



Select Agent Program Workshop

November 2011

Agricultural Select Agent Program (USDA/APHIS)
CDC Select Agent Program (HHS/CDC)
Bioterrorism Risk Assessment Group (FBI/CJIS)



Addressing Biosecurity: Roles and Responsibilities of the Science and Security Communities

Edward H. You
Supervisory Special Agent

FBI
Weapons of Mass Destruction Directorate
Biological Countermeasures Unit



Weapons of Mass Destruction Directorate



July 2006

FBI consolidated all WMD operations into the new WMD Directorate

1. Countermeasures and Preparedness
2. Investigative and Operations
3. Intelligence Analysis



FBI WMD Biological Countermeasures Unit Objectives

- ✓ Build national and international bioterrorism threat detection, identification, and reporting capabilities
- ✓ Improve bioterrorism assessment and investigative capabilities
- ✓ Enhance bioterrorism scientific, industry, and academic outreach





FBI WMD Coordinators

The Primary Point of Contact

- At least one WMD Coordinator in all of the FBI's 56 Field Offices
- Contacted by state and local Emergency Responders when confronted by a WMD threat or incident
- Liaison with Federal regional counterparts and state, county and local response agencies
- Liaison with entities in their jurisdiction (industry, academia)
- Act as a conduit to FBIHQ and the Federal Government for technical information, advice, and assistance



TO: Responsible Officials and Alternate Responsible Officials

SUBJECT: SA GRAM 04/01/2011: Posting of Frequently Asked Questions Regarding Reporting Incidents Involving Select Agents and Toxins

How can I report suspicious activity that may be criminal in nature concerning a registered entity, its personnel, or its select agents or toxins?

You can notify a ***Federal Bureau of Investigation Weapons of Mass Destruction Coordinator*** of any suspicious activity that you believe may be criminal in nature concerning an entity, its personnel, or its select agents or toxins. To locate your Federal Bureau of Investigation Weapons of Mass Destruction Coordinator, refer to <http://www.fbi.gov/contact-us/field>.



What is

BIOSECURITY ?



Dual Use?

Proper Handling of
Materials?



Physical Security?

Exploitation?



Acquisition of Biological Agent

- Purchased
- Stolen
 - Supply houses
 - Universities
 - Research Laboratories
 - Hospitals
 - Veterinary Clinics
- Isolated from environmental sources



Biological Weapons Statutes

- Title 18 United States Code, Section 175(a)
 - Illegal to knowingly develop, produce, stockpile, transfer, acquire, retain or possess any ***biological agent, toxin or delivery system for use as a weapon***
- Title 18 United States Code, Section 175 (b)
 - Illegal to knowingly ***possess*** any ***biological agent, toxin, or delivery system*** that is not reasonably justified by prophylactic, protective, or bona fide research or other peaceful purposes



Select Agent Program

FBI Security Risk Assessment (SRA)

The term "restricted person" means an individual who--

1. Is under indictment for a crime punishable by imprisonment for a term exceeding 1 year;
2. Has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year;
3. Is a fugitive from justice;
4. Is an unlawful user of any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));
5. Is an alien illegally or unlawfully in the United States;
6. Has been adjudicated as a mental defective or has been committed to any mental institution;

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INFORMATION SERVICES DIVISION
CLARKSBURG, WEST VIRGINIA



Select Agent Program

FBI Security Risk Assessment (SRA)

The term "restricted person" means an individual who—

7. Is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country as to which the Secretary of State, pursuant to section 6(j) of the Export Administration Act of 1979 (50 U.S.C. App. 2405(j)), section 620A of chapter 1 of part M of the Foreign Assistance Act of 1961 (22 U.S.C. 2371), or section 40(d) of chapter 3 of the Arms Export Control Act (22 U.S.C. 2780(d)), has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism;
8. Has been discharged from the Armed Services of the United States under dishonorable conditions.

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INFORMATION SERVICES DIVISION
CLARKSBURG, WEST VIRGINIA



Looking Ahead

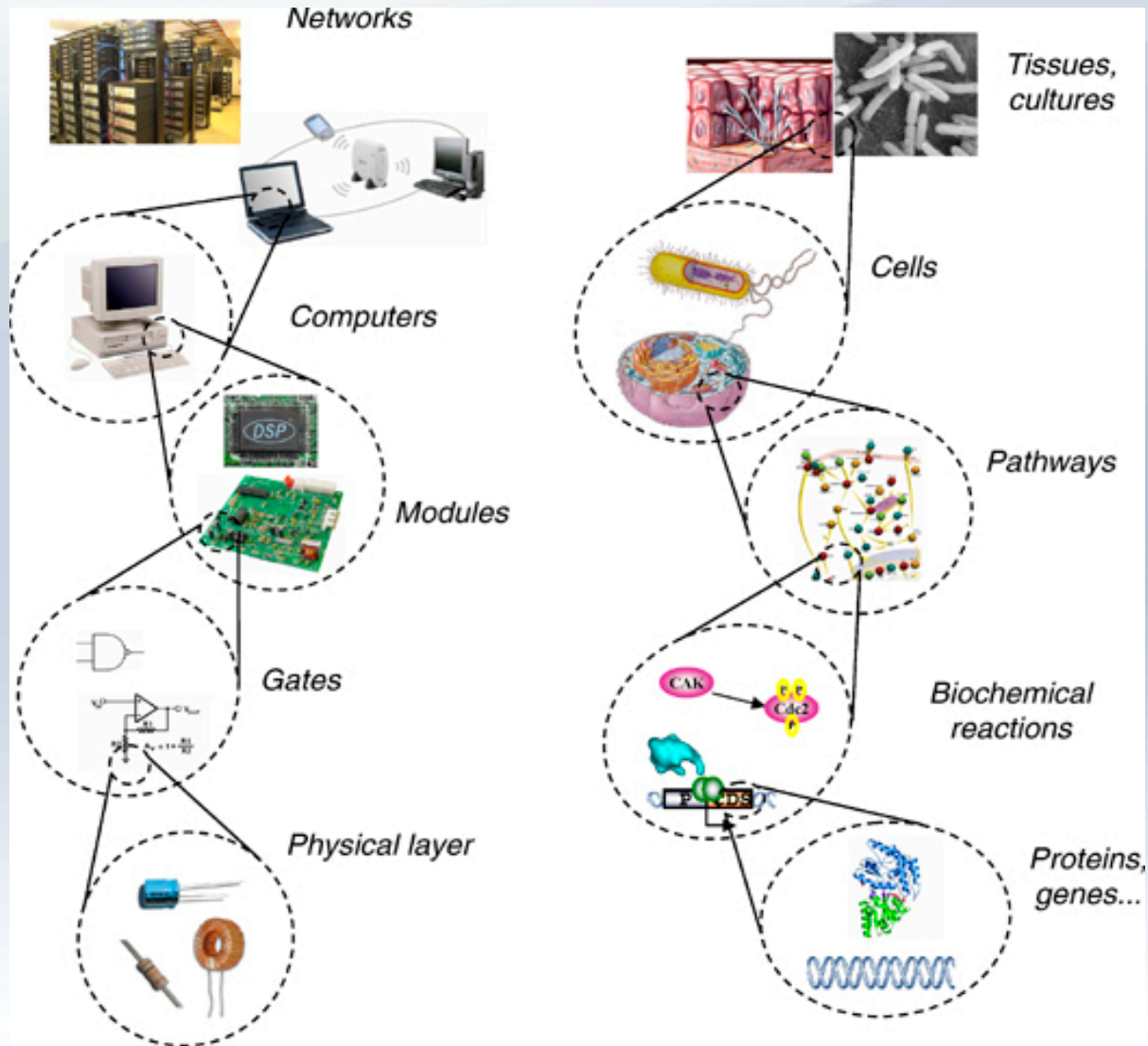


The Challenge

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Synthetic Biology



Molecular Systems Biology 2 Article number: 2006.0028 doi:10.1038/msb4100073
Published online: 16 May 2006



Synthetic Biology



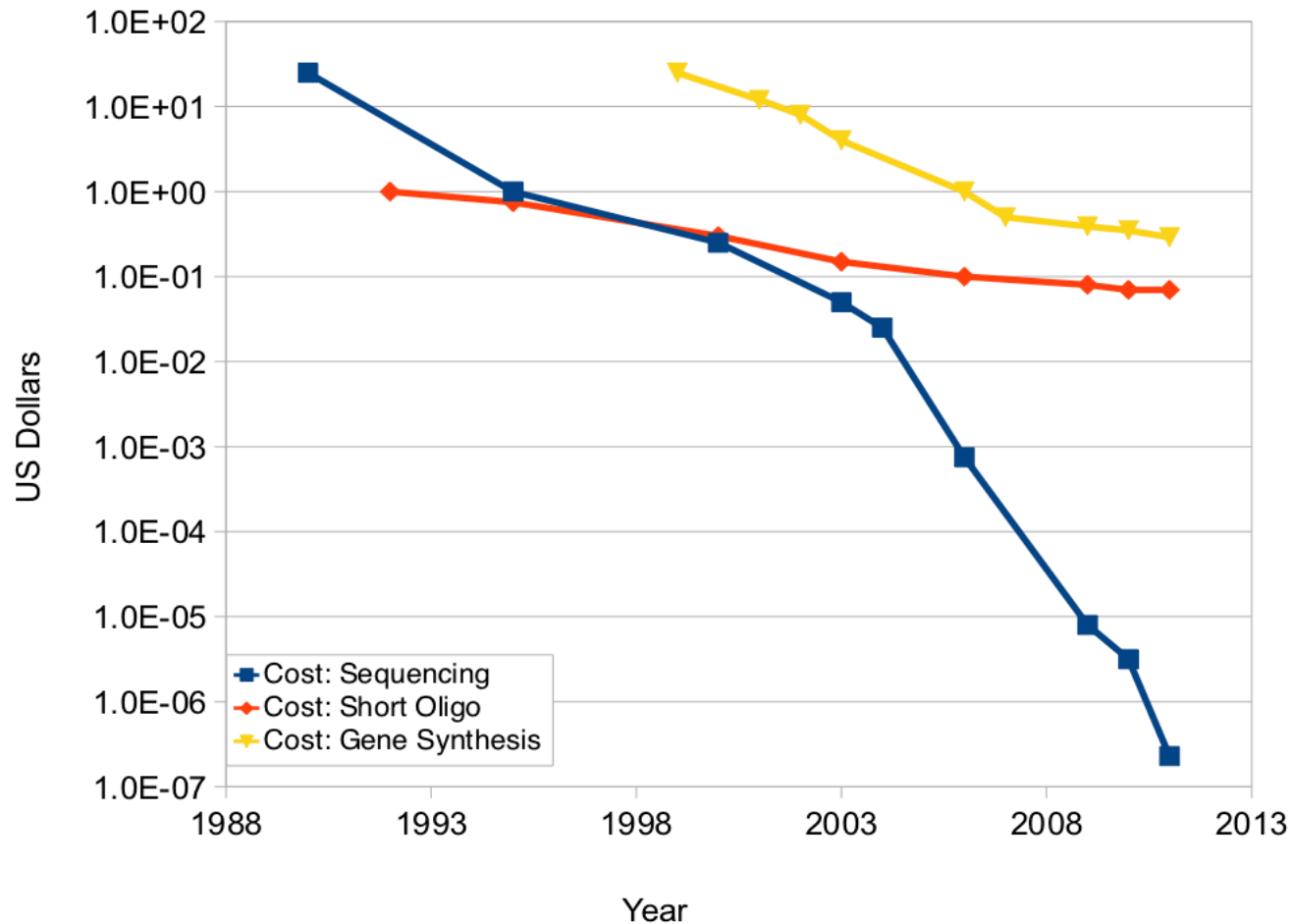
Carlson, [Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science](#)
[Volume 1 Number 3](#), August 2003



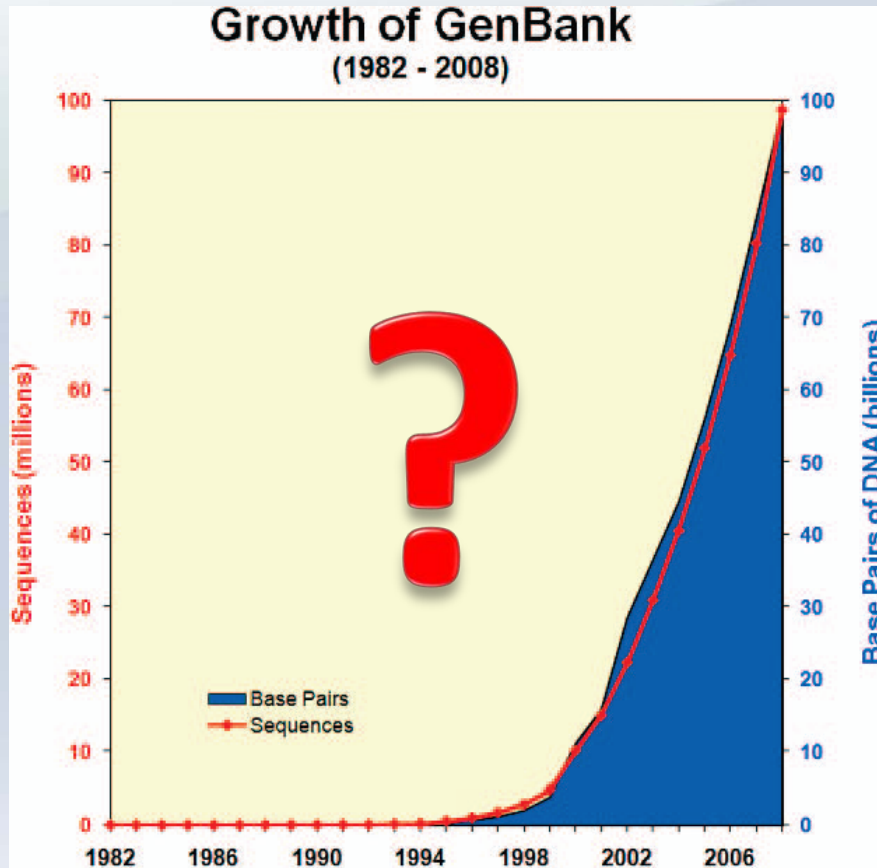
Synthetic Biology

Cost Per Base of DNA Sequencing and Synthesis

Rob Carlson, June 2011, www.synthesis.cc



SYNTHETIC BIOLOGY



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

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

- New pathogens
- New virulence factors



SYNTHETIC BIOLOGY



Creation of a Bacterial Cell Controlled by a Chemically Synthesized Genome



Life re-created. Blue colonies (*top*) indicate a successfully transplanted genome, with self-replicating bacteria revealed in an electron micrograph.



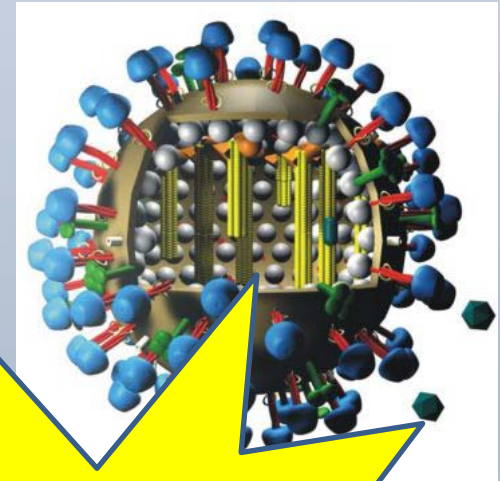
1918 INFLUENZA PANDEMIC

- An estimated one third of the world's population (or ≈ 500 million persons) were infected and had clinically apparent illnesses
- Total deaths were estimated at ≈ 50 million internationally



SYNTHETIC BIOLOGY

- Reconstruction of the influenza A (H1N1) orthomyxovirus responsible for the 1918 "Spanish flu" pandemic
- RNA genetic code comprised of approximately 13,500 nucleotides



GenScript

The Biology CRO

Largest Gene

—Any gene you d

- 100% sequence guarantee
- Largest capacity at **4.5 million bp/** with
- Advanced OptimumGene™ codon optimization
- Competitive price as low as **\$0.29/bp**

\$3,915.00



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

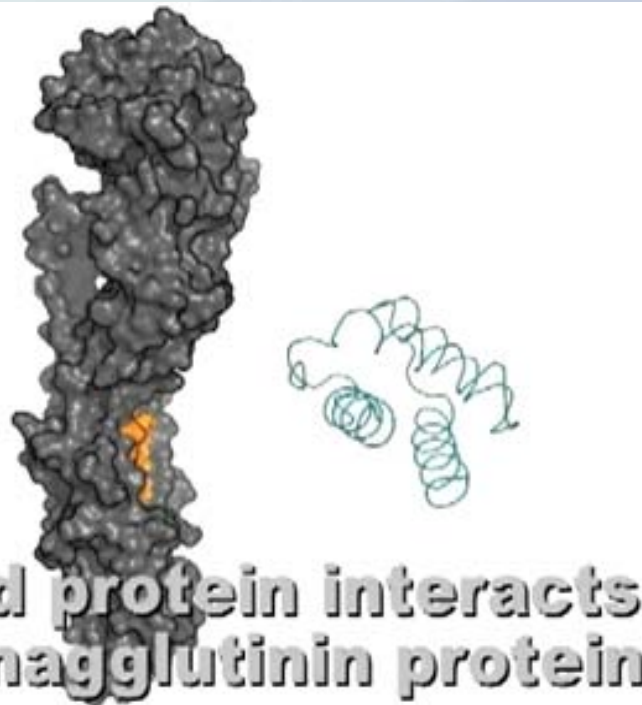
Wednesday 14 June 2006



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



De Novo Protein Design



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

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



Gamers Succeed Where Scientists Fail: Molecular Structure of Retrovirus Enzyme Solved, Doors Open to New AIDS Drug Design



ScienceDaily (Sep. 18, 2011) — Gamers have solved the structure of a retrovirus enzyme whose configuration had stumped scientists for more than a decade. The gamers achieved their discovery by playing Foldit, an online game that allows players to collaborate and compete in predicting the structure of protein molecules.



Looking Ahead



The Threat

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ethics eth·ics (ěth'iks)

a social, religious, or civil code of behaviour considered correct, esp that of a particular group, profession, or individual

“DO NO HARM”



Cyber Security

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



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.





Al-Qaeda seeks WMD, US unprepared: reports

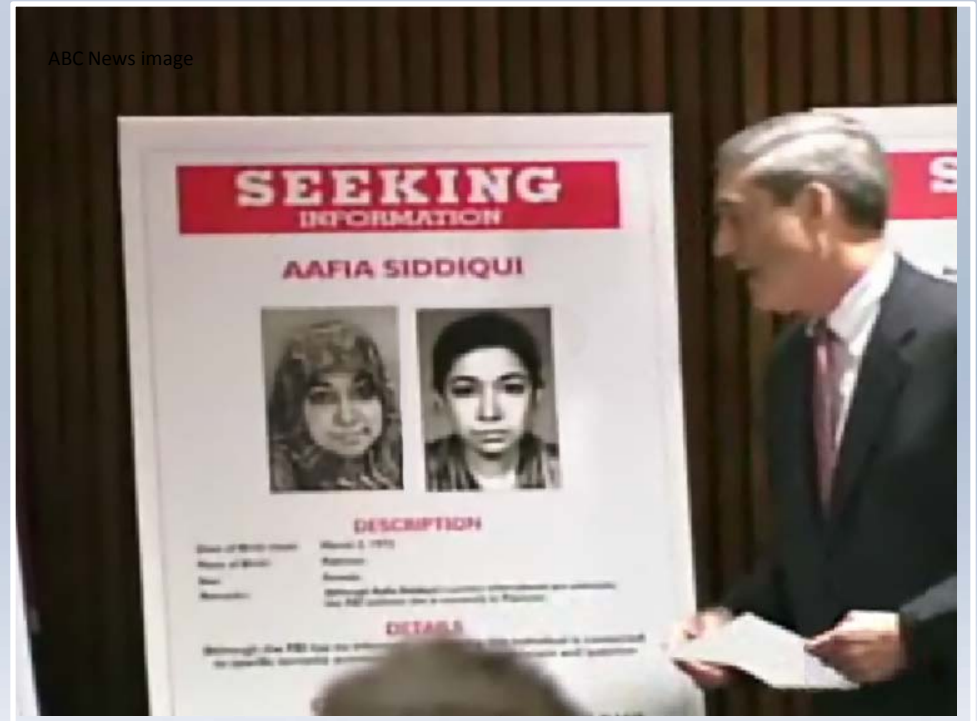
“Washington no longer has the luxury of a slow learning curve, when we know Al-Qaeda is interested in *bioweapons*.”

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



Al Qa'ida Linked Subject

- Aafia Siddiqui sought by FBI for questioning since 2004
- MIT & Brandeis educated neuroscientist arrested in Afghanistan on 17 July 2008.
- Search of computer data included references to Plum Island ADC, as well as other information regarding chemical and biological materials.
- Convicted on charges of assault and attempted murder charges in February 2010



FBI Director Robert Mueller briefs during DOJ press conference August 2004



2007 Glasgow International Airport Bombing



Dr. Bilal Talal Samad Abdullah

- Born Aylesbury, Buckinghamshire, UK
- Graduated in Baghdad, Iraq, in 2004
- Registered as Medicine Doctor in UK in 2006
- Sentenced to life imprisonment (minimum 32 years)



Kafeel Ahmed

- Born in Bangalore, India
- Raised in Saudi Arabia
- Pursued a PhD in computational fluid dynamics at Anglia Ruskin University, Cambridge
- Perished from injuries as a result of the bombing



Domestic Terrorism

UCLA Newsroom

Chancellor condemns firebombing claimed 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



Domestic Terrorism

Novartis CEO's Home Burned; Mother's Grave Desecrated; Animal Rights Activists Suspected



Novartis CEO Dr. Daniel Vasella spoke to CNBC about the arson attack on his vacation home in Austria. The Wall Street Journal reports that MFAH Austria, an animal rights group, has claimed responsibility. The group's goal is to get Novartis to sever ties with Huntingdon Life Sciences, which Novartis claims it no longer works with.

There is no update on what happened to Dr. Vasella's mother's ashes, which were stolen the week before.

Huffington Post | Katherine Goldstein First Posted: 08-11-09



Animal Rights Activism



HOME CAMPAIGNS & ISSUES NEWSLETTER GET INVOLVED EVENTS ABOUT US BLOG CONTACT LINKS DONATE

UW KILLS ANIMALS

[HOME](#) [ABOUT](#) [WHAT YOU CAN DO](#)

17
APR

Companies That Supply Animals to UW

Boyd's Bird Co Inc.
Charles D. Sullivan Co Inc.
Charles River Laboratories
Covance Research Products Inc.
Elm Hills Labs/Cady Ridge Farms
Featherland Farms
Harlan Sprague Dawley
Jackson Labs
JM Hazen Frog Co.
Magnolia Bird Farms
Marshall BioResources
NASCO West

Progressive Pig Farm
Q-Bar Farm
Rana Ranch Bullfrog Farm
R&R Rabbitry
Simonsen Labs
Sinclair Research Center
Taconic Farms
Western Oregon Rabbit Co.
WSU Swine Center
Xenopus Express
Xenopus I Inc.
Zebrafish International Resource Center



International Terrorism

MEXICO CITY (AP & staff) — An anti-technology group calling itself “**Individuals Tending to Savagery**” was responsible for a package bomb that injured two university professors just outside Mexico City

“...the group opposes experiments with nanotechnology and has staged attacks on academics before.”



 Associated Press MEXICO CITY August 10, 2011 (AP)



Domestic Terrorism

Bringing the War to the Student Body – The Soft-Bellied Target of the Vivisection Complex

Posted by [Negotiation Is Over](#) on March 29, 2011

“Students are far more open to objective information and far more susceptible to applied *persuasion tactics*. The vested interests of industry-entrenched vivisectors lie in their bloody wallets and, truly, the only effective approaches to veteran abusers appear to be through *incendiaries, intimidation, and violence. On the other hand, as Alena demonstrated, students are far more malleable and easily manipulated.*”



Campus Violence



A flier bearing photos of Annie Le is posted outside the doors of the New Haven, Conn., building that houses the lab where the Yale student worked. Le, a doctoral student in pharmacology at Yale, was last seen Tuesday morning. She was set to be married Sept. 13, 2009. (Thomas Cain/AP Photo)

Amy Bishop Arrested: University of Alabama Huntsville Shooting Suspect is Biology Professor, Harvard University-Trained
(Huffington Post, October 12, 2010)



Campus Violence



- Virginia Tech shooting took place on Monday, April 16, 2007
- 32 killed; multiple wounded
- Deadliest peacetime shooting incident by a single gunman in United States history, on or off a school campus



Looking Ahead



FBI Security Risk Assessment

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Select Agent Program FBI Security Risk Assessment (SRA)

FD-961 (Rev. 10-31-09) OMB No. 1110-0039 - Exp. 10-31-2012

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

Title 18 Section 1001 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 APHIS or CDC): _____

2. Address (Street, City, Country, State, Zip Code): _____

3. Type of Applicant:
First Time Applicant
Repeat Applicant
Renewal Applicant
Reactivation Applicant

Section II: Individual Information

4. Full Name (Last, First, Middle): _____

4a. Aliases/Maiden 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 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

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INFORMATION SERVICES DIVISION
CLARKSBURG, WEST VIRGINIA



Select Agent Program Applicant #1

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 (2nd 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 #1

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 #1 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.



Select Agent Program Applicant #2

Applicant checked “yes” to question 12E, which asked, “Have you ever been adjudicated as a mental defective or been committed to any mental institution?”

Applicant provided documentation concerning past treatment received on an inpatient basis at mental health facilities. This documentation stated the following:

- Chief complaint “I am depressed and suicidal.”
- History of depression and bipolar disorder
- History of suicidal and homicidal ideations
- Difficulty concentrating on job and afraid of making mistakes at work
- Attempted suicide using a gun



Select Agent Program Applicant #2 Conclusion

Applicant does not meet the “adjudicated as a mental defective or committed to any mental institution” restrictor. All commitments to mental institutions disclosed were voluntary. The medical records provided by the applicant did not reveal a determination by a court, board, commission, or other lawful authority that he/she was a danger to himself or others.



Campus Violence



- Virginia Tech shooting took place on Monday, April 16, 2007
- 32 killed; multiple wounded
- Deadliest peacetime shooting incident by a single gunman in United States history, on or off a school campus

- Court adjudicated as a risk to himself and others



Looking Ahead



Biosecurity Policy

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Universities in Crisis: Dollars and Time

- Funding crises at state and federal levels
- Funds for administration are “capped” at 26% by OMB Circular A21
- Support personnel not covered
- 42% of researcher’s time is devoted to administration
- Regulations, guidelines, guidance and training requirements are ever increasing



Compliance added since 1991 (COGR)

- Federal Policy for the Protection of Human Subjects (Common Rule, 1991)
- Nonindigenous Aquatic Nuisance Prevention & Control Act of 1990(Implemented, 1992)
- NIH Guidelines for Research Involving Recombinant DNA Molecules (1994)
- Deemed Exports (1994, EAR & ITAR)
- DFARS Interim Export Control Compliance Clauses (July 2008)
- Conflict of Interest
- Public Health Service/NIH Objectivity in Research (1995)
- NSF Financial Disclosure Policy (1995)
- Lobbying Disclosure Act of 1995
- Cost Accounting Standards (CAS) in OMB Circular A-21(1995)
- Health Insurance Portability & Accountability Act of 1996 (HIPAA) Privacy Rule
- OMB Elimination of Utility Cost Adjustment (UCA) (1998)
- Data Access /Shelby Amendment (FY 1999 Omnibus Appropriations Act); related amendments to OMB Circular A-110
- Policy on Sharing of Biomedical Research Resources (NIH, 1999)
- Misconduct in Science (Federalwide Policy, 2000)
- HHS Centers for Medicare and Medicaid Services (CMS) National Coverage Determination for Routine Clinical Trials (Clinical Trials Policy), 2000
- Executive Order 13224, Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit or Support Terrorism (September 2001, also EO 12947, 1995)
- Select Agents & Toxins (under CDC and USDA/APHIS) Public Health Security & Bioterrorism Preparedness & Response Act of 2002; companion to the USA PATRIOT Act (2001)
- FISMA Federal Information Security Management Act (Title III, E Government Act of 2002) OMB Circular A-130, Management of Federal Information Resources, Appendix III, Security of Federal Automated Information Systems
- CIPSEA Confidential Information Protection and Statistical Efficiency Act (OMB Implementation Guidance 2007, Title V, E Government Act of 2002)
- Federal Policy on Embryonic Stem Cell Research (2003)
- Data Sharing Policy (NIH, 2003)



Compliance added since 1991

- Homeland Security Presidential Directive (HSPD) – 12, Common Identification Standards for Federal Employees and Contractors (2004)
- Higher Education Act, Section 117 Reporting of Foreign Gifts, Contracts and Relationships (20 USC 1011f, 2004)
- Model Organism Sharing Policy (NIH, 2004)
- Constitution & Citizenship Day (2005, Consolidated Appropriations Act FY 2005)
- Genomic Inventions Best Practices (2005)
- Combating Trafficking in Persons (2008)
- Code of Business Ethics & Conduct (FAR) 2008
- Homeland Security Chemical Facilities Anti-Terrorism Standards (CFATS) 2008
- E-Verify 2008
- Military Recruiting and ROTC Program Access (2008, Solomon Amendment, National Defense Authorization Act for FY 2005)
- Nuclear Regulatory Commission Order Imposing Fingerprinting and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Materials (Feb 2008, Section 652, Energy Policy Act of 2005)
- National Institutes of Health Public Access Policy (2008, Consolidated Appropriations Act of 2008, Division G, Title II Section 218)
- Certification of Filing and Payment of Federal Taxes (Labor, HHS, Education and Related Agencies Appropriations Act of 2008, Division G, Title V, Section 523)
- Health and Human Services/FDA Clinical Trials Registry
- Export Controls: Export Administration Regulations (EAR) & International Traffic in Arms Regulations (ITAR) (2003)
- Responsible Conduct of Research Training – NSF (America COMPETES Act 2006)
- Federal Funding Accountability and Transparency Act (FFATA) Subrecipient Reporting (2006)
- National Science Advisory Board for Biosafety (NSABB) Oversight of Dual Use Life Sciences Research of Concern
- Nuclear Regulatory Commission – Considerations concerning the Security and Continued Use of Cesium-137 Chloride Sources (July 2008)
- USAID Partners Vetting System (re: EO 13224 et al re: terrorist financing)
- USDA Animal Welfare Act, Contingency Planning (2008)



Compliance added since 1991

- Foreign Nationals (See COGR/AAU/FDP Troublesome Clause Report, 2008)
- Publication Restrictions (see COGR/AAU/FDP Troublesome Clauses, 2008)
- PL 106-107/Grants.gov: Electronic Applications, Financial Reporting, Progress Reports, iEdison Invention Reporting, etc.
- CCR/DUNS Registry requirements
- Subrecipient Monitoring (OMB Circular A-133, Compliance Supplement)
- Changes to A-21 F&A Proposal Format
- Federal Policy for the Protection of Human Subjects:
- Federalwide Assurance (2004), mandatory training
- IRB Registration (2008)
- Title IX of Education Amendments of 1972: Access to science and math educational programs (2007+)
- EPA Hazardous Waste, Subpart K (2008)
- IRS 990 Reporting

- **COUNCIL ON GOVERNMENTAL RELATIONS**



CIRCULAR A-21 Revised 05/10/04



TO THE HEADS OF EXECUTIVE DEPARTMENTS AND ESTABLISHMENTS

SUBJECT: Cost Principles for Educational Institutions

1. *Purpose.* This Circular establishes principles for determining costs applicable to grants, contracts, and other agreements with educational institutions.

Request for Information (RFI): Input on Reduction of Cost and Burden Associated with Federal Cost Principles for Educational Institutions (OMB Circular A-21)

Notice Number: NOT-OD-11-091

Key Dates

Release Date: June 28, 2011

Response Date: July 28, 2011



The Public Safety Squeeze

First responders are feeling the effects of the weak economy—while municipalities struggle to keep the public safe.

BY KELLEY VLAHOS
WASHINGTON CORRESPONDENT
ANTHONY KIMERY
SENIOR REPORTER

On a morning last summer, residents of Maywood, Calif., woke up and found that the city police department was gone. In early 2011, the city of Camden, N.J., one of the most dangerous cities on the East Coast, laid off 167 police officers and 60 firefighters in one fell swoop. In February, every firefighter in Allen Park, Mich., was given a pink slip.

From coast to coast, local governments have faced significant revenue shortfalls, budget deficits and shelving assistance from state and federal sources due to the ongoing recession. First responders have hardly been immune. From layoffs to pay cuts, hiring freezes to the outright elimination of local services, it appears that hard economic times might finally be affecting their ability to keep people safe.

"We're getting calls from numbers all over the country—from California to Texas to Maine—saying they are facing crises unlike they have ever seen in the past," John Firman, spokesman for the International Association of Chiefs of Police (IACP), which has 22,000 members across the United States, told Homeland Security Today.

Collectively, states are far ahead year 2011, according to the National Association of State Budget Directors (NASBD), the largest spending cuts of the survey.

When the report was surveyed were making a number in growing, judgments every day. "It

“ The United States has 50,000 fewer public health workers than it did 20 years ago, and one-third of current workers are eligible to retire within five years. ”

CRIME SCENE

Notice of Dismissal
Effective August 1



Progress In Emergency Bio-Preparedness Undermined By Budget Cuts

By: Anthony Kimery

10/18/2011 (10:00am)

Continuing cuts in state and local public health agencies' budgets is the biggest threat to US public health preparedness, said Dr. Ali S. Khan, director of the Centers for Disease Control and Prevention's (CDC) Office of Public Health Preparedness and Response.

"A 2009 survey found that only 37 state epidemiologists reported "substantial-to-full capacity" to respond to bioterrorism emergencies, a 10 percent decline since the peak of federal funding in 2004," Khan adding last year 12 states could not submit *Escherichia coli* test results to the CDC within four working days, slowing identification of outbreaks."



U.S. is unprepared for major bioterrorism attack, commission finds

The [report](#), which measured the government's performance in 17 key areas, gave the White House and Congress "F" grades for not building a rapid-response capability for dealing with disease outbreaks from bioterrorism, or providing adequate oversight of security and intelligence agencies.



Biosecurity Legislation

SENATE COMMITTEE ON
**HOMELAND SECURITY
& GOVERNMENTAL AFFAIRS**

PRESS

Contact: Leslie Phillips
(202) 224-2627
September 8, 2009

LIEBERMAN, COLLINS SEEK TO PROTECT U.S. AGAINST BIOLOGICAL AND OTHER TERRORIST WMD ATTACKS

Legislation Responds To Warnings of a WMD Terrorist Attack By 2013

WASHINGTON – As the nation prepares to mark the eighth anniversary of the 9/11 attacks and the subsequent anthrax attacks, Homeland Security and Governmental Affairs Committee Chairman Joe Lieberman, ID-Conn., and Ranking Member Susan Collins, R-Me., Tuesday introduced legislation to prevent and prepare for terrorist attacks from biological weapons and other weapons of mass destruction (WMD).



H.R. 5498, THE WMD PREVENTION AND PREPAREDNESS ACT OF 2010

As introduced by Rep. Bill Pascrell (D-NJ) and Rep. Peter King (R-NY)

On June 10, 2010

EXECUTIVE SUMMARY

Purpose: To enhance homeland security by improving efforts to prevent, deter, prepare for, detect, attribute, respond to, and recover from an attack with a weapon of mass destruction (WMD) and for other purposes.





Federal Register

Vol. 75, No. 130

Thursday, July 8, 2010

Presidential Documents

Title 3—

Executive Order 13546 of July 2, 2010

The President

Optimizing the Security of Biological Select Agents and Toxins in the United States

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Policy. It is the policy of the United States that:

(a) A robust and productive scientific enterprise that utilizes biological select agents and toxins (BSAT) is essential to national security;

(b) BSAT shall be secured in a manner appropriate to their risk of misuse, theft, loss, and accidental release; and

(c) Security measures shall be taken in a coordinated manner that balances their efficacy with the need to minimize the adverse impact on the legitimate use of BSAT.



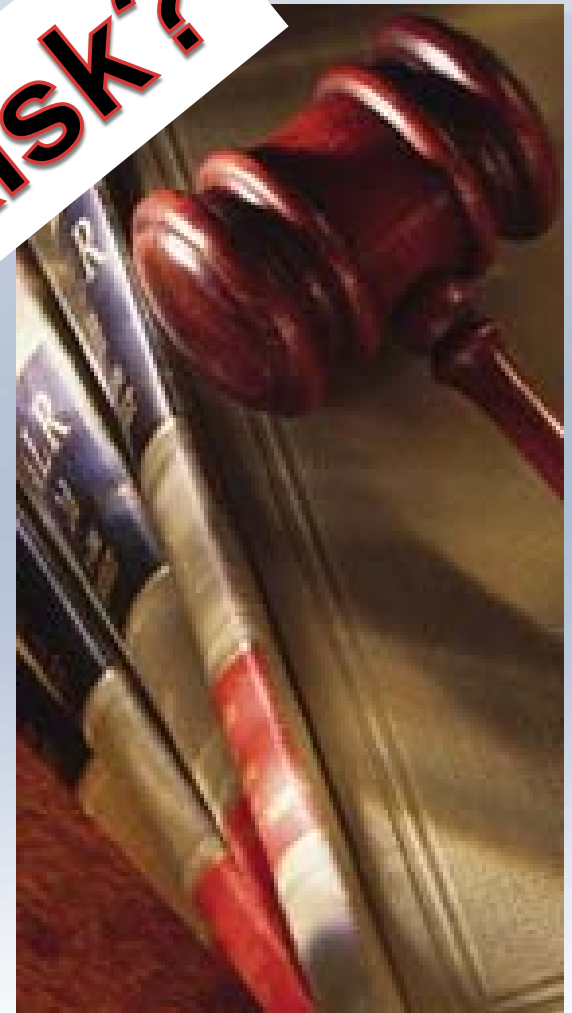
Legislation & Regulation

- Increased restrictions
- Oversight



- Potentially increased
- Possible negative impact on research and

National Security Risk?



Looking Ahead



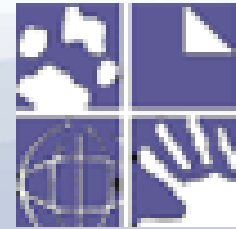
FBI Outreach

Nov 2011 Select Agent Program Workshop





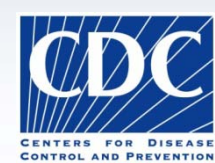
FBI-MSMR Biosecurity Conference



The 3 I's: Learning through Collaboration, Connection and Community ...
Advancing Bioscience and Security

May 3-4, 2010

- First biosecurity conference organized by FBI WMD Directorate in partnership with the Massachusetts Society for Medical Research (MSMR) attended by:
 - Institutional Biosafety Committee Members
 - Institutional Review Board Members
 - Institutional Animal Care and Use Committee Members
- Focused on how the research and security communities can work together in addressing biosafety and biosecurity



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



www.academicbiosecurityworkshops.org

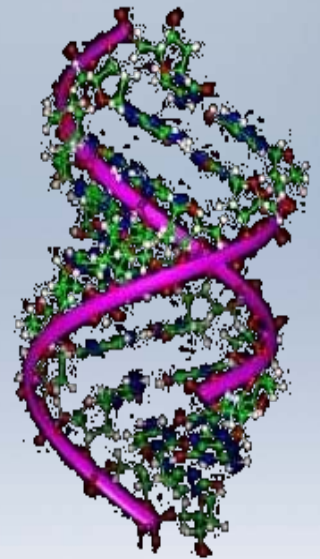
Nov 2011 Select Agent Program Workshop



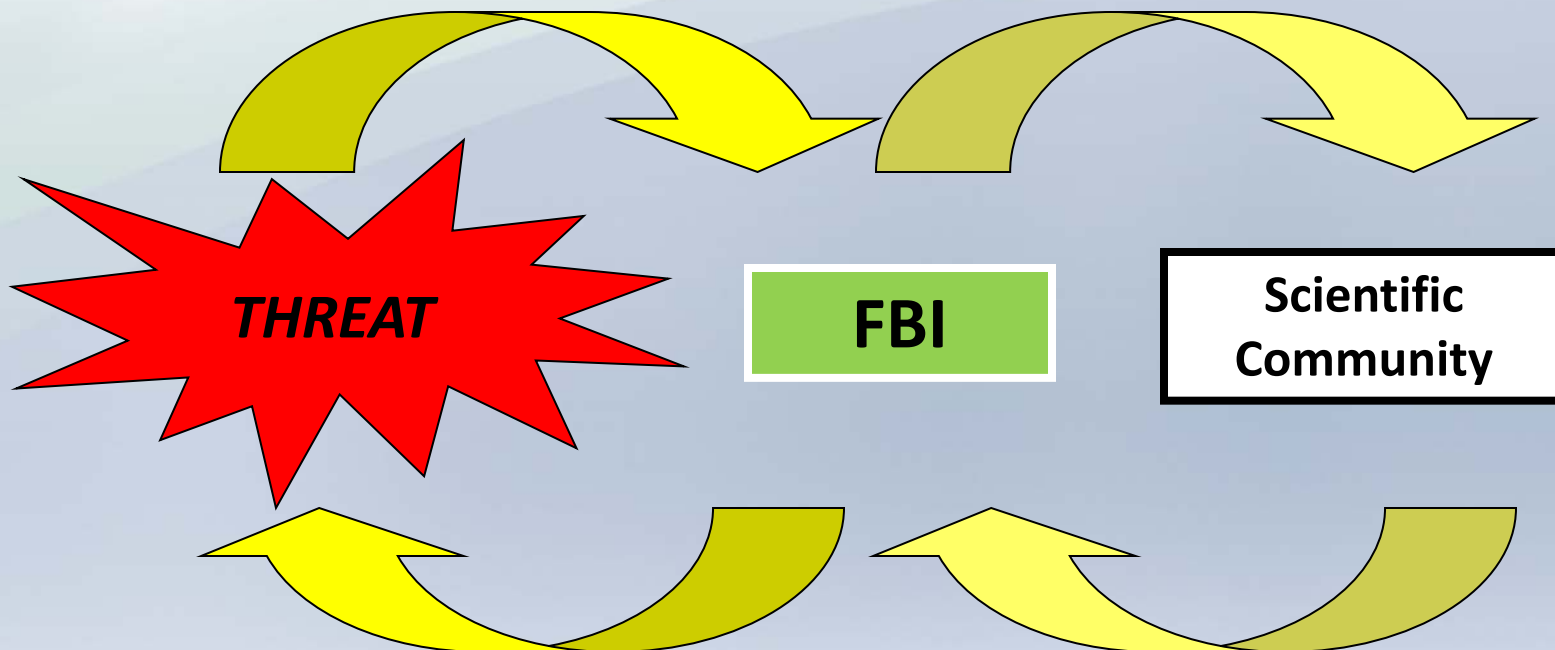
FBI Synthetic Biology Tripwire Initiative

- 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
 - Shared best practices with Germany and Canada during bilateral meetings (2009)

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



The Role of the FBI

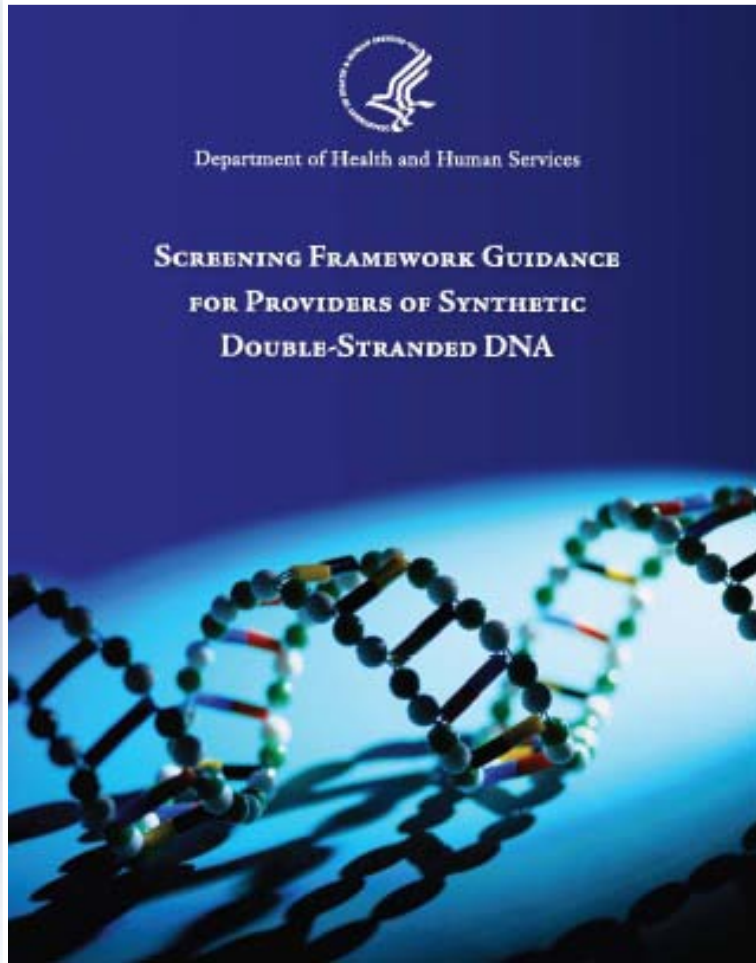


Meeting the Biosecurity Challenge:

- **Outreach**
- **Partnership**
- **Risk Mitigation/Effective Policy Making**



Federal Guidance to Synthetic DNA Providers



1. Customer Screening
2. Sequence Screening
3. Follow-Up Screening
4. Government Notification
 - FBI WMD Coordinator
 - Dept. of Health and Human Services
 - Dept. of Agriculture
 - Dept. of Commerce

Goal: Reduce risk of misuse while promoting science



International Genetically Engineered Machine Competition



2010 iGEM team helps prevent rogue use of synthetic biology



VIRGINIA BIOINFORMATICS INSTITUTE
AT VIRGINIA TECH



Bronze Medal, Safety Commendation



Federal Experts Security Advisory Panel Recommendations Concerning the Select Agent Program

1. Designation of Tier 1 BSAT
2. Reduction in the number of BSAT on the Select Agent List
3. Establishment of appropriate practices to ensure reliability of personnel with access to Tier 1 BSAT at registered facilities
4. Establishment of appropriate practices for physical and cyber security for facilities that possess Tier 1 BSAT



Behavioral Threat Assessment and Management Team

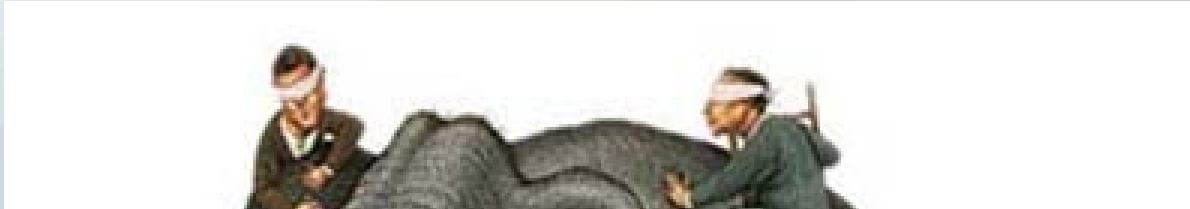
The Behavioral Threat Assessment and Management Team exists to mitigate behavioral threat on campus through an integrated process of:

Communication
Education
Prevention
Problem Identification
Assessment
Intervention
Response to Incidents



Dual Use?

Proper Handling of
Materials?



Culture of Responsibility and Security



Physical Security?

Exploitation?



Remarks by President Obama in Address to the United Nations General Assembly

United Nations
New York, New York

The White House
Office of the Press Secretary
For Immediate Release
September 21, 2011



To stop disease that spreads across borders, we must strengthen our system of public health. We will continue the fight against HIV/AIDS, tuberculosis and *malaria*. We will focus on the health of mothers and of children.

And we must come together to prevent, and detect, and fight *every kind of biological danger -- whether it's a pandemic like H1N1, or a terrorist threat, or a treatable disease.*

And today, I urge all nations to join us in meeting the WHO's goal of making sure all nations have core capacities to address public health emergencies in place by 2012. That is what our commitment to the health of our people demands.





Select Agent Program Workshop

November 2011

For more information, please contact the Select Agent Program

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Select Agent Program.

