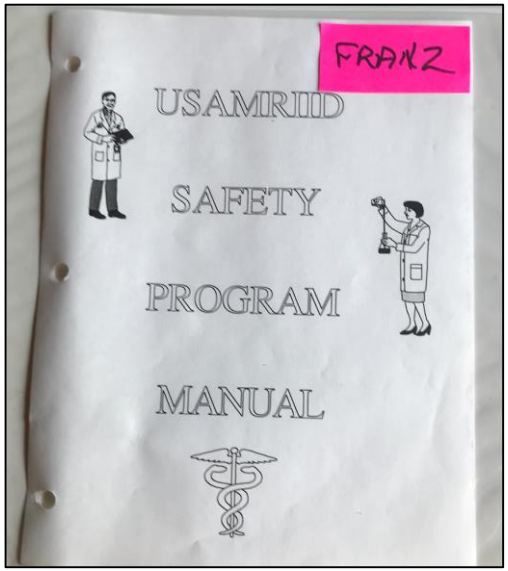
In addition to Bob, we had other advantaged in the ‘90s

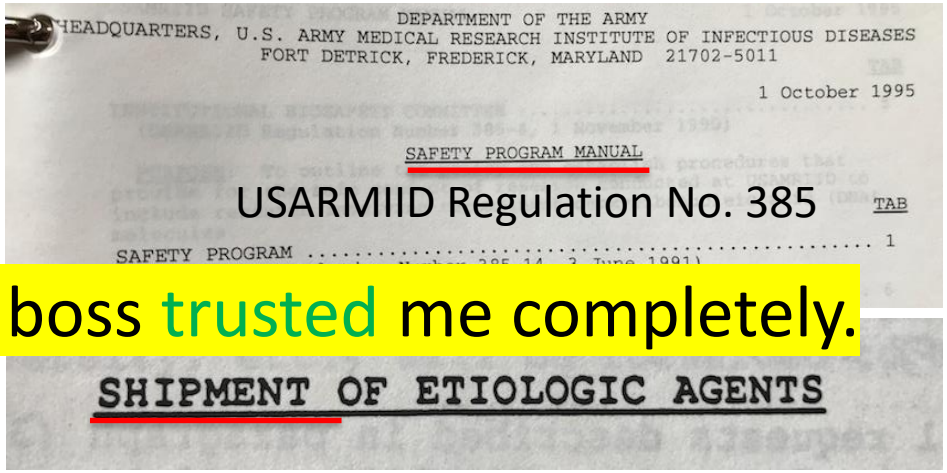
1.



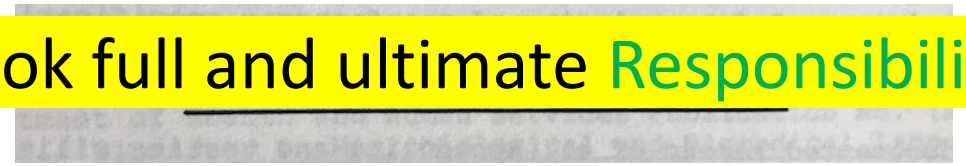
The ‘bible’ from CDC
‘Guidelines’

2.

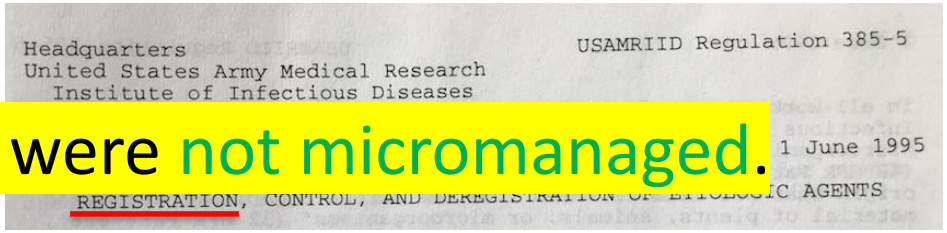




3. My boss trusted me completely.



4. I took full and ultimate Responsibility.



5. We were not micromanaged.

…and many other subsections to Reg #385

International
Health
& the Cold War

'Real
Threat Reduction'

The In-between Period

IHRs

Global Health
'Security'

CDC Safety Lapses

rH5N1

Anthrax/H5N1

Dugway Anthrax

H5, MERS, SARS

WH Pause

GoF Guidlines

Draft…

AR 50-1…Surety

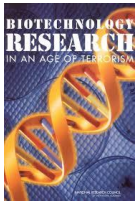
Select Agent Rule II

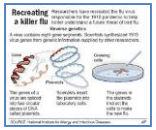
Select Agent Rule I

Lab Safety → Lab Security → Community Safety

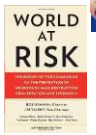
1996 1997 2001 2003 2004 2005 2008 2011 2012 2014 2015 2016

The Last
25 Years

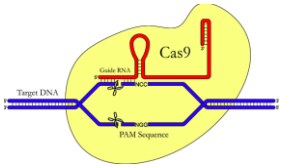


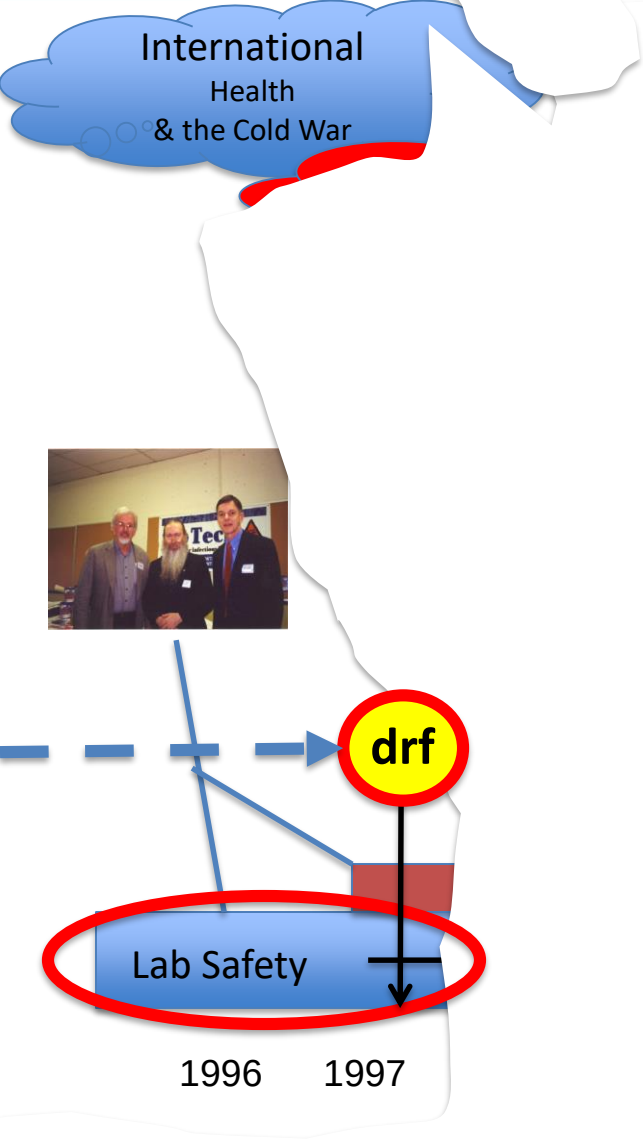


PDD-2



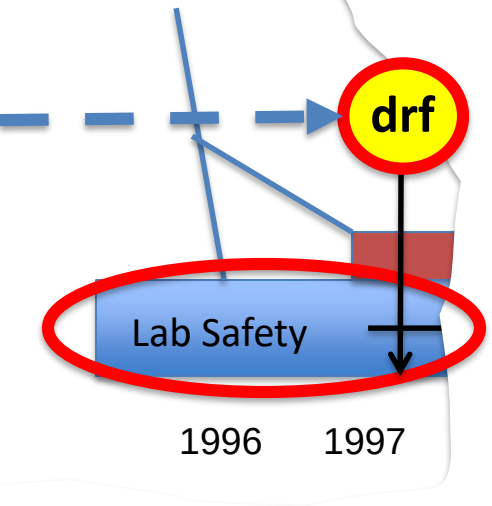
GHSA





I was watching from the Stands…

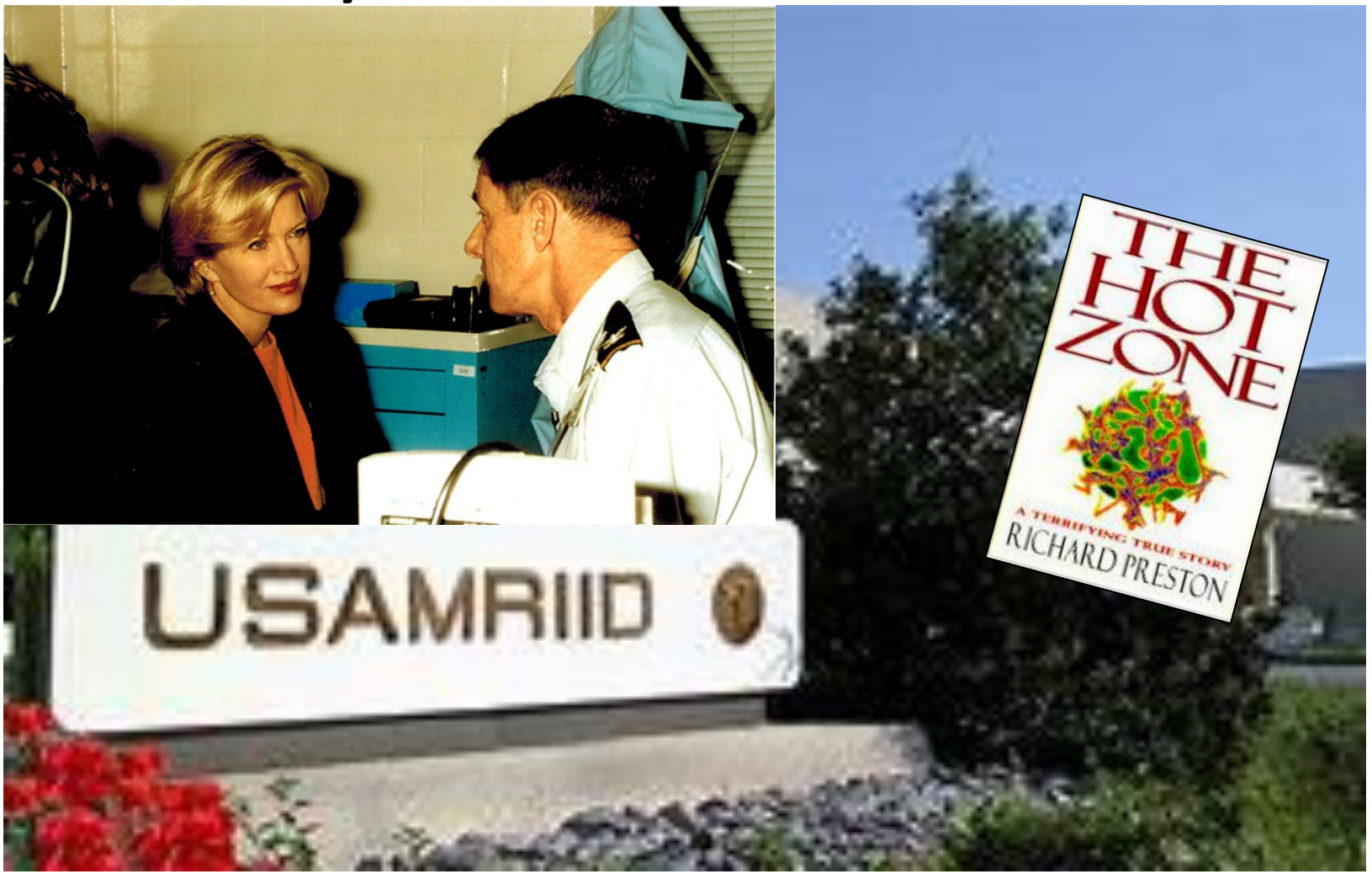
International
Health
& the Cold War



My six years in the front office…

-Pre-9/11
-Pre-10/4 (anthrax letters)
-'Containment' was RIID and the CDC
-A focus on Safety; "1st, 2nd and 3rd"
-We lived by safety 'guidelines' (BMBL)
-I was given authority & took responsibility
-Security was not a major issue
-Intact/clear Chains-of-Command
-A clearly defined mission
-Lots of *freedom* to work…even globally
-we operated as a community of "Trust"
-Without significant accident or incident

Everyone loved USAMRIID



The media showed up with a smile and softball questions.

Journal of Biosafety and Biosecurity 1 (2019) 98–99

Contents lists available at ScienceDirect

Journal of Biosafety and Biosecurity

March 2019

journal homepage: www.elsevier.com/locate/jobb

Editorial

Facilities, equipment and procedures: An historic glimpse at high-containment lab safety and security

Check for updates

Facilities
Equipment
Procedures

I trusted others re. Engineering

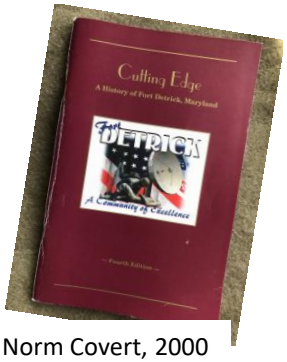
I was able to Influence the culture

About:
- People
- Training
- Attitudes
- Culture

Arnold G. Wedum, M.D.

Director of Industrial Health and Safety

- 1943 – 1958 Ft. Detrick occupational illnesses
  - '43-'45---55 illnesses/million person hours
  - 1958---11.45 illnesses/million person hours
- Major contribution to 1st (1984) BMBL
- 1958: Speaking to National Media Organization
- "…highly critical focus (of media) on Ft. Detrick while ignoring poor safety records of industry in that era."
- We are held to a higher standard



Norm Covert, 2000

USA TODAY

Biolabs In Your Backyard: More from our local investigations

Pentagon No. 2 to lead investigation into handling of anthrax

Latest military lab concerns involve plague bacteria, deadly viruses

CDC labs repeatedly faced secret sanctions for mishandling bioterror germs

Army metes out punishment in anthrax scandal

Hundreds of safety incidents with bioterror germs reported by secretive labs

Regulator hired to oversee safety at U.S. biodefense labs in wake of accidents

Army lashes general over anthrax debacle

USA TODAY NETWORK biolabs investigation wins national journalism prize

ils of

CDC to review oversight of bioterror labs after USA TODAY investigation

Alison Young , USA TODAY 6:25 p.m. EDT July 21, 2015

CDC failed to disclose lab incidents with bioterror pathogens to Congress

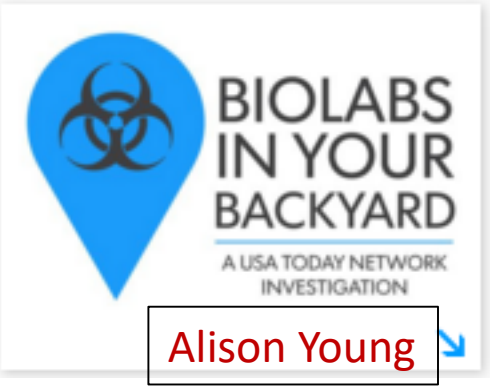
GAO finds more gaps in oversight of bioterror germs studied in U.S. labs

CDC lab shipped virus without following key safety steps

Senators, health experts demand action to address biolab accidents

Top U.S. lab regulator replaced in wake of incidents with bioterror pathogens

FedEx no longer to transport bioterror germs in wake of anthrax lab mishaps



Finding Balance in Reporting

Three (infectious) human deaths during US offensive biowarfare program pre-1969

Two anthrax, one Machupo Virus

One (non) 'Select Agent' Death in a US biodefense program in the last 40 years.

-Malcolm John Casadaban, Age 60
-University of Chicago
-*Yersinia pestis* (plague) researcher
-Attenuated strain with defective genes for iron uptake
-Dr. Casadaban had undiagnosed hereditary hemochromatosis

Ca. 687,000+ Hospital Acquired Infections yearly*
Ca. 72,000 deaths due to HAIs*
Ca. 250,000 deaths due to 'medical mistakes'

*CDC 2015

A principle:

Actions by a few impact the 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

GoF Work continues → …but debate goes on.
…but then CDC safety lapses…and the **White House pause**.
2014

"I'm sure there will be many changes to come," said biosafety consultant Debra Sharpe. "I just hope they will be well thought out and not knee-jerk fixes for political expediency."

Actions by a few impact the many

Government(s) react to surprises…

Larry-Wayne Harris 1996 → Select Agent Rule '97

Government Guidelines and Regulations are NECESSARY BUT NOT SUFFICIENT
If we lose the BALANCE we can do harm to this CRITICAL ENTERPRISE

Aug 2013

GoF Work continues → …but debate goes on.
…but then CDC safety lapses…and the **White House steps in**.

2014

"I'm sure there will be many changes to come," said biosafety consultant Debra Sharpe. "I just hope they will be well thought out and not knee-jerk fixes for political expediency."

USG Often Substitutes *Regulation* for *Leadership*

It's easier…
but does it make us safer
or more secure?

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 governm
even before Al Qaida–manned planes took down
World Trade Center towers. The anthrax letters gr
heightened that concern and extended it to our citize
well. The nation responded with billions of dollars:
defense research and development, medical counter

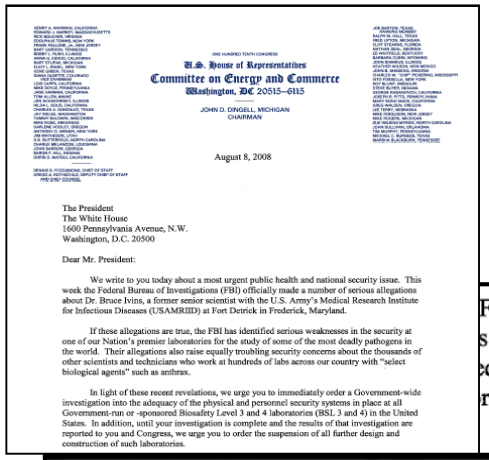
A culture of:

Responsibility
Accountability
Trust
Openness

A leader is:

Engaged
Caring
Accessible
Trustworthy

We've got to be REALLY careful with Regulations


U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

August 8, 2008

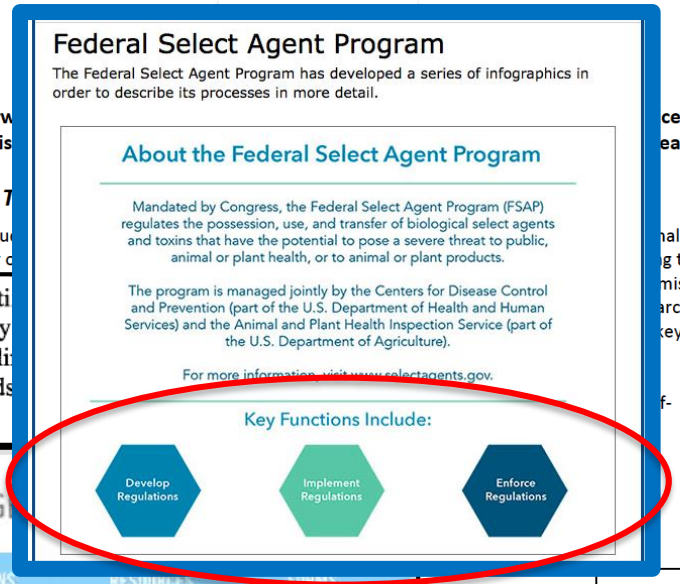
The President
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

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.


Federal Select Agent Program

The Federal Select Agent Program has developed a series of infographics in order to describe its processes in more detail.

About the Federal Select Agent Program

Mandated by Congress, the Federal Select Agent Program (FSAP) regulates the possession, use, and transfer of biological select agents and toxins that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products.

The program is managed jointly by the Centers for Disease Control and Prevention (part of the U.S. Department of Health and Human Services) and the Animal and Plant Health Inspection Service (part of the U.S. Department of Agriculture).

For more information, visit www.selectagents.gov.

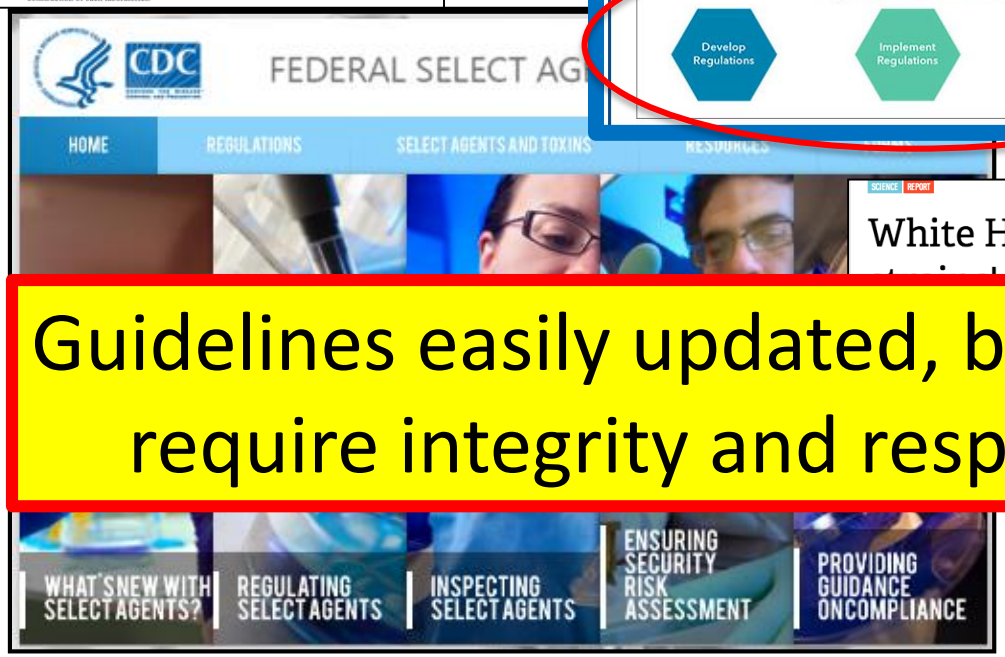
Key Functions Include:

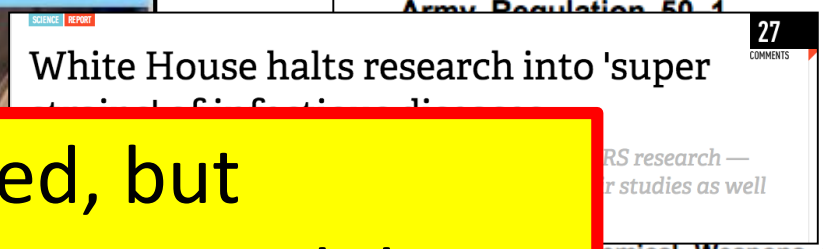
Develop Regulations

Implement Regulations

Enforce Regulations

Regulation is necessary, but there must be balance




SCIENCE REPORT

White House halts research into 'super

27 COMMENTS

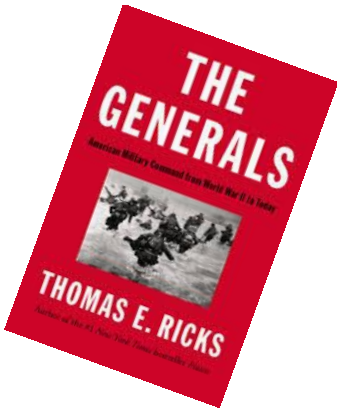
RS research —
r studies as well

Guidelines easily updated, but require integrity and responsibility….

emical Weapons and

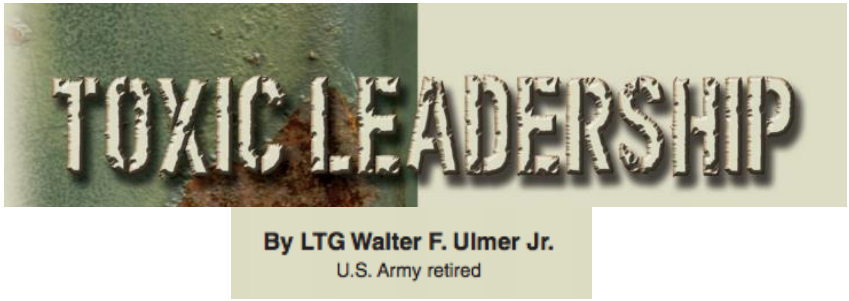
Biological Surety

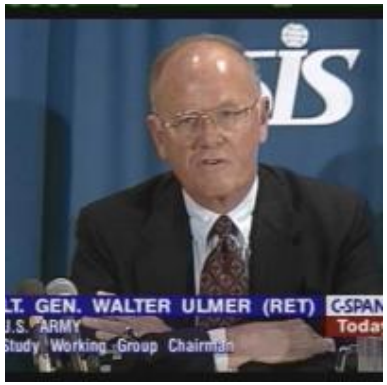
An inverse relationship
between
Trust and *Micromanagement*



"Not trusting people is an
invitation to organizational disaster."

LTG Walter F Ulmer Jr. (RET)





The failure, micromanagement and hyper-regulation loop

The Power of **Trust**

what they did. In practice, the only way I could manage the balance between assuming the risk for their actions and allowing them enough autonomy was through trust, and lots of it. It had taken four years

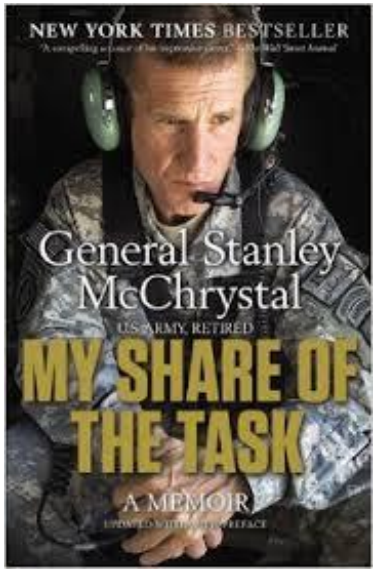
The **Responsibility** of a Senior Leader

CG Joint Special Operations Command Task Force (TF 714), Iraq

ators of what had occurred and how to move forward. But it was important the men understood I did not question the decisions they made once bullets started flying. I did not want them to feel that they could

The **Freedom** of the Operators

Commander, International Security Assistance Forces & US Forces, Afghanistan



The Power of Trust

what they did. In practice, the only way I could manage the balance between assuming the risk for their actions and allowing them enough autonomy was through trust, and lots of it. It had taken four years

ators of what had occurred and how to move forward. But it was important the men understood I did not question the decisions they made once bullets started flying. I did not want them to feel that they could

The **Responsibility** of a Senior Leader

The **Freedom** of the Operators

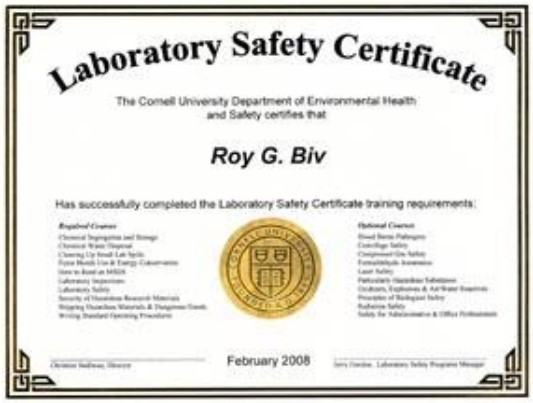
A Triad for Success

- -In War
- -In business
- -In Science
- -In Life

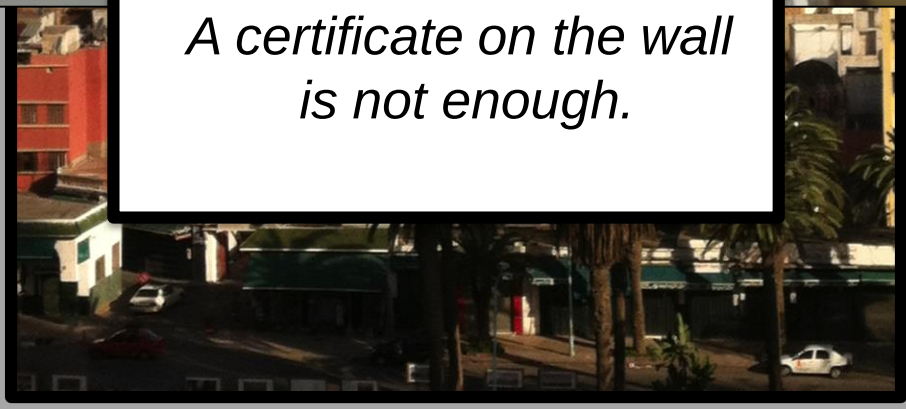
Leaders make Safety '*Part of the Soup*'.

Biosafety and biosecurity have 'got to be part of the soup…"'

Leaders make Safety '*Part of the Soup*'.



A certificate on the wall is not enough.

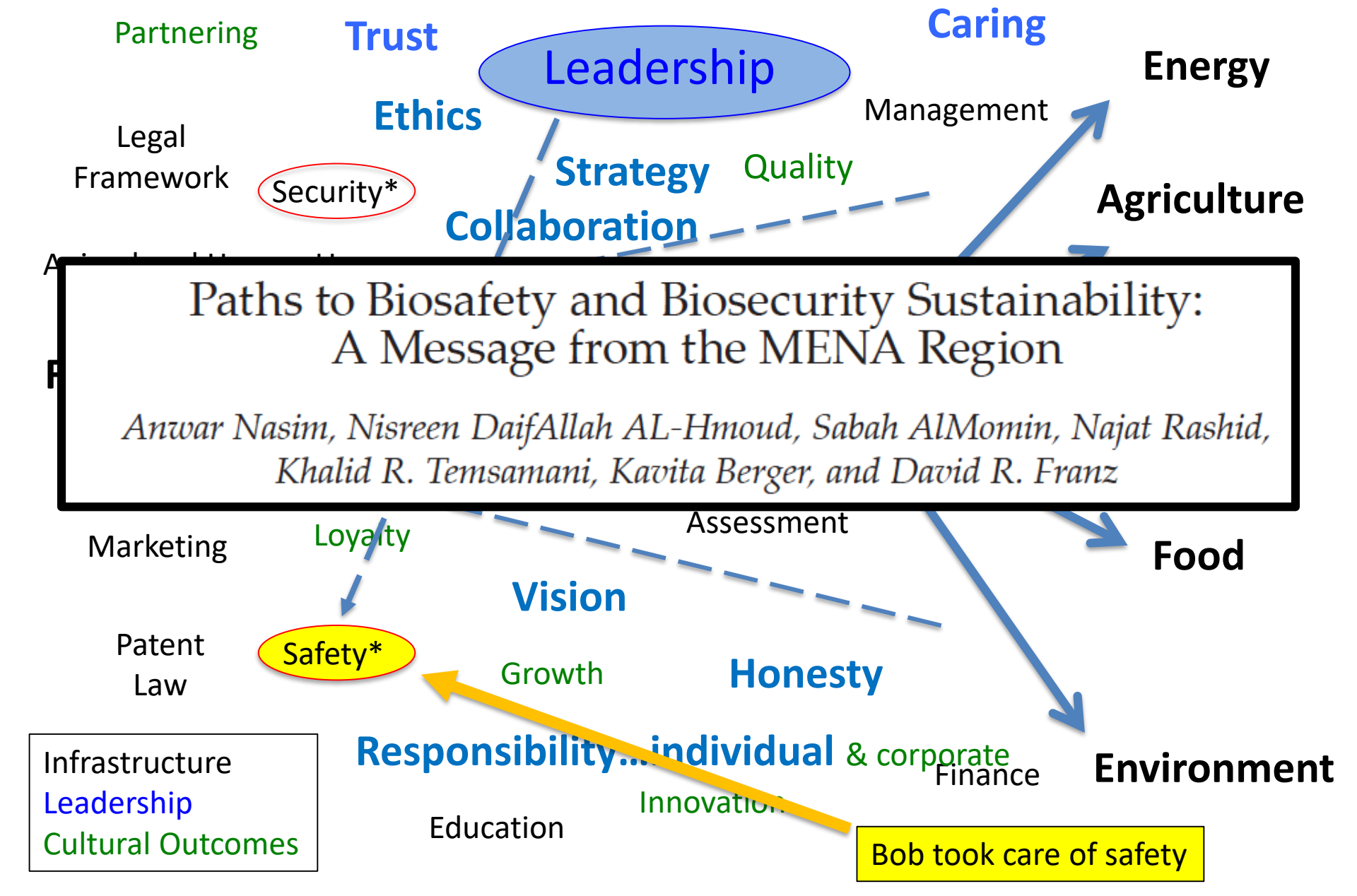


Biosafety and biosecurity have 'got to be part of the soup…"'

Safety is a Small, but ABSOLUTELY CRITICAL Piece

Safety is a Small, but ABSOLUTELY CRITICAL Piece

Safety is a Small, but ABSOLUTELY CRITICAL Piece



An Example from Industry

A crisis at

ALCOA

New Leadership
from the top down…

Alcoa was struggling...

Putting Worker Safety First

1987

Paul O'Neill

The new CEO's briefing for shareholders…

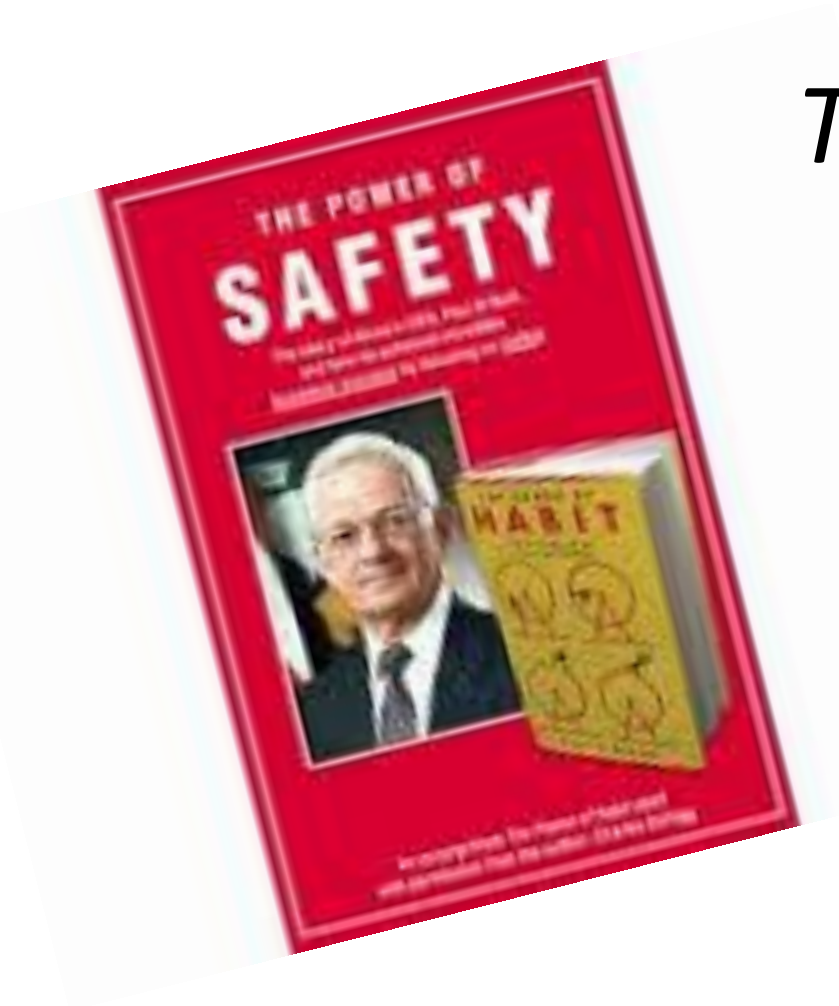
"I want to talk to you about worker safety."

Shareholders wondered why he had omitted to talk about improving profits. Alcoa was in a mess!

"I'm not certain you heard me. If you want to understand how Alcoa is doing, you need to look at our workplace safety figures. If we bring injury rates down, it won't be because of cheerleading or nonsense you sometimes hear from other CEOs. **It will be because individuals at this company have agreed to become part of something important**… They've devoted themselves to creating a habit of excellence. Safety will be an indicator that we're making progress in changing our habits across the entire institution. That's how we should be judged."

The company's market value increased from $3 billion in 1986 to $27.53 billion in 2000, while net income increased from $200 million to $1.484 billion.

14 years of Safety Focus
Company Value up 9x
Net Income up 7.5x



The Power of Safety

O'Neill found something everyone could agree on—worker safety—and harnessed that as a basis for change.

Pocket-size Safety Guidelines for Visitors

Hyderabad, India
2019

A Safety Focus in China

New Labs
New Journals
Safety & Lab Security
Ethics

Wuhan Inst of Virology

EDITORIAL

Network for safe and secure labs

The current outbreak of Ebola virus in the Democratic Republic of the Congo is a reminder that dangerous diseases exist in many corners of the world and that they can cause substantial human suffering and financial devastation locally and internationally. In response, institutions and nations are constructing maximum biocontainment laboratories (MCLs) to address these threats. MCLs operate at the highest level of biological containment to diagnose, perform research on, and validate cures for life-threatening diseases like Ebola. There are more than 50 MCLs that are operational, under construction, or in advanced planning around the world. The global proliferation of these facilities raises questions about how to ensure their safe and secure operations while enhancing their contributions to science and global health. One solution is to establish an MCL network that enables the sharing of best practices, collaboration, transparency, and exchange of specimens and technology.

A multitude of challenges are associated with MCLs. Even at the idea stage, a serious issue is the objection of local communities to the construction of an MCL in their neighborhood. Several MCL operations were delayed or never realized because of public concern. Gaining community trust and support is therefore vital to planning and operating MCLs, so a network of such labs would be valuable for sharing experiences and providing guidance in these situations.

Besides the millions of dollars that it costs to build a modern MCL, there are annual operations—maintenance, utility, and security—that can amount to 5 to 10% of the construction costs. Moreover, there is a need for experienced guidance and qualified oversight to ensure that an MCL is built and operated safely and securely. Yet, few such resources exist, and available training opportunities are inconsistent and often costly. An MCL network could fill the personnel pipeline more efficiently by connecting experienced personnel and professional societies to develop standards for globally accepted training and create mentoring opportunities.

Importantly, MCLs must share a culture of responsibility. These labs handle the world's most dangerous pathogens known, and there must be safeguards to prevent theft or misuse. At the same time, security must be balanced against mechanisms that support collaboration, including specimen sharing. Again, by working together through an MCL network to develop standards and guidelines, a culture of responsibility could be fortified.

We direct a newly constructed MCL in Wuhan, China (Z.Y.), and an established MCL in the United States (J.W.L.), in Galveston, Texas. In preparation for the opening of the new China MCL, we engaged in short- and long-term personnel exchanges focused on biosafety training, building operations and maintenance, and collaborative scientific investigations in biocontainment. We succeeded in transferring proven best practices to the new Wuhan facility. Both labs recently signed formal cooperative agreements that will streamline future scientific and operational collaborations on dangerous pathogens, although funding for research and the logistics of exchanging specimens are challenges that we have yet to solve. Ours is a promising first step in MCL partnerships; however, wider national, regional, and international cooperation is needed. We benefited from meetings jointly sponsored by the U.S. National Academy of Sciences and the Chinese National Academy of Sciences, and from World Health Organization initiatives, but stakeholders are not limited to human and animal health. Our partnership still requires input from foundations and governmental agencies that are involved in security, commerce, and transportation, as well as from the commercial sector.

Not every country requires an MCL, but every country can benefit from the collaborative operation of these labs. We encourage existing MCLs to convene a forum that brings together all stakeholders to conceive of an MCL network so that these critical labs can tackle urgent global health needs safely, securely, and productively.

–James W. Le Duc and Zhiming Yuan

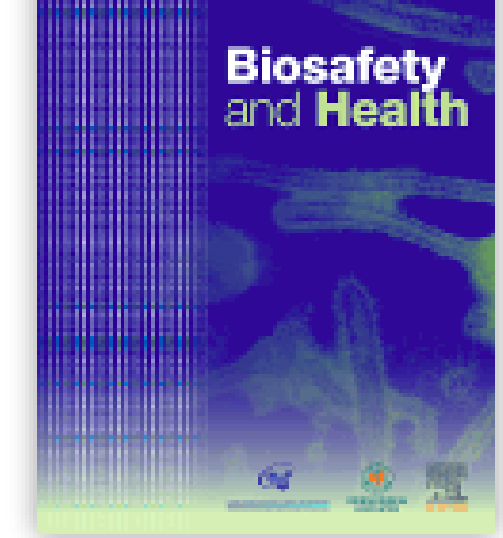
A training session in Galveston National Laboratory.

"These labs handle the world's most dangerous pathogens..."

James W. Le Duc *is the director of the Galveston National Laboratory and a professor in the Department of Microbiology and Immunology at the University of Texas Medical Branch, Galveston, Texas, USA. jwleduc@utmb.edu*

Zhiming Yuan *is the director of the Wuhan National Biosafety Laboratory of the Chinese Academy of Sciences and a professor at the Wuhan Institute of Virology, Wuhan, China. yzm@wh.iov.cn*

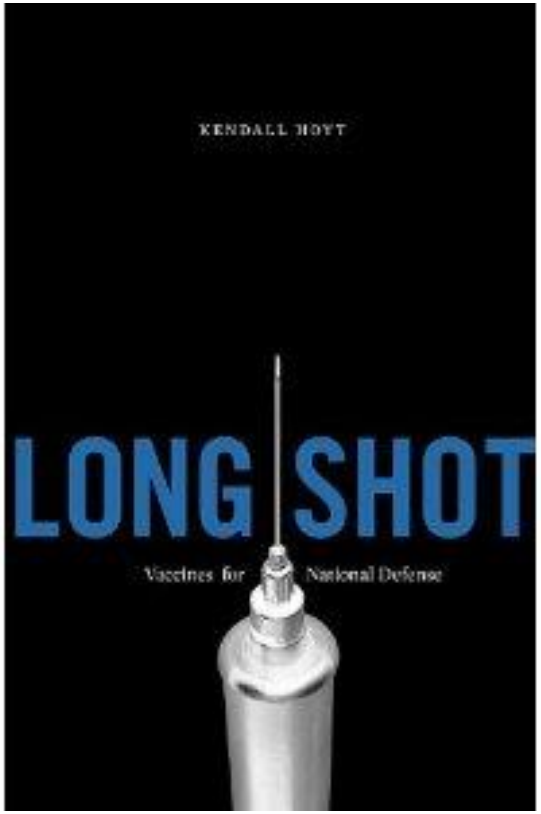
10.1126/science.aav7120



China CDC

ELSEVIER

Proposing a Network of BSL-4s



productivity

A example from a national enterprise

Long Shot:

Vaccines for National Defense

Kendall Hoyt
Dartmouth

Success in producing vaccines:

1. A 'champion'

2. Communities of Trust

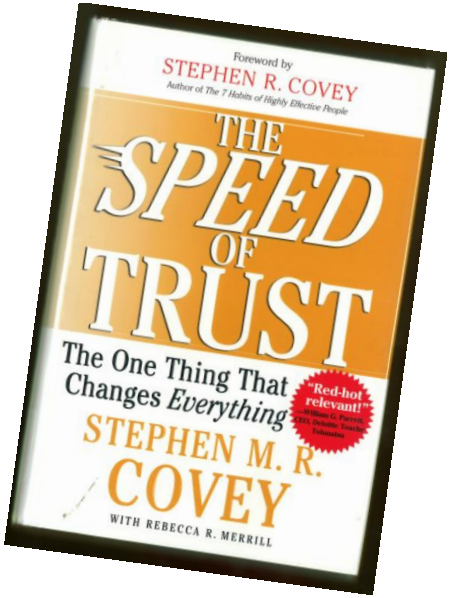
The *Value* of Trust

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

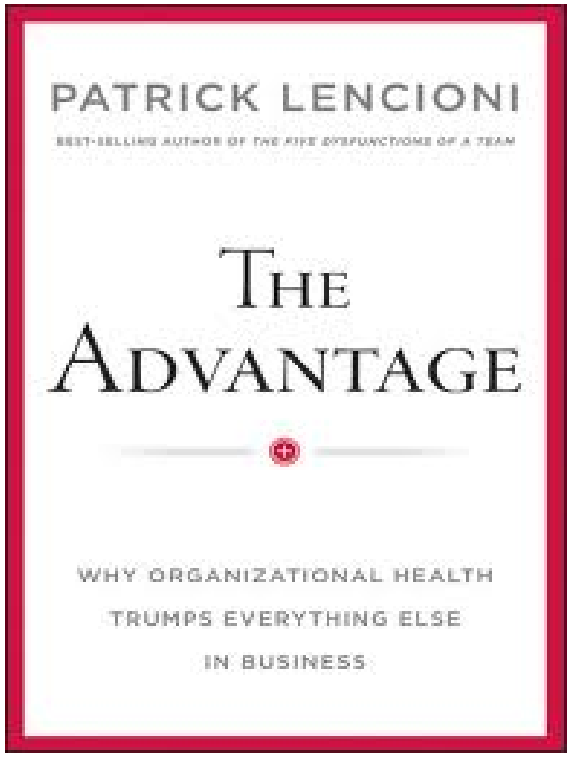


1-Leadership can make this much difference!

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?

Healthy Organizations



An organization must be:

Smart *and* **Healthy**

- **Strategy**
- **Marketing**
- **Finance**
- **Technology**

- **Minimal Politics**
- **Minimal Confusion**
- **High Morale**
- **High Productivity**
- **Low Turnover**

"It's getting ever more difficult to have a competitive advantage based on knowledge or technologies…"

And back in our world,

Leaders influence culture…

Enlightened Leadership	Regulatory Oversight
Lead with Science	***Lead with Security***
Quality Research	Guns, Gates and Guards
Emphasis on Safety	Background Checks
Vision	Psychological Evaluation
Education	Lists & Pathogen Control
Responsibility	*A Culture of Mistrust?*
Accountability	
Honesty	
Transparency	
Ethics	
A Culture of Trust	

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

at all levels of an organization

Leaders influence culture…

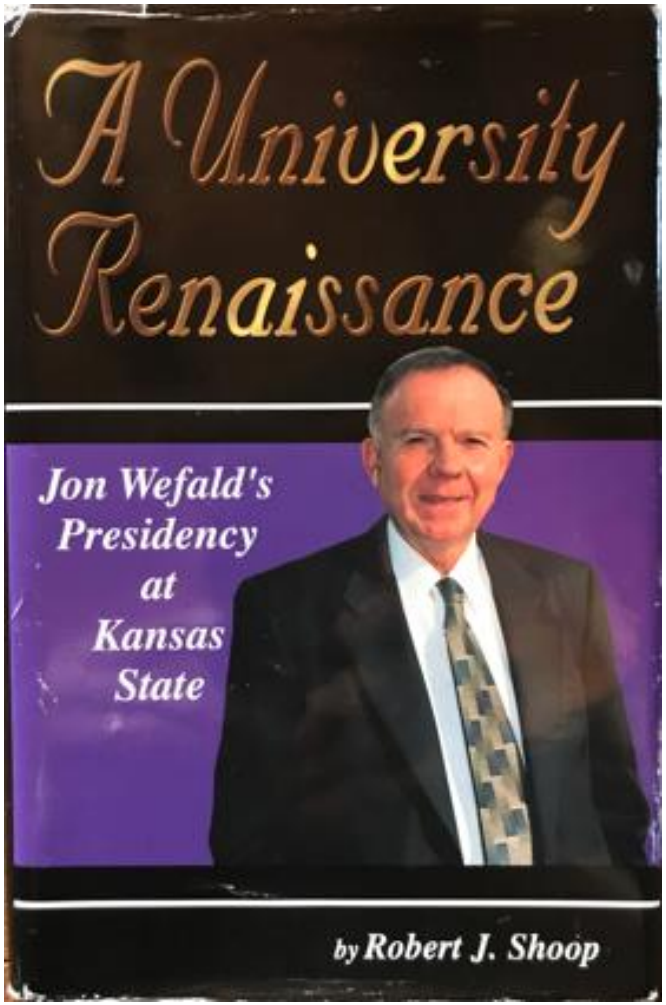
Enlightened Leadership	Regulatory Oversight
Le	
Qu	ds
En	
Vis	on
Ed	ol
Re	
Accountability	
Honesty	
Transparency	
Ethics	
A Culture of Trust	

A healthy culture is:

- ***safer***,
- ***more secure***
- **AND *more productive***

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

Characteristics of Excellent Leadership



1. Have a **Vision** and Develop a Game Plan
2. **Communicate** your Vision
3. Hire **Excellent People**
   and **Delegate** Authority and Responsibility
4. **Make Decisions** and Take Risks
5. **Admit Mistakes** and Apologize When Necessary
6. Be **Trustworthy** and **Care** about Others
7. **Never Give Up**
8. Have a **Sense of Humor**

9. Be **Technically Competent**

Happy, Safe, Productive Teams