



# SAFEGUARDING THE LIFE SCIENCES AND THE FUTURE:

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## ROLES AND RESPONSIBILITIES OF THE SCIENCE AND SECURITY COMMUNITIES

Edward H. You  
Supervisory Special Agent  
Federal Bureau of Investigation  
Weapons of Mass Destruction Directorate  
Biological Countermeasures Unit

October 8, 2014



# What the FBI is not....





# FBI WMD Directorate

- In 2006, FBI consolidated its investigation, intelligence, and prevention efforts into one HQ Division, the WMD Directorate → Centralized structure affords a more **cohesive and coordinated approach** to incidents involving WMD; **focus on prevention.**



FBI Headquarters (Washington, DC)

- FBI WMD Directorate actively engaged in building capacities by developing national-level policy, guidance, and countermeasures to prevent, detect, disrupt, and respond to WMD.
- WMD Directorate taps into the tactical and technical expertise of other FBI operational and support divisions, embedding personnel in these components as needed and coordinating investigations and initiatives.





# United States Federal Laws

## U.S. Criminal Code, Title 18 (Crimes)

### Biological crimes

18 USC 175(a)	Crime to knowingly possess a biological agent, toxin, or delivery system for use as weapon → establishes BWC violations as crime
18 USC 175(b)	Crime to knowingly possess a biological agent, toxin, or delivery system if not for peaceful research purposes
18 USC 175b	Crime to knowingly possess select agent, regardless of intent, if not registered with Select Agent Program
18 USC 175c	Crime to produce, engineer, or synthesize smallpox

### WMD crimes

18 USC 806	Enhances ability to seize assets of those with WMD intent
18 USC 842	Crime to teach or demonstrate the making or use of a WMD
18 USC 2332a	Crime to use (or conspire, threaten, or attempt to use) a WMD

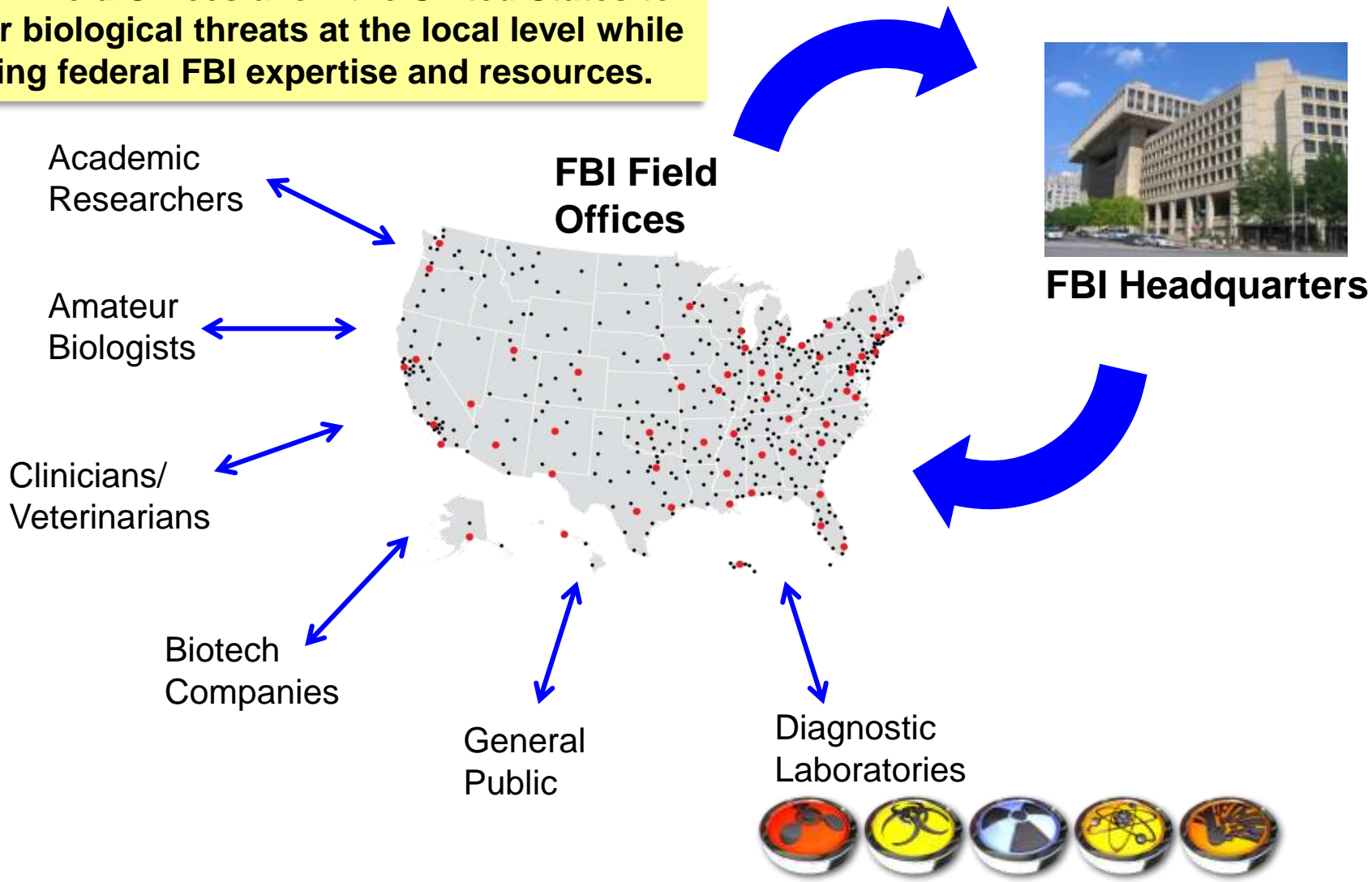






# FBI WMD Coordinators

The FBI Field Offices allow the United States to counter biological threats at the local level while utilizing federal FBI expertise and resources.





# WMD Coordinator Responsibilities

- **Conduct outreach** with federal, state, and local stakeholders (including industry, academia, and scientific communities)
  - Conduct biosecurity outreach to universities to promote a culture of security
  - Develop partnerships with industry leaders
- **Implement countermeasures** to detect and deter biological threats
  - Conduct assessments within area of responsibility; identify risks and vulnerabilities
  - Promote biosecurity guidelines (ex. HHS Screening Guidance for Synthetic DNA Providers)
- **Investigate bio crimes and acts of bioterrorism**
  - Coordinate with public health Laboratory Response Network
- **Provide training** to both FBI and public community
  - Conduct Joint Criminal-Epidemiological Investigation Training
  - Conduct exercises with local law enforcement and first responders





# ***Looking Ahead***



# **The Challenge**





Dual Use?

Proper Handling of  
Materials?



Physical Security?

Risk Assessment?







# Biosafety/Biosecurity Stand Down

004392

THE WHITE HOUSE  
WASHINGTON

August 18, 2014

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MEMORANDUM FOR DEPUTY SECRETARY OF STATE  
 DEPUTY SECRETARY OF DEFENSE  
 DEPUTY ATTORNEY GENERAL  
 DEPUTY SECRETARY OF AGRICULTURE  
 DEPUTY SECRETARY OF TRANSPORTATION  
 DEPUTY SECRETARY OF COMMERCE  
 DEPUTY SECRETARY OF HEALTH AND HUMAN SERVICES  
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 DEPUTY SECRETARY OF VETERANS AFFAIRS  
 DEPUTY SECRETARY OF HOMELAND SECURITY  
 DEPUTY ADMINISTRATOR OF THE ENVIRONMENTAL  
 PROTECTION AGENCY  
 PRINCIPAL DEPUTY DIRECTOR OF NATIONAL INTELLIGENCE  
 DEPUTY DIRECTOR OF THE NATIONAL SCIENCE FOUNDATION  
 DEPUTY DIRECTOR OF INTERIOR  
 ASSISTANT ADMINISTRATOR OF THE UNITED STATES AGENCY  
 FOR INTERNATIONAL DEVELOPMENT  
 VICE CHAIRMAN OF THE JOINT CHIEFS OF STAFF  
 DEPUTY DIRECTOR OF THE FEDERAL BUREAU OF  
 INVESTIGATION

## Ensuring Biosafety and Biosecurity in U.S. Laboratories

Subscribe

Posted by Lisa Monaco and Dr. John Holdren on August 28, 2014 at 10:31 AM EDT

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Nearly every day, the American public is reminded of the critical role that life-sciences researchers and public health workers play in mitigating the threat of infectious diseases. Whether these diseases arise naturally in the United States or in other parts of the world, as is the case with the current unprecedented outbreak of Ebola in West Africa, or are deliberately released to cause harm here at home, as occurred with the anthrax attacks in 2001, U.S. government scientists are charged with confronting threats to the health and well-being of the citizens, economy, and security of the United States. Working with pathogens in the laboratory is vital to ensuring that the United States and the global community possess a robust set of tools—such as drugs, diagnostics, and vaccines—to counter the ever evolving threat of infectious diseases. That's why, when we learned earlier this summer of several incidents within the Nation's premier laboratories of the Centers for Disease Control and Prevention and on the campus of the National Institutes of Health, we immediately sought meaningful measures to address the underlying causes and reduce the risk that such incidents would occur again in the future.

SUBJECT: ENHANCING BIOSAFETY AND BIOSECURITY IN THE UNITED STATES

It is essential for the United States Government to conduct life sciences research to prevent, detect, and respond to infectious disease threats posed by natural events or deliberate acts of bioterrorism. It is also the government's responsibility to ensure that infectious disease research in the United States is conducted safely and securely. The United States Government has acted swiftly to address three recent U.S. biosafety and biosecurity incidents. To improve U.S. preparedness for such threats and incidents, it is imperative that infectious disease researchers: (1) conduct a comprehensive review of current biosafety and biosecurity protocols and procedures to ensure they are adequate and appropriate for today's infectious disease research; (2) inventory and document their culture collections; and (3) increase attentiveness throughout the research community

<http://www.whitehouse.gov/blog/2014/08/28/ensuring-biosafety-and-biosecurity-us-laboratories>





# National Science Advisory Board on Biosecurity

## Definition of Dual Use Research of Concern

Research that, **based on current understanding**, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agriculture, plants, animals, the environment, or materiel





# US Government Issues Policy on Oversight of Life Science Dual Use Research of Concern

## 1) Agents and toxins:

- a) Avian influenza virus (highly pathogenic)
- b) *Bacillus anthracis*
- c) Botulinum neurotoxin
- d) *Burkholderia mallei*
- e) *Burkholderia pseudomallei*
- f) Ebola virus
- g) Foot-and-mouth disease virus
- h) *Francisella tularensis*
- i) Marburg virus
- j) Reconstructed 1918 Influenza virus
- k) Rinderpest virus
- l) Toxin-producing strains of *Clostridium botulinum*
- m) Variola major virus
- n) Variola minor virus
- o) *Yersinia pestis*

## 2) Categories of experiments:

- a) Enhances the harmful consequences of the agent or toxin;
- b) Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification;
- c) Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies;
- d) Increases the stability, transmissibility, or the ability to disseminate the agent or toxin;
- e) Alters the host range or tropism of the agent or toxin;
- f) Enhances the susceptibility of a host population to the agent or toxin;
- g) Generates or reconstitutes an eradicated or extinct agent or toxin listed in Section (III.1) above.







# Dual Use Challenge

## Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox

RONALD J. JACKSON,<sup>1,2\*</sup> ALISTAIR J. RAMSAY,<sup>2†</sup> CARINA D. CHRISTENSEN,<sup>2</sup> SANDRA BEATON,<sup>1</sup>  
DIANA F. HALL,<sup>1‡</sup> AND IAN A. RAMSHAW<sup>2</sup>

*Pest Animal Control Cooperative Research Centre, CSIRO Sustainable Ecosystems,<sup>1</sup> and Division of Immunology and Cell Biology, John Curtin School of Medical Research, Australian National University,<sup>2</sup> Canberra, Australia*

Received 25 July 2000/Accepted 13 November 2000

Genetic resistance to clinical mousepox (ectromelia virus) varies among inbred laboratory mice and is characterized by an effective natural killer (NK) response and the early onset of a strong CD8<sup>+</sup> cytotoxic T-lymphocyte (CTL) response in resistant mice. We have investigated the influence of virus-expressed mouse interleukin-4 (IL-4) on the cell-mediated response during infection. It was observed that expression of IL-4 by a thymidine kinase-positive ectromelia virus suppressed cytolytic responses of NK and CTL and the expression of gamma interferon by the latter. Genetically resistant mice infected with the IL-4-expressing virus developed symptoms of acute mousepox accompanied by high mortality, similar to the disease seen when genetically sensitive mice are infected with the virulent Moscow strain. Strikingly, infection of recently immunized genetically resistant mice with the virus expressing IL-4 also resulted in significant mortality due to fulminant mousepox. These data therefore suggest that virus-encoded IL-4 not only suppresses primary antiviral cell-mediated immune responses but also can inhibit the expression of immune memory responses.







# Problem: Australian Mouse Plague





# CONSPIRACY PLANET

THE ALTERNATIVE NEWS & HISTORY NETWORK

*There's No "Theory" in Criminal Conspiracy*

Tuesday, December 6, 2011

## Mad Scientists Create H5N1 GM BioTerrorism Virus

by MARTIN ENSERINK (SCIENCE INSIDER)

(November 23, 2011) Locked up in the bowels of the medical faculty building here and accessible to only a handful of scientists lies a man-made flu virus that could change world history if it were ever set free.

The virus is an H5N1 avian influenza strain that has been genetically altered and is now easily transmissible between ferrets, the animals that most closely mimic the human response to flu.

Scientists believe it's likely that the pathogen, if it emerged in nature or were released, would trigger an influenza pandemic, quite possibly with many millions of deaths.





# SYNTHETIC BIOLOGY

## Life Technologies Introduces the Benchtop Ion Proton™ Sequencer

**Designed to Decode a Human Genome in  
One Day for \$1,000**



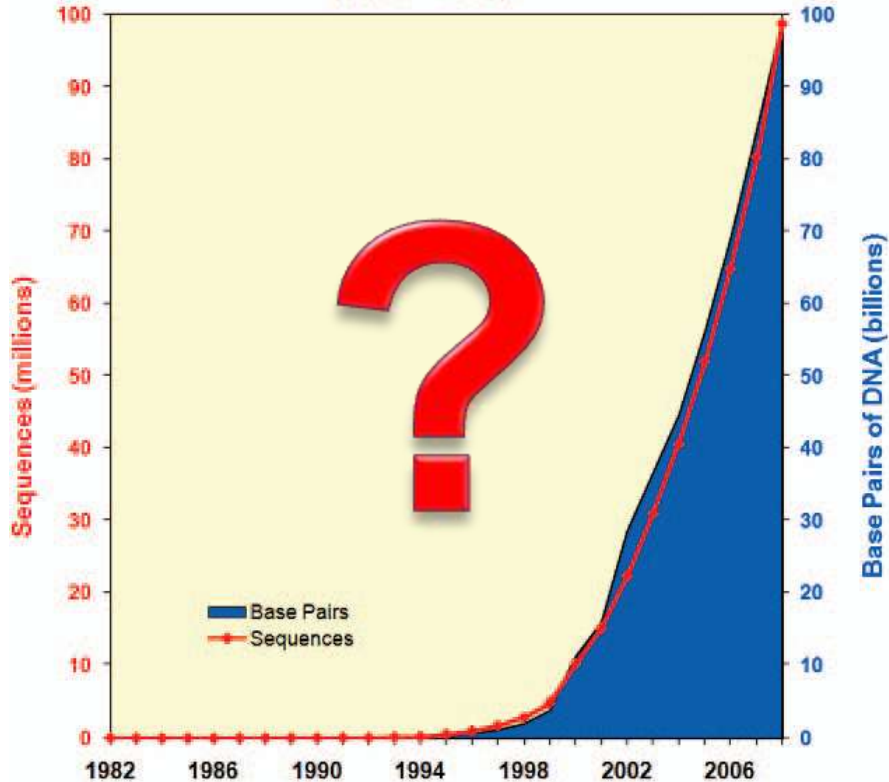
SAN FRANCISCO, Jan. 10, 2012 /PRNewswire





# SYNTHETIC BIOLOGY

## Growth of GenBank (1982 - 2008)



- New pathogens
- New virulence factors

Growth of the publicly available gene-sequence database from its inception through 2008

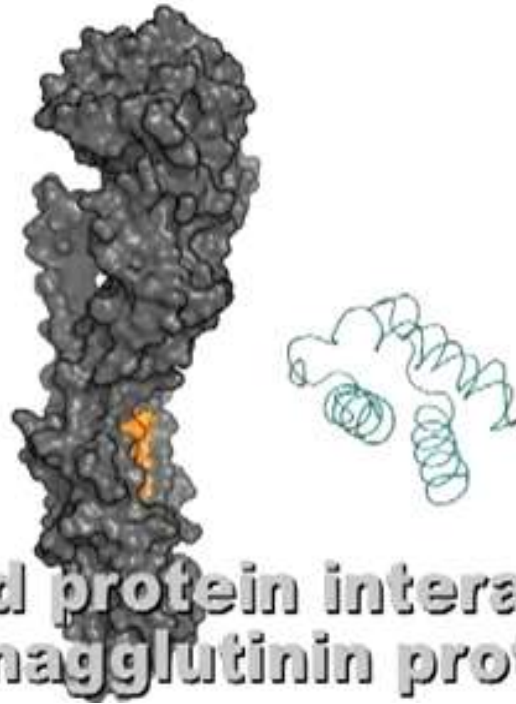
<http://www.ncbi.nlm.nih.gov/Genbank/genbankstats.htm>





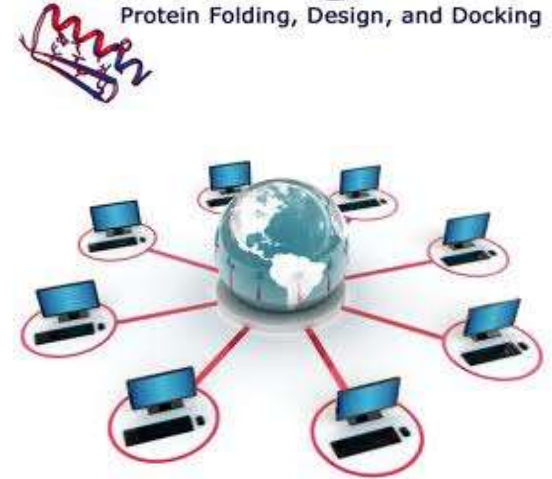


# De Novo Protein Design



Designed protein interacts  
with hemagglutinin protein

**Rosetta@home**  
Protein Folding, Design, and Docking



**Computational Design of Proteins Targeting the Conserved Stem  
Region of Influenza Hemagglutinin**

Sarel J. Fleishman, *et al.*  
*Science* **332**. 816 (2011):





# DNA origami gets into the fold of drug delivery

Using DNA building blocks that can be manipulated into many complex shapes, scientists are hoping to develop 'nanorobots' that could potentially deliver drugs to target cancer cells

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Ed Yong

theguardian.com, Tuesday 15 May 2012 00.05 BST



Similar to the ancient art of paper folding (above), DNA origami involves folding the famous "molecules of life" into intricate contortions to build sculptures just nanometres in size. Photograph: Ocean/Corbis





# Harvard scientists to make LSD factory from microbes

Simple microbes such as those found in baker's yeast can be modified to make LSD, suggests research by Harvard scientists



Students on a bread making course. But did the tutor remember to warn them about the other things that yeast turn into? Photograph: Fabio De Paola

Ian Sample Tuesday 21  
June 2011 15.55 BST  
[guardian.co.uk](http://guardian.co.uk)



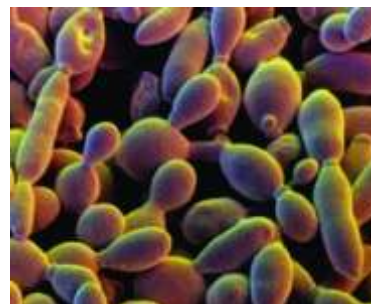


The  
Economist

## Biotechnology A new opium pipe

Aug 30th 2014

# Narcotic drugs could soon be manufactured by yeast



Though this prototype yeast was not particularly efficient, some further tweaking converted it into a veritable drug factory—capable of cooking up 131mg of opioids (the equivalent of about 26 medical doses of diamorphine) per litre of culture over a four-day manufacturing cycle.

<http://www.economist.com/news/science-and-technology/21614093-narcotic-drugs-could-soon-be-manufactured-yeast-new-opium-pipe>







# ***Looking Ahead***



## **The Threat**





# CDC Smallpox and Anthrax Mishaps Signal Other Potential Dangers

By Susan Scutti

Filed: 7/19/14 at 3:19 PM

**Newsweek**



*U.S. Centers for Disease Control and Prevention (CDC) Director Tom Frieden testifies before the House Committee on Energy and Commerce Oversight and Investigations Subcommittee hearing on "Review of CDC anthrax Lab Incident" on Capitol Hill in Washington July 16, 2014. REUTERS/Kevin Lamarque*

Could a **theft of secrets (or substances)** take place at one of the Centers for Disease Control and Prevention (CDC) federal laboratories handling select agents—the killer biological pathogens, such as anthrax and smallpox, used in biowarfare?





# *Bacillus anthracis* Bioterrorism Incident, Kameido, Tokyo, 1993



What went wrong when the Aum Shinrikyo cult attempted to kill thousands of people by spraying steady mists of anthrax from a rooftop and a vented van in Japan in 1993.



The use of an attenuated *B. anthracis* strain, low spore concentrations, ineffective dispersal, a clogged spray device, and inactivation of the spores by sunlight are all likely contributing factors to the lack of human cases.

[http://wwwnc.cdc.gov/eid/article/10/1/03-0238\\_article](http://wwwnc.cdc.gov/eid/article/10/1/03-0238_article)





# Edward Bachner

## ( Intent to Use Bio as Weapon)

**(Illinois, 2008)** – Posed as doctor in attempt to purchase 98 mg of tetrodotoxin (TTX) online from a New Jersey chemical company so to murder his wife and collect \$20M in life insurance.

- Made four separate TTX orders; an employee became concerned at quantity Bachner ordered (total of 98 mg) and alerted FBI.
- Intended to use TTX for use as a weapon (18 USC 175 part a)
- Did not possess TTX for peaceful purposes (18 USC 175 part b)
- TTX is a US Select Agent (100mg and above); Bachner was not registered with US Select Agent Program (18 USC 175b) and ordered a total of 98 mg of TTX over four separate orders.
- Sentenced to 7 years and 8 months in federal prison (wire fraud and possession of TTX with intent to use as a weapon).







# Larry Wayne Harris



- Former neo-Nazi sympathizer and trained microbiologist
- Purchased three vials of plague bacteria (*Yersinia pestis*) from the American Type Culture Collection
- Pled guilty to wire fraud- most serious charge possible at the time

**Motivation for the establishment of the Select Agent Program – control access, possession, and transfer**





# Al-Qaeda seeks WMD, US unprepared: reports

“Washington no longer has the luxury of a slow learning curve, when we know Al-Qaeda is interested in *bioweapons*.”

-Former Senator Bob Graham, Chair of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism.





# Aafia Siddiqui



Khalid Sheikh Mohammed

## **Aafia Siddiqui** (*Group: Al Qaeda*)

Pakistani that came to the U.S. in 1990 to receive education (B.S. in biology from MIT, Ph.D in neuroscience from Brandeis in 2001). After 9/11, she left the U.S. to serve as a mujahideen medic; married nephew of KSM, chief planner of 9/11. Currently serving an 86 year prison sentence.





# Newsweek

## Aafia Siddiqui: The Woman ISIS Wanted to Trade for Foley, Then Sotloff

By Janine di Giovanni / September 16, 2014



Before the Islamic State, the group commonly known as ISIS, murdered American journalist James Foley, the insurgents sent an email to his family saying they were open to a prisoner exchange for “Muslims currently in your detention.”

A woman they specifically mentioned was Aafia Siddiqui. Two weeks after Foley was beheaded, ISIS suggested that it would trade American journalist Steven Sotloff for Siddiqui. There was no deal, and Sotloff, too, was beheaded.

<http://www.newsweek.com/2014/09/26/aafia-siddiqui-woman-isis-wanted-trade-foley-then-sotloff-270830.html>







# Domestic Terrorism

UCLA Newsroom

**Chancellor condemns firebombing  
claimed by extremists**

By Phil Hampton March 09, 2009



**Firebombings Target 2 Calif. Scientists  
Animal-Rights Activists Apparently  
Behind Rash Of Attacks At U. Of Calif.,  
Santa Cruz**

CBS News, San Francisco, August 4, 2008





# Threat to Students

## **STUDENTS EARN EASY MONEY!!!**

**Negotiation Is Over** would like to pay you  
**\$100 cash**  
for information about each biomed  
student who is learning to experiment on  
animals in your university.

**Provide us with the following,  
you can quit your part time job:**

- ❖ name of vivisection student
- ❖ picture of student
- ❖ address, phone and any other contact info
- ❖ pictures and/or summary of animal experiments in which student is involved

To claim your reward money anonymously, simply contact  
NIO at (352) 396-4132  
or write to us at [camille@negotiationisover.com](mailto:camille@negotiationisover.com)

*“Secure schedules for science classes at your local college or university. Find a vivisection instructor and choose a lecture. You will walk into that classroom, take it over, and assault them with science and facts.”*

-- Negotiation Is Over





# David Kwiatkowski

(Lab Tech – Workplace Violence – Use of Bio Agent)



**(Colorado, 2012)** – Radiological technician accused of infecting at least 31 hospital patients with Hepatitis C by stealing fentanyl syringes and replacing them with dirty ones tainted with his blood.

- Worked in ten hospitals over four years in eight different states; several misconduct and disciplinary incidents but
- Derogatory info never reported to HR or supervisors at new jobs and hiring institutions didn't require or follow-up on references.





# Cyber Security

## Hacking of DuPont, J&J, GE Were Undisclosed Google-Type Attacks

SAN FRANCISCO  
**Chronicle**

Tuesday, March 8, 2011

The incidents described in the stolen e-mails portray industrial espionage by hackers based in China, Russia and other countries. U.S. law enforcement agencies say the attacks have intensified in number and scope over the past two years.

"We are on the losing end of the biggest transfer of wealth through theft and piracy in the history of the planet," said Democratic Senator Sheldon Whitehouse of Rhode Island, who chaired a U.S. Senate Select Committee on Intelligence task force on U.S. cyber security in 2010.







# Your medical record is worth more to hackers than your credit card



REUTERS

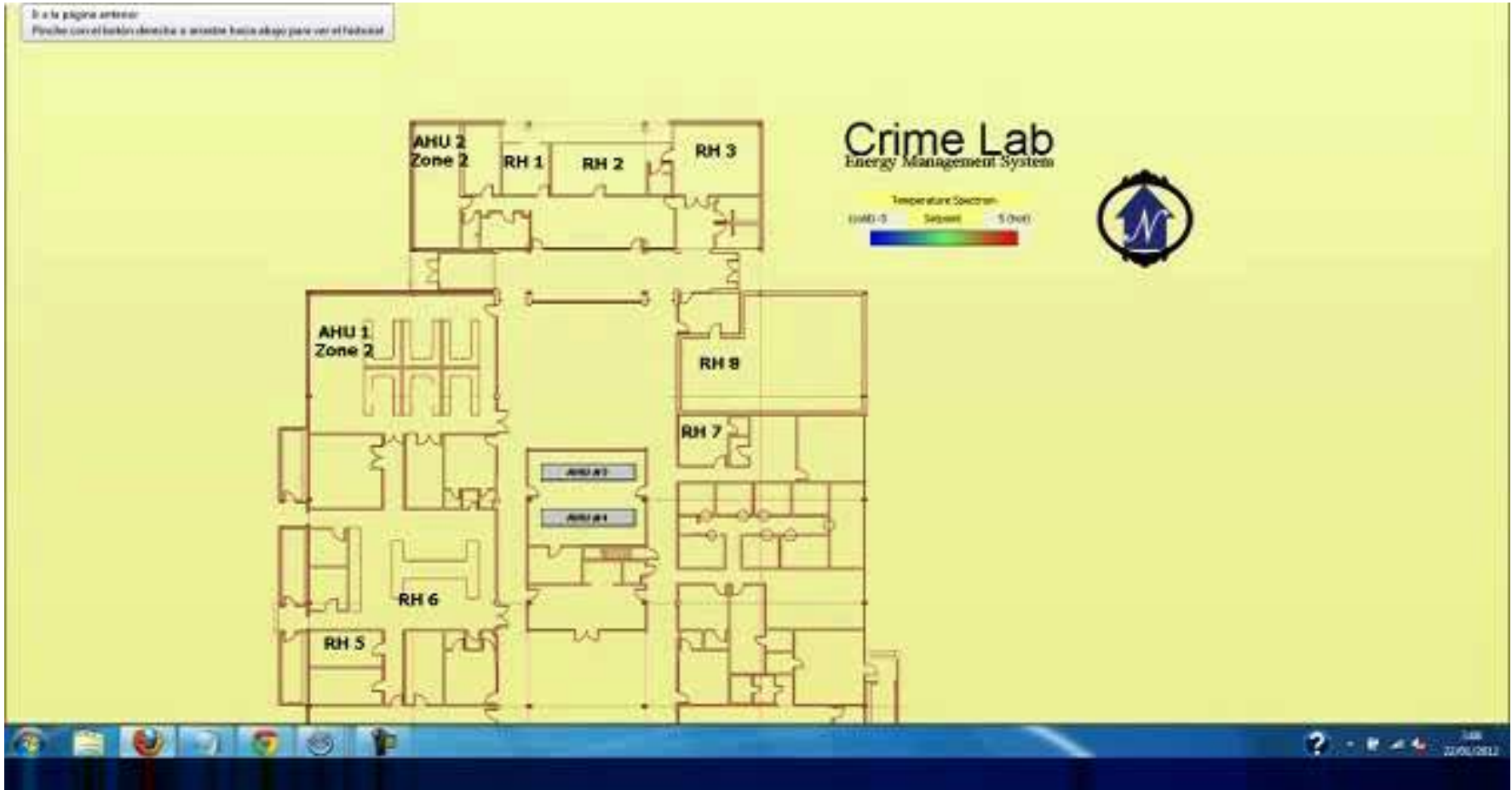
By Caroline Humer and Jim Finkle, Sep. 24, 2014

The FBI warned healthcare providers to guard against cyber attacks after one of the largest U.S. hospital operators, Community Health Systems Inc, said Chinese hackers had broken into its computer network and stolen the personal information of 4.5 million patients.





# Cyber Intrusion: Laboratory Environmental Control





# Revealed: the lax laws that could allow assembly of deadly virus DNA

Urgent calls for regulation after Guardian buys part of smallpox genome through mail order  
James Randerson, science correspondent

**guardian.co.uk**

Wednesday 14 June 2006



A vial containing an incomplete sequence of smallpox DNA, obtained by the Guardian over the internet





# ***Looking Ahead***



## **FBI Security Risk Assessment**







# Statutory Prohibitors

## USA PATRIOT Act (18 USC 175b)

- Under indictment for crime punishable by imprisonment for term exceeding one year
- Convicted of crime punishable by imprisonment for a term exceeding one year
- Fugitive from justice
- Unlawful user of any controlled substance
- Alien illegally or unlawfully in United States
- Adjudicated as a mental defective or has been committed to any mental institution
- Is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country that has repeatedly provided support for acts of international terrorism
- Discharged from Armed Services of United States under dishonorable conditions
- Member of, or acts on behalf of, a terrorist organization as defined in the Immigration and Nationality Act (8 USC 1182)

## Bioterrorism Response Act

- Committing crime specified in 18 USC 2332b(g)(5) [Acts of Terrorism Transcending National Boundaries]
- Having a knowing involvement with organization that engages in domestic or international terrorism (as defined in 18 USC 2331) or with any other organization that engages in international crimes of violence
- Being an agent of a foreign power (as defined in 50 USC 1801)





# Select Agent Program FBI Security Risk Assessment (SRA)

FD-961 (Rev. 10-31-09) OMB No. 1520-0039 - Exp. 10-31-2012

FEDERAL BUREAU OF INVESTIGATION  
BIOTERRORISM PREPAREDNESS ACT: ENTITY / INDIVIDUAL INFORMATION

Title 18 Section 1003 of the U.S. Code provides that knowingly falsifying or concealing a material fact is a felony that may result in fines or imprisonment for not more than 5 years or both.

Section I: Entity Information

1. Legal Name of Entity and Entry Application Number (Supplied by APRIS or CDC)

2. Address (Street, City, County, State, Zip Code)

3. Type of Applicant

First Time Applicant   
 Repeat Applicant   
 Renewed Applicant   
 Reinstatement Applicant

Section II: Individual Information

4. Full Name (Last, First, Middle)

4a. Alias/Other Name

5. Date of Birth (Month, Day, Year)

6. Social Security Number

7. Residence Address (Number, Street, City, State, Zip Code)

8. Sex

Male   
 Female

9. Place of Birth (City, State or Foreign Country)

IF NOT BORN IN THE UNITED STATES PLEASE COMPLETE QUESTIONS BELOW TITLED FOREIGN BORN INFORMATION:

10. Race

White   
 Black or African   
 Hispanic or Latino   
 Asian/Native Hawaiian/Pacific Islander   
 American Indian or other Alaska Native

**FD-961**



FBI Background Check  
Database Check



Prohibitor



No Prohibitor

FEDERAL BUREAU OF INVESTIGATION  
JUSTICE INFORMATION SERVICES DIVISION  
CLARKSBURG, WEST VIRGINIA





# Select Agent Program Applicant

DOA – 12/06/1986

Charge 1 – **Fraud**

Conviction: Fraud (Misdemeanor)

DOA – 01/20/1990

Charge 1 – **Theft By Check**

Conviction: Theft By Check (Misdemeanor)

DOA – 06/24/1995

Charge 1 - **Aggravated Assault With Deadly Weapon**

Conviction: Aggravated Assault ( 2<sup>nd</sup> Degree Felony)

Sentence: 5 Year Suspended, Probation Discharge, Conviction Set-Aside

DOA – 07/06/1997

Charge 1 – **Assault Causes Bodily Injury**

Disposition: Dismissed





## Select Agent Program Applicant

DOA – 07/06/1997

Charge 1 – **Theft Property  $\geq$ \$20  $<$ \$500 By Check**

Conviction: Theft  $\geq$ \$20  $<$ \$500 (Misdemeanor)

DOA – 07/12/1997

Charge 1 – **Assault Causes Bodily Injury**

Conviction: Assault Family Violence (Misdemeanor)

DOA – 01/14/2011

Charge 1 – **Driving While Intoxicated**

Charge 2 – **Possession Controlled Substance PG 3 $<$  28G**

Disposition: Pending/Referred to County Attorney







# Select Agent Program Applicant Conclusion

The maximum imprisonment for misdemeanors in Texas does not exceed 1 year; therefore, the applicant did not meet the “convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year” restrictor.

The applicant did not meet the “unlawful user of any controlled substance” restrictor.

The BRAG PSS will regularly check with the court for a final disposition on the most recent arrest. If the applicant is convicted of possession of a controlled substance, he/she will be meet the “unlawful user of any controlled substance” restrictor.





## Legislation & Regulation

- Increased restrictions
- Oversight



- Possible negative impact on research activities

**National Security Risk**

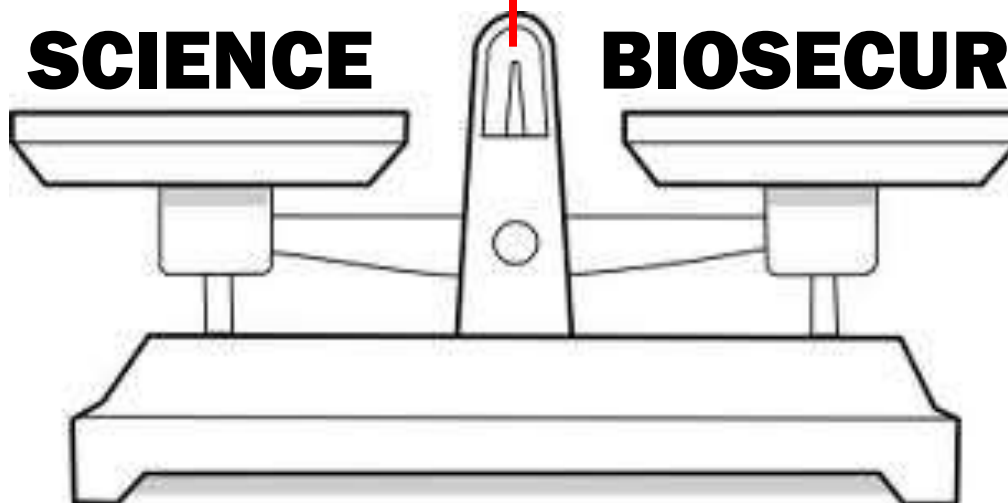




**NATIONAL  
SECURITY**

**SCIENCE**

**BIOSECURITY**





# ***Looking Ahead***



**FBI Outreach  
Safeguarding Science  
Building Partnerships**







# FBI Regional Academic Biosecurity Workshops



## Workshop Goal:

Improve the cooperation among law enforcement agencies and research institutions to mitigate potential biosecurity issues that may affect public health and safety

## Target Audience:

- Biosafety Professionals/Responsible Officials
- First Responders (Law, Fire, EMS)
- Public Health
- Environmental Health & Safety Professionals
- Emergency Management
- Institutional Leadership
- Human Resources
- Faculty, Post Docs and Students



KSTATE



RICE



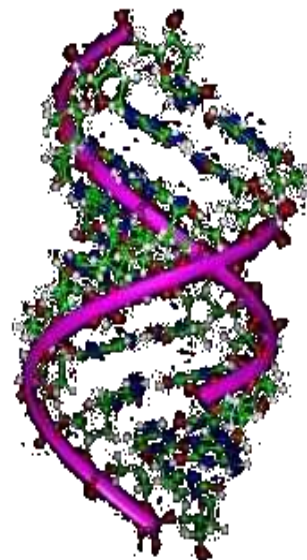
THE UNIVERSITY OF TEXAS  
MD ANDERSON  
CANCER CENTER





# FBI Synthetic Biology Tripwire Initiative

- Partnership with the U.S. synthetic biology industry to report suspicious requests for genetic sequences
  - Reporting mechanism in place between participating industry leaders and FBI field office WMD Coordinators
  - Participated in ICLS meetings with commercial synthetic DNA manufacturing consortia (IGSC, IASB)

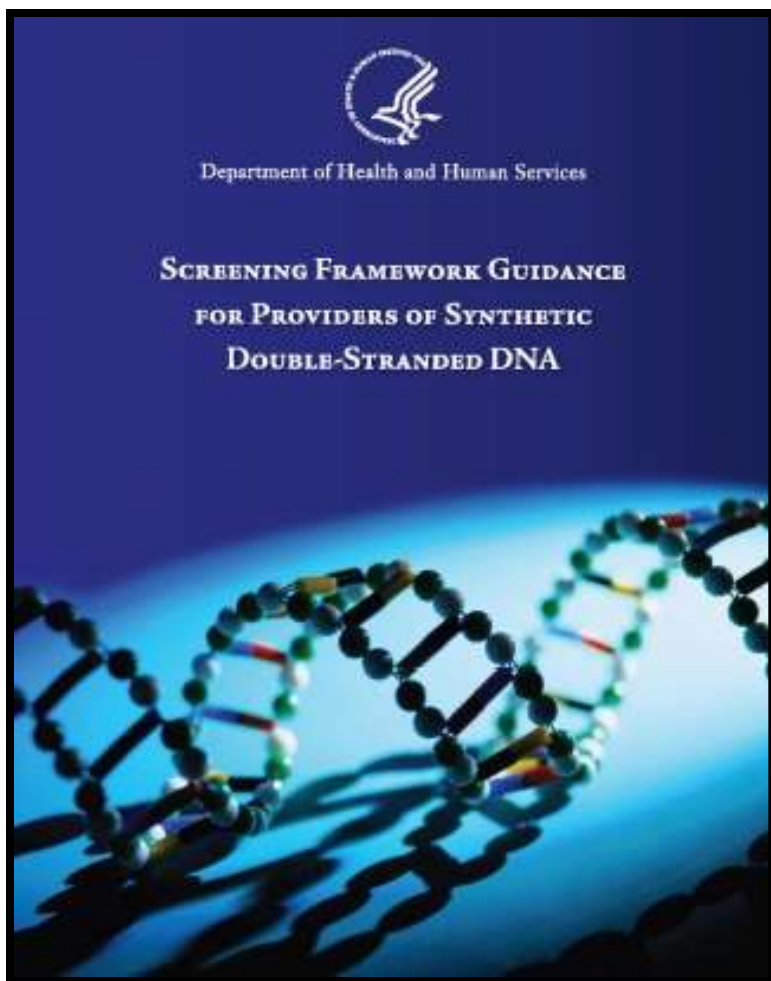


Industry very happy that problem of “who to call” was resolved





# Federal Guidance to Synthetic DNA Providers



1. Customer Screening
2. Sequence Screening
3. Government Notification
  - FBI WMD Coordinator





# Synthetic Biology

based on standard parts



**2012 Jamboree**

**3,000+ Participants**

**34 Countries**

**190 University Teams**

**FBI Sponsor of iGEM since 2009**

**FBI Biosecurity Workshop**

**FBI Outreach Booth**







# Synthetic Biology

based on standard parts

## Security

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"Biology should be more fun. It should be about exploring the world around us. We should want to get out there and do things. We should be able to do things more easily. Securing biology should be something that helps us do that. It cannot be something that gets in the way."

## Security in Practice

Ensuring that biology is used safely, securely and constructively should be of concern to us all. This is a challenge we will have to face together. To do this we will need to figure out what we want biological engineering to look like, what we are prepared for others to do with it, and just how we want to tackle security issues. This page provides a space to focus on these issues and for you to help shape what should be done to stop those with a malign intent. There is a real opportunity here for iGEM and those participating in iGEM, not only to shape how they will deal with security issues but to drive their national and even international processes. You can make a real difference in securing biology – in your lab, in your country and across the world.





Synthetic Biology  
based on standard parts

Have Fun!

Be Guardians of Science!

Pass It On!





# Synthetic Biology

based on standard parts

## A security related iGEM project: VT-ENSIMAG Biosecurity 2010



The **VT-ENSIMAG Biosecurity** team from 2010 focused their efforts on a security related bioinformatics project. They succeeded in creating screening software to identify uniquely related to agents of concern (pathogens and toxins). The team then used the screening software to show that virtually no parts in the registry came from such agents. The single part that was identified had already been clearly labelled as coming from a pathogen. This project demonstrated that **security and science can be mutually beneficial** and how effectively iGEM has engaged in these areas. For their work, VT-ENSIMAG Biosecurity won a special award in safety and security.

## A security related human practices project: PKU Beijing 2009



The **PKU Beijing team in 2009**, as its human practices project, conducted a survey of 17 biotech supply companies to see if they would deliver a variety of laboratory resources to a domestic address. The PKU Beijing team in 2009, as its human practices project, conducted a survey of 17 biotech supply companies to see if they would deliver a variety of laboratory resources to a domestic address. The team discovered that many of the companies they contacted would complete their orders. As a result, PKU Beijing 2009 made a series of **suggestions on how regulators, companies and the community might work together to enable exciting science whilst minimizing associated risks**. These suggestions were then forwarded to the relevant authorities in their own country for further consideration.







# FBI-DIYbio Workshops



Yes this is real: FBI Biosecurity Outreach (read: Trading) cards. via [@biocuriouslab](https://twitter.com/biocuriouslab) [pic.twitter.com/An21hkM](https://pic.twitter.com/An21hkM)

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“We reached out to our local weapons of mass destruction coordinator. We are very friendly with our local FBI representative. He has come to our workshops and he came to our opening.

The FBI wishes us well because they know the more educated the public is about what could constitute a biological threat, the easier its job is going to be.”

-Dr. Ellen Jorgenson, Genspace  
Discover Magazine, October 2011

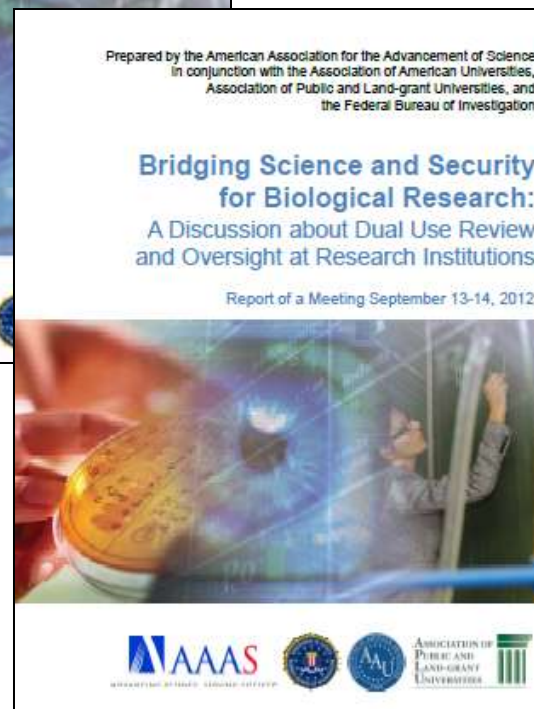
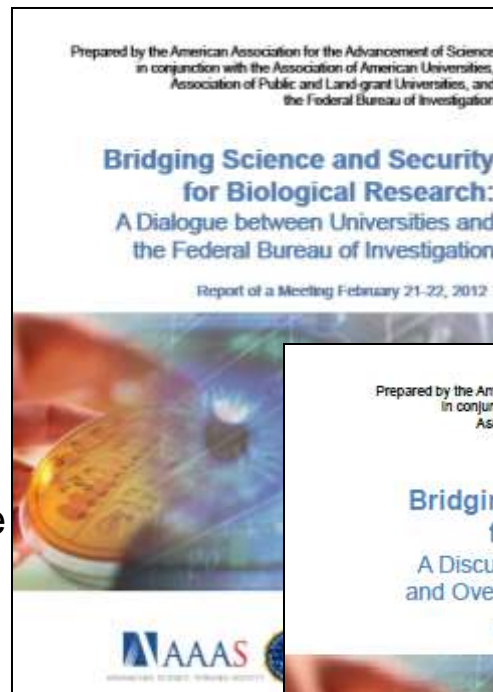




# FBI-AAAS-AAU-APLU Partnership

1. Facilitate open communication between the security and the scientific communities
2. Determine how the university and security communities can work together
3. Develop and disseminate to both the security and academic communities recommendations for building a collaborative framework
4. Develop and disseminate to the scientific community and policy-makers possible solutions

<http://www.aaas.org/cstsp/programs/bridging-science>





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1  
APR

# Big Data, Life Sciences, and National Security

Like 13 Tweet 21 reddit this! Email Print



1 Apr 2014 through 1 Apr 2014

8:15 am to 6:00 pm

Webcast

Renaissance Downtown Hotel

RSVP

Agenda available for download here

TAGXEDO.COM

This event brought together scientists across a range of disciplines, security professionals, and science and security policy experts to explore ways to leverage the beneficial applications and identify potential risks of big data and analytics to biological security

<http://www.aaas.org/cstsp/bigdata>





# FBI-AAAS-AAU-APLU Partnership

- Highlighting and sharing of best practices
- A few research administrators at the meeting stated that they might not know all of the international collaborations occurring at the scientist-to-scientist level
- Potential lapse in integrity might involve scientists who accept money to republish scientific articles with joint affiliations

## Future Challenges

- IRB challenges with protecting identity (de-anonymization)
- Personal health data security
  - Not just PII/financial data
  - Clinical trials/drug studies







# Letter to U.S. Congress



ASSOCIATION OF  
AMERICAN UNIVERSITIES

ASSOCIATION OF  
PUBLIC AND  
LAND-GRANT  
UNIVERSITIES



June 11, 2012

The Honorable Harry M. Reid  
Majority Leader  
U.S. Senate  
Washington, DC 20510

The Honorable Mitch McConnell  
Minority Leader  
U.S. Senate  
Washington, DC 20510

The Honorable John Boehner  
Speaker of the House  
U.S. House of Representatives  
Washington, DC 20515

The Honorable Nancy Pelosi  
Minority Leader  
U.S. House of Representatives  
Washington, DC 20515

Dear Majority Leader Reid, Minority Leader McConnell, Speaker Boehner and Minority Leader Pelosi:

On behalf of the Association of Public and Land-grant Universities (APLU) and the Association of American Universities (AAU), whose combined members include the majority of the nation's public and private research universities, we write to express our serious concern with Section 308 of H.R. 2146, the Digital Accountability and Transparency Act, and Sec. 501 of S. 1789, the 21st Century Postal Service Act. These provisions, inserted as amendments to the underlying bills in their respective chambers, would place severe restrictions on the ability of government employees to attend important meetings, workshops, and conferences at our educational institutions.

We believe it is important to prevent wasteful government spending. However, these provisions as written would inadvertently harm the partnership between the federal government and the nation's higher education institutions that has served the country so well over many decades. Higher education institutions, particularly research universities, have daily interactions with many Federal agencies, ranging from the Department of Education (ED) to the National Institutes of Health to the Department of Homeland Security. Whether it is a meeting between an ED official and our financial aid officials on student aid programs, a university conference on research advances in clean coal technology that includes a Department of Energy participant, or a meeting between university research administrators and weapons of mass destruction coordinators from the Federal Bureau of Investigation regarding biosecurity safeguards, these interactions between higher education and the federal government are important to our national security, public health, education, and global competitiveness.

Under these provisions, these types of interactions would be severely curtailed because a government agency would not be permitted to expend any funds, however small it may be, on more than one visit per year to the same university. This would be harmful to continuing projects, programs, initiatives, and discussions that require more than a single in-person meeting or conference. Given that many campus departments have good reasons to interact with the same federal agencies, this could also create an unintended and unproductive competition within a single campus to be the first to arrange a campus visit from a federal agency official.

Association of American Universities • 1200 New York Ave., NW, Suite 550, Washington, DC 20005 • (202) 462-7500

Association of Public and Land-grant Universities • 1307 New York Ave., NW, Washington, DC 20005 • (202) 478-6040





# Letter to U.S. Congress

On behalf of the Association of Public and Land-grant Universities and the Association of American Universities, whose combined members include the majority of the nation's public and private research universities

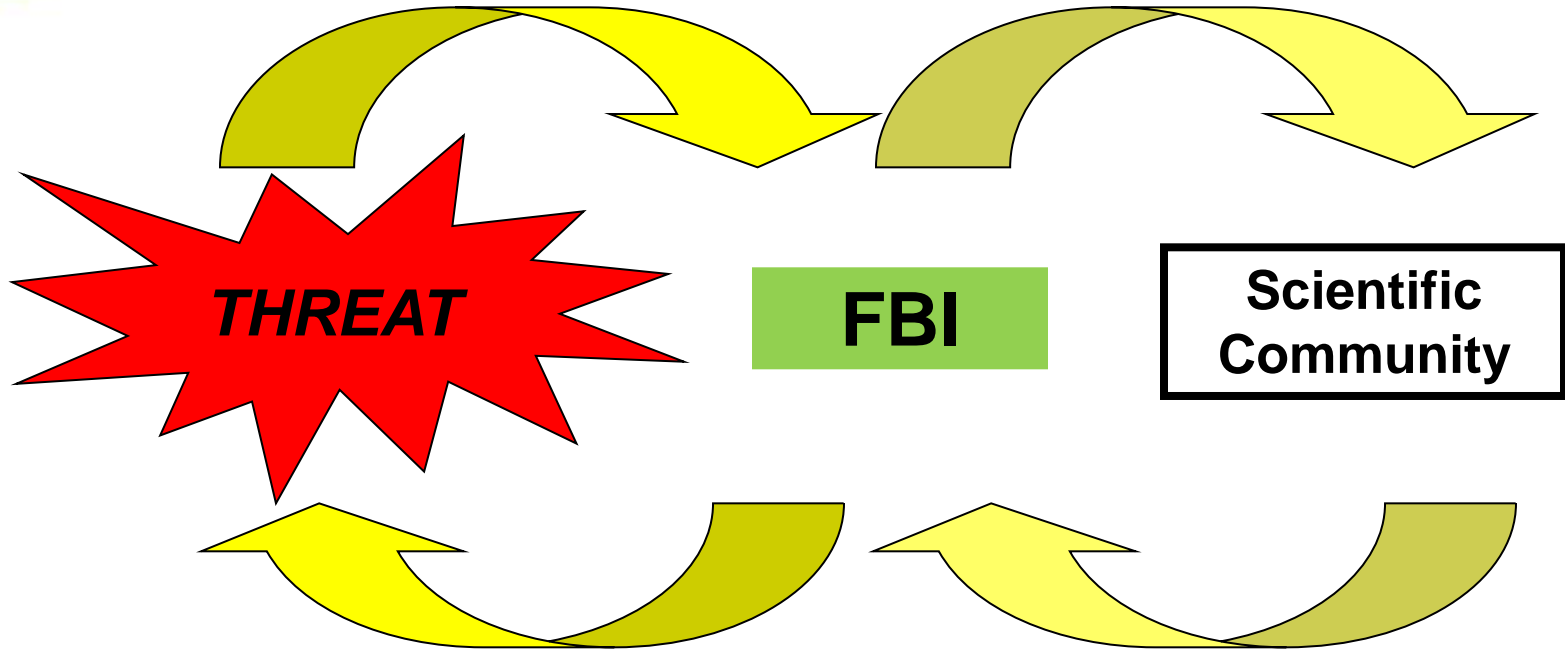
We believe it is important to prevent wasteful government spending. However, ...

...meeting between university research administrators and **weapons of mass destruction coordinators from the Federal Bureau of Investigation** regarding biosecurity safeguards, these interactions between higher education and the federal government are **important to our national security, public health, education, and global competitiveness.**





# The Role of the FBI



## Meeting the Biosecurity Challenge:

- Outreach
- Partnership
- Effective Risk Mitigation/Policy Making





# Disarmament

## The Biological Weapons Convention

### Key Provisions of the Biological Weapons Convention

Article	Provision
Article I	Never under any circumstances to acquire or retain biological weapons.
Article II	To destroy or divert to peaceful purposes biological weapons and associated resources prior to joining.
Article III	Not to transfer, or in any way assist, encourage or induce anyone else to acquire or retain biological weapons.
Article IV	To take any national measures necessary to implement the provisions of the BWC domestically.
Article V	To consult bilaterally and multilaterally to solve any problems with the implementation of the BWC.
Article VI	To request the UN Security Council to investigate alleged breaches of the BWC and to comply with its subsequent decisions.
Article VII	To assist States which have been exposed to a danger as a result of a violation of the BWC.
Article X	To do all of the above in a way that encourages the peaceful uses of biological science and technology





**THANK YOU**

