

[redacted]

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**From:** [redacted]  
**Sent:** Wednesday, February 02, 2011 5:21 PM  
**To:** [redacted]  
**Cc:** [redacted]  
**Subject:** RE: Columbia professor Cole

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b7C

Hi [redacted]

Although WMDD has not provided a public statement, our role (CJIS background database checks) has been commented in several reports. I'd be happy to forward copies to you. Bottom line, we are just the gatekeepers. Once individuals have entered the Select Agent program, it is incumbent upon the scientific community to monitor themselves. We definitely do not regulate the materials or the research.

The reports I mentioned were drafted by the National Science Advisory Board for Biosecurity and the National Research Council (no slouches). That should provide credible rebuttal material.

Hope this helps.

Regards,

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 [redacted]  
 Supervisory Special Agent

[redacted]  
 FBI Weapons of Mass Destruction Directorate

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**From:** [redacted]  
**Sent:** Wednesday, February 02, 2011 5:13 PM  
**To:** [redacted]  
**Cc:** [redacted]  
**Subject:** FW: Columbia professor Cole

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b7C  
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[redacted]

The FBI's National Security Higher Education Advisory Board (NSHEAB) Chairman, Penn State President Graham Spanier, is speaking at a big meeting of the American Council on Education in about a month. He is expecting criticism of the FBI related to the book mentioned below, which was written by a former Columbia University official. Do you know if WMDD has released any public statements refuting the allegations made in the book? It may be a long-shot, but I need to ask.

Thank you, [redacted]

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2/3/2011

**From:** [REDACTED]  
**Sent:** Wednesday, February 02, 2011 4:12 PM  
**To:** [REDACTED]  
**Subject:** Columbia professor Cole

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b7C

This is just FYI for you. I'm working on collecting "successful examples" and will get that to you later.

Columbia Provost position-

1989-1994 Jonathan R. Cole, Provost

1994-2003 Jonathan R. Cole, Provost and Dean of Faculties

There have been 2 provosts since Cole.

His book: **The Great American University: Its Rise to Preeminence, Its Indispensable National Role, Why It Must Be Protected.** Jan. 2010

It gets mixed reviews on Amazon.  
Cole is a sociologist.

Regarding his allegations in the interview/book:

His example is about research with toxins and viruses. I believe Cole is wrong when he lists "FBI." It appears it is HHS that has the control. To work in some labs basic background name checks need to be made, and that can be any DOJ entity...I presume. I've never heard of the [REDACTED] I don't know what "reporting requirements to the FBI" he is talking about, unless it is the background checks. There are reporting requirements to HHS. Maybe WMD would know more.

b7E

Here are some articles on the topic.

**Source:** Chronicle of Higher Education, May 24, 2002.

### **Bioterrorism Legislation Puts New Scrutiny on Researchers, Allows Current Projects to Continue**

By RON SOUTHWICK

Congress approved bioterrorism legislation this week that would give universities more responsibility for guarding biological agents they use in research, but would not greatly disrupt such studies, college lobbyists say.

The legislation, HR 3448, would provide \$4.6-billion to state programs and improve federal laboratories. It represents a compromise of competing bills that had previously passed the House of Representatives and the Senate. The Senate approved the compromise measure on Thursday, a day after the House overwhelmingly passed it by a vote of 425 to 1. President Bush is expected to sign the bill.

Under the legislation, every university and laboratory that works with "select agents" -- defined as biological material that could be used to pose a public health threat -- would have to be registered with the U.S. Department of Health and Human Services or the U.S. Department of Agriculture. Current law requires only laboratories that ship such materials to be listed with the government. Lawmakers have complained that they do not have a clear idea of how many people are working with potentially dangerous biological materials.

The legislation would impose new steps designed to limit access to 42 biological agents, including anthrax, the Ebola virus, and smallpox. The bill would bar from working with those materials any scientists from countries that are listed as sponsoring terrorism, including Iraq and Iran, and any researchers with criminal records. However, all scientists handling such agents -- including U.S. citizens -- would have to be screened by the government.

College lobbyists say it is unlikely that a university researcher currently working with biological materials or toxins would be restricted from such work in the future. Lobbyists said they were especially pleased that the

legislation spells out that scientists who are in the midst of a research project will be allowed to continue their work while the government performs its background checks.

"We were very concerned that there would be a period of time when research would come to a halt," said Janet Shoemaker, director of public affairs for the American Society for Microbiology.

Under the terms of the bill, colleges would have to submit the names of researchers studying biological agents to the Department of Health and Human Services. Universities would also have to get clearance for scientists doing research on plant and animal pathogens for the U.S. Department of Agriculture. The U.S. attorney general's office would conduct the background checks, a step sought by college lobbyists, who had feared that research institutions would have to perform screening themselves.

If a university wished to hire a new scientist to work on select agents, that person would not be allowed to begin work on those materials until the screening is complete. The legislation also includes provisions for an appeals process if the government denies approval.

While college lobbyists are glad that universities themselves will not be responsible for screening employees, some wonder how long the government reviews will take, Ms. Shoemaker said.

In the event of an emergency, the measure would allow scientists to work on biological agents without being screened. Researchers had feared that in a crisis involving bioterrorism, scientists would lose valuable time waiting to gain clearance.

The Health and Human Services Department and the Agriculture Department would each have to draw up regulations regarding the study of biological agents. College lobbyists said they would work with the agencies to see that those rules do not go beyond the protections spelled out in the bioterrorism legislation.

The Centers for Disease Control and Prevention would get \$300-million to modernize its laboratories under the legislation. Lawmakers in Congress, chiefly Sen. Arlen Specter, a Pennsylvania Republican, have said that the center's facilities are in dire need of upgrades.

Here's a link to a pdf that compares and analyzes the "Public Health Security and Bioterrorism Preparedness and Response Act of 2002" to a prior law.

<http://www.unh.edu/ehs/pdf/Biosafety-Regulations-Compared.pdf>

*This seems to be a fairly balanced review of the idea.*

<http://harvardmagazine.com/2003/11/bioterrorism-and-the-uni.html>

[Redacted]  
Intelligence Analyst  
[Redacted]

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**NATIONAL  
SCIENCE  
ADVISORY  
BOARD FOR  
BIOSECURITY**

**Enhancing Personnel Reliability among  
Individuals with Access to Select Agents**



**Report of the  
National Science Advisory Board for Biosecurity  
(NSABB)**

**May 2009**

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## **ABBREVIATIONS AND ACRONYMS**

<b>APHIS</b>	Animal and Plant Health Inspection Service
<b>ARO</b>	Alternate Responsible Official
<b>CDC</b>	Centers for Disease Control and Prevention
<b>DoD</b>	Department of Defense
<b>DOE</b>	Department of Energy
<b>DURC</b>	Dual Use Research of Concern
<b>FBI</b>	Federal Bureau of Investigation
<b>HHS</b>	Department of Health and Human Services
<b>IBC</b>	Institutional Biosafety Committee
<b>NIH</b>	National Institutes of Health
<b>NSABB</b>	National Science Advisory Board for Biosecurity
<b>PI</b>	Principal Investigator
<b>PRP</b>	Personnel Reliability Program
<b>RO</b>	Responsible Official
<b>SRA</b>	Security Risk Assessment
<b>USG</b>	United States Government
<b>USDA</b>	United States Department of Agriculture

## Executive Summary

***NSABB charge and key considerations.*** In response to heightened security concerns surrounding the potential misuse of dangerous pathogens within research settings, the National Science Advisory Board for Biosecurity (NSABB) has been charged with recommending to the United States Government (USG) strategies for enhancing personnel reliability among individuals with access to select agents and toxins.<sup>1,2</sup> The challenge inherent in addressing the risk of the “insider threat” to high-containment biological facilities is to effectively address biosecurity concerns without unduly hindering the pace of life sciences research. Indeed, security measures that are overly burdensome could serve as a powerful disincentive to those who wish to and will responsibly conduct research on select agents, while measures that are too weak could leave the U.S. vulnerable to those who wish to misuse select agents toward malevolent ends.

***Select agent research is critical to public health and national security.*** Scientific research on highly pathogenic microorganisms and toxins underpins our ability to successfully combat infectious diseases affecting humans, animals and plants, and enables the development of effective countermeasures against bioterrorism threats. An in-depth understanding of biological select agents has been essential to the development of new and improved detection and diagnostic capabilities; antimicrobial and antitoxin treatments, and preventative measures. Such research has been responsible for the development of numerous vaccines, therapeutic antibodies, antimicrobial treatments, and strategies aimed at augmenting the human immune response to more effectively target pathogens. Historically, research on pathogens or toxins that are now designated select agents, such as the variola virus, has resulted in vaccines and/or therapies that have greatly reduced the rates of human morbidity and mortality across the globe, and, in turn, significantly lengthened the human lifespan. Such research conducted on plant and animal pathogens has greatly contributed to the development of a safe and nutritious food supply that is readily available at a fairly low cost. In addition, select agent research is critical to developing rapid detection and diagnostic technologies that will greatly enhance our capabilities to respond to disease outbreaks and acts of bioterrorism.

***Controls on access to select agents were significantly strengthened after the anthrax mailing incident.***<sup>3</sup> After the terrorist attacks in 2001, various laws and regulations have been enacted to more rigorously control access to select agents, including an expansion of the Select Agent Rules<sup>4</sup> to require that all entities that possess, use, or transport select agents must register with

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<sup>1</sup> Meeting of the National Science Advisory Board for Biosecurity, December 10, 2008, [oba.od.nih.gov/biosecurity/nsabb\\_past\\_meetings.html](http://oba.od.nih.gov/biosecurity/nsabb_past_meetings.html) (accessed April 15, 2009).

<sup>2</sup> Select Agents are biological agents and toxins that have the potential to pose a severe threat to public, animal, or plant health, or to animal or plant products, and whose possession, use, and transfer are regulated by the Select Agent Rules (7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73). The current *List of Select Agents and Toxins* can be found at [www.cdc.gov/od/sap/docs/salist.pdf](http://www.cdc.gov/od/sap/docs/salist.pdf) (accessed April 15, 2009).

<sup>3</sup> Spores of *Bacillus anthracis*, the pathogen that causes the disease known as anthrax, were sent through the mail in 2001. The NSABB notes that the colloquial expression “anthrax mailing” is imprecise as anthrax, the disease, was not mailed; however, this phrase is commonly used to refer to the mailing of these spores.

<sup>4</sup> The Select Agent Regulations are: *Possession of Biological Agents and Toxins*, 7 CFR Part 331; *Possession, Use, and Transfer of Select Agents and Toxins*, 9 CFR Part 121; and *Select Agents and Toxins*, 42 CFR Part 73. The text

the Centers for Disease Control and Prevention (CDC) or the U.S. Department of Agriculture (USDA) and that personnel who have access to these materials must undergo a Security Risk Assessment (SRA). The expanded Select Agent Rules also described security, inventory, and personnel training requirements. In addition, there are civil and criminal penalties for non-compliance with the Select Agent Rules.

***Personnel Reliability Programs address the insider threat.*** Research programs that have utilized materials that are deemed sensitive from a national security perspective (i.e., nuclear and chemical weapons programs) have addressed the insider threat as a component of larger “surety” programs. Surety programs contain features aimed at ensuring that the materials are physically secure, safely handled, and properly inventoried. Surety programs also have formal personnel reliability components to help ensure that the individuals with access to sensitive materials are trustworthy and reliable. These formal Personnel Reliability Programs (PRPs) may include background investigations, security clearances, medical examinations, psychological evaluations, polygraph testing, drug and alcohol screening, credit checks, and systems of ongoing monitoring.

***Select agent research poses unique security challenges.*** Biological select agents are unlike nuclear and chemical surety material in fundamental ways that make biological select agents unsuitable for traditional surety programs. First, most current biological select agents and toxins are naturally occurring and can be isolated from natural sources, such as endemic areas, soils, or infected hosts, well beyond the safe confines of laboratory walls.<sup>5</sup> Even if the physical security of pathogens contained within research facilities could be fully guaranteed, these measures would at best only partially mitigate the overall risk of a harmful application of these agents. Second, whereas nuclear and chemical materials exist in discrete quantities, most biological select agents are *living* organisms that can be grown into large quantities from a minimal starting sample, manipulated in non-laboratory settings, and disseminated. These attributes make attempts to maintain accurate inventories far more challenging.

Further distinguishing biological agents from nuclear or chemical surety material are the very natures of their respective research programs. The original PRPs were implemented for federal research programs that were “born classified” and applied to participants for whom strict security measures in the workplace were routine. Conversely, virtually all research on biological select agents is unclassified,<sup>6,7</sup> and much of it is conducted in university settings that have a long history of openness, national and international collaboration, and ready sharing of research

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of these regulations is available at [www.selectagents.gov/agentToxinList.htm](http://www.selectagents.gov/agentToxinList.htm) (accessed April 15, 2009) and the Government Printing Office, Code of Federal Regulations, [www.gpoaccess.gov/cfr/](http://www.gpoaccess.gov/cfr/) (accessed May 1, 2009).

<sup>5</sup> The disease smallpox has been eradicated in nature but the causative agent, variola virus, exists in two repositories as designated by the World Health Assembly under resolution WHA 33.4: the CDC, in Atlanta, Georgia, and the State Center of Virology and Biotechnology (VECTOR), in Kotsovo, Russia.

<sup>6</sup> The Department of Health and Human Services is the largest provider of grants and contracts for select agent research and does not fund classified research. This research is aimed at developing vaccines, therapeutics, and diagnostics against diseases caused by bioterrorism agents to help first responders provide treatments to patients exposed to bioterrorism agents. See [www3.niaid.nih.gov/](http://www3.niaid.nih.gov/) for more information about this research. In addition, the USDA conducts research and develops countermeasures against plant and animal pathogens. Neither the USDA nor the National Science Foundation funds or conducts any classified work.

<sup>7</sup> The small fraction of individuals conducting classified research on select agents is subject to rigorous security and personnel reliability measures.



materials. This culture of openness has a long and fruitful history in academia that includes research on pathogens that have only relatively recently been designated “select agents.”

***Mandating a national Personnel Reliability Program could have unintended consequences within the life sciences research community.*** Although the risk of the insider threat is uncertain, it is likely quite small based on history. Even in the open climate that is the hallmark of most life sciences research, the overwhelming majority of such research – including select agent research – has been conducted by responsible researchers toward commendable aims. The potential benefits of enhanced personnel reliability measures must be carefully weighed against the potential negative consequences that such measures would likely have on the research community. A robust and agile research enterprise that has access to a diverse workforce and spans government, private, and academic sectors provides innumerable benefits to society. The promulgation of additional reliability measures could serve as a powerful disincentive to those who wish to and would responsibly conduct research on select agents because the most talented young researchers, those with many options for research paths, may be far more likely to enter fields with less onerous regulatory requirements. Thus, a burdensome national personnel reliability program may not only drive scientists from important select agent research, but also drive select agent research out of academia and potentially out of the U.S. into countries with less stringent regulations. Furthermore, the institution of onerous reliability measures could isolate select agent researchers from the mainstream scientific community, isolation that might inhibit research and paradoxically increase the risk of the insider threat.

***NSABB approach.*** The NSABB Working Group on Personnel Reliability was briefed on many extant personnel reliability programs, as well as safety and security measures, established for chemical, nuclear, and select agent research programs. The group reviewed extant models for ensuring personnel reliability with particular interest in the costs, impact, and effectiveness that such measures would have on the scientific enterprise, as well as the feasibility of their implementation nationally in academic settings.

***NSABB findings.*** During its deliberations, the NSABB Working Group on Personnel Reliability found that 1) the select agent program has been significantly strengthened since 2001 to include measures that address personnel reliability; 2) local institutions already do an extremely effective job at screening individuals requiring access to select agents as evidenced by the extremely low rate of individuals who receive unfavorable SRAs; 3) there is very little evidence that supports the effectiveness and predictive value of many additional assessments that would be conducted under PRPs with respect to the assessments’ ability to detect the traits or individuals who pose an insider threat; and 4) engaged institutional leadership has been cited often as the most effective way to mitigate the risk of an insider threat.

***NSABB recommendations.*** In light of these findings, the NSABB recommends the following:

- 1. It is appropriate to enhance extant personnel reliability measures, but the promulgation of a formal, national Personnel Reliability Program is unnecessary at this time.** The NSABB has concluded that 1) the select agent regulations have already been significantly strengthened to appropriately address the possibility of an insider threat; 2) there is currently insufficient evidence of the effectiveness of PRP measures