

# Bio & Terror Bible

## EXPOSING THE COMING BIO-TERROR PANDEMIC

**BIOTERRORBIBLE.COM:** The following news and events are in respect to bio-terror and pandemic related legislation which occurred within the calendar year of 2010. The American government, more than any other nation, has been systematically preparing its population for an upcoming bio-terror related pandemic by passing draconian bio-terror legislation in the wake of the 9/11 attacks.

**LEGISLATION:** [Bio-Terror Legislation \(2001\)](#), [Bio-Terror Legislation \(2002\)](#), [Bio-Terror Legislation \(2003\)](#), [Bio-Terror Legislation \(2004\)](#), [Bio-Terror Legislation \(2005\)](#), [Bio-Terror Legislation \(2010\)](#), [Bio-Terror Legislation \(2011\)](#), and [Bio-Terror Legislation \(2012\)](#).

**Title:** Remarks By The President In State Of The Union Address

**Date:** January 27, 2010

**Source:** [White House](#)

**Abstract:** That's the leadership that we are providing -- engagement that advances the common security and prosperity of all people. We're working through the G20 to sustain a lasting global recovery. We're working with Muslim communities around the world to promote science and education and innovation. We have gone from a bystander to a leader in the fight against climate change. We're helping developing countries to feed themselves, and continuing the fight against HIV/AIDS. And we are launching a new initiative that will give us the capacity to respond faster and more effectively to bioterrorism or an infectious disease -- a plan that will counter threats at home and strengthen public health abroad ([White House, 2010](#)).

**Title:** Ireland Calls For Tougher Restrictions On Bioweapons

**Date:** February 11, 2010

**Source:** [Bio Prep Watch](#)

**Abstract:** A spokesman for Ireland's Labour Party has called for new legislation banning biological weapons to also include the prohibition of transmission of bioweapons through Irish airspace.

"There is evidence of the use of biological weapons in practically every other major conflict, so this legislation is urgent," a Labour TD told the Irish Times. "It is very important that we not only prohibit any work in this regard but also, as a country interested in international law, that we bring forward the legislation dealing with Shannon

Ireland's Cabinet approved the Biological Weapons Bill this week, which prohibits the use, development, production, manufacture, possession, stockpiling, acquisition and retention or transfer of biological weapons.

Ireland's new ban will apply to all vessels and aircraft registered in Ireland as well as to members of the Defence Forces and citizens of Ireland outside of the nation.

Michael Higgins, the spokesman on foreign affairs for Labour, told the Irish Times that the bill, as it currently stands, does not extend the ban to the transmission of biological weapons through Shannon and other airports.

Higgins also said that the bill should be brought forward in conjunction with the newly announced Air Navigation Bill, which is being discussed by the Cabinet subcommittee on extraordinary rendition ([Bio Prep Watch, 2011](#)).

**Title:** Biosecurity Laws Hobble Research

**Date:** May 10, 2010

**Source:** [The Scientist](#)

**Abstract:** Ever since the U.S. government has taken steps to protect and encourage research involving pathogens that could be used as biological weapons, that research has become much less efficient, according to a new analysis.

Though funding for research on so-called "select agents," or pathogens that can be used as weapons, has shot through the roof, and the number of papers using those organisms has risen in recent years, the work has become up to five times less efficient -- meaning, the same amount of funding produces fewer papers than it did before.

"The price of the research was multiplied by maybe a factor of 5 for anthrax and maybe a factor of 2 for Ebola," said Carnegie Mellon University associate professor [Elizabeth Casman](#), who led an [analysis](#) of the select agent literature that is published in this week's issue of the *Proceedings of the National Academy of Sciences*. Casman told *The Scientist* that her group found, for example, that prior to 2002, an average of 17 papers on anthrax were published for every \$1 million of funding, whereas after 2002, that average dropped to 3.

At issue, according to the analysis, are two laws designed to regulate select agent research: the [PATRIOT Act](#) and the [Public Health Security and Bioterrorism Preparedness and Response Act](#), enacted in 2001 and 2002, respectively.

The laws' new regulations govern the exhaustive documentation of the transportation, guarding, and use of select agents. As a result, they are burying researchers studying select agents with administrative duties, Casman noted. Researchers to whom Casman spoke "all complained of the paperwork," she said. "A lot of it, they just find overwhelming."

Some researchers told Casman that their work took twice as long to carry out because of all the paperwork related to select agents, and that money was being diverted from research expenses to pay for things like security cameras, hiring guards, and building walls. "It's expensive to comply with the regulations," Casman said.

"It is getting grossly impossible to do meaningful research," [Martin Hugh-Jones](#), Professor Emeritus at Louisiana State University and coordinator for the World Health Organization's Working Group on Anthrax Research and Control, told *The Scientist*. "The paperwork now is unbelievable," said Hugh-Jones, who Casman interviewed as part of the study.

Casman and her team also found that US labs working on anthrax or Ebola are also collaborating less with labs outside of the US, likely a result of restrictions in the laws. "International collaborations between a US author and a non-US author were inhibited," she said.

[Lisa Hensley](#), virologist and chief of the Viral Therapeutics and Virology Division at the US Army's Research Institute of Infectious Diseases in Maryland, agreed that it is much harder for her to work with foreign labs on projects involving Ebola or any of the other potentially weaponizable pathogens she studies. Also, Hensley told *The Scientist* that other countries have adopted stringent laws around working with select agents that mirror the US laws and create a "hesitancy by international partners to share viral stock samples with us."

For example, Hensley's lab has faced huge obstacles in obtaining a sample of a Crimean-Congo

hemorrhagic fever virus that killed a US Army soldier in Afghanistan last year. Hensley said that the soldier was taken to a German research institute for further study after his death, but that samples of the virus have not yet made it to her lab. "We've been trying for nine months to get the isolate shipped to us," she said, adding that the US Army enforces further regulations beyond those codified in the PATRIOT Act and other federal laws.

Hensley also noted that in 1998, when she first came to her Army lab, it took her about a month to get clearance to enter the BSL-4 facility, which is the highest security level lab, necessary to house and study Ebola virus. Now with all the background checks and psychological and medical testing required of laboratory workers, she said, "It easily takes close to 6-9 months from the time somebody walks into the door before they have access to a containment lab." And that's just to get into a BSL-3 lab to train to be in a BSL-4 lab.

Casman said that the key to increasing the efficiency and reach of select agent research starts with reducing the amount of paperwork required of researchers. For instance, they must record precise volumes of samples and submit those values to authorities -- even when moving droppers of virus or bacteria from one container to another within a lab. "There are certain things that can be done to make the lives of the scientists easier," Casman said. "Making the paperwork less absurd would really help."

Hensley, who was also interviewed by Casman as part of the study, said that she marshals on with her work, despite its administrative burden. "We accept all the regulations as the price of doing business, but it does slow down the timeline," she said. "It's just a much different world than it used to be" ([The Scientist, 2010](#)).

**Title:** Regulations Increase Cost Of Dangerous-Pathogen Research

**Date:** May 10, 2010

**Source:** [Nature](#)

**Abstract:** Complex US regulations governing experiments with dangerous pathogens and toxins have reduced research efficiency, according to a study published in the Proceedings of the National Academy of Sciences<sup>1</sup> this week. The average cost of a research paper on the Ebola virus has increased from about US\$59,000 to \$333,000 since the restrictive regulations were adopted in 2001–02.

But more researchers have entered the field and the number of publications has increased, despite concerns from some microbiologists that regulations were driving talented scientists away (see [Driven out of research](#)).

"Some of the worst fears about regulation becoming so intrusive that things couldn't get done have probably not been realized," says Kenneth Berns, a virologist at the University of Florida, Gainesville, and a member of the National Science Advisory Board for Biosecurity in Bethesda, Maryland.

The study, led by Elizabeth Casman of Carnegie Mellon University in Pittsburgh, Pennsylvania, evaluated the effects of two government acts on biomedical research — the Bioterrorism Preparedness and Response Act of 2002, and the USA PATRIOT Act that was passed about six weeks after the terrorist attacks on 11 September 2001. The two laws limit research with 'select agents' — pathogens such as *Bacillus anthracis* and toxins such as ricin that could potentially be used as bioweapons — and their measures include researcher background checks and training, protocols for handling the agents and extensive documentation at every stage of the research.

Some researchers decried the regulations, saying that they went too far and would smother the research needed to understand and develop treatments for biothreats. "We all agree that we need to be careful," says Arturo Casadevall, a microbiologist who works with *B. anthracis* at the Albert Einstein College of Medicine of Yeshiva University in New York. "But it is very difficult. The paperwork required is enormous."

In a survey published in 2009, 64% of 198 biodefence researchers reported a high level of concern that they might unintentionally violate the regulations and damage their careers in the process..

### **Bureaucratic tangle**

In the latest research, Casman and her colleagues gathered data on research publications involving two select agents: the Ebola virus and B. anthracis. They found that most researchers had started working with the pathogens after the biosecurity regulations were enacted, suggesting an influx of scientists into the field — even after accounting for a natural rise in research due to funding increases for the work.

This trend was not seen with authors of publications about *Klebsiella pneumoniae*, a bacterium that can infect people with weakened immune systems. Although concerns about the spread of antibiotic-resistant *K. pneumoniae* have stimulated research in the field, the bacterium is unlikely to be of use to terrorists and is not a select agent.

The number of collaborations for research into Ebola virus and B. anthracis — within the United States and internationally — has also grown, although international collaborations occur with fewer countries now that the biosecurity regulations are in place.

Despite these gains, there are signs that the procedures are a burden on the research community. Before 2002, there were 17 papers published on Ebola research for every \$1 million spent. This fell to three papers per \$1 million after 2002. The average number of *K. pneumoniae* publications fell only from 26 to 17 under the same conditions.

### **Case for Streamlining**

One problem with the policies is that some were based on the measures used to regulate nuclear-weapons research, says Vickie Sutton, director of the Center for Biodefense, Law and Public Policy at Texas Tech University in Lubbock.

For example, regulations require researchers to create an inventory of each sample of a select agent and to document any changes. A missing test tube would draw immediate attention from the US Centers for Disease Control and Prevention, says Sutton. But the system does nothing to prevent the use of samples withdrawn from a live culture to seed a new culture. "You could every day be giving this agent out to someone," she says. "It's nonsense."

Nevertheless, studies such as Casman's strengthen the case for streamlining the regulations. Some important steps have already been taken, says Casadevall. In 2008, for example, the US Department of Agriculture removed several plant pathogens from the select-agents list after they were deemed by researchers to pose little threat. "I'm optimistic that we'll work this out," he says, "but it will take time" ([Nature, 2010](#)).

**Title:** Study: Patriot Act Made Anthrax Research 5-6x More Expensive

**Date:** May 11, 2010

**Source:** [Discovery](#)

**Abstract:** The USA Patriot Act and the [Bioterrorism Preparedness Act](#), both enacted not long after the 9/11 attacks, contained measures to make it harder for anybody to get their hands on the kind of pathogens one might need to launch a bioterror attack. There was just one problem: The rules also slowed down and constrained our own scientists' abilities to learn about those pathogens, according to a [study](#) out this week in the *Proceedings of the National Academy of Sciences*.

To be specific, lead researcher Elizabeth Casman found while there was a touch of good news—the laws didn't appear to deter new scientists from entering the field—the major effect of those acts has been to make research on ebola virus and anthrax much more expensive, and much slower.

The researchers did find an increase in the total number of papers published. But before the laws, 17 anthrax papers appeared per million dollars of funding. With the restrictions, only three papers appeared per million dollars of funding. For ebola, the numbers dropped from 14 to six papers per million dollars. Figures for the control stayed the same

In other words, a scientific paper on anthrax became five or six times more expensive, and a paper on ebola twice as expensive. And a lot of the problem is simply the exhaustive record-keeping required.

The laws' new regulations govern the exhaustive documentation of the transportation, guarding, and use of select agents. As a result, they are burying researchers studying select agents with administrative duties, Casman noted. Researchers to whom Casman spoke "all complained of the paperwork," she said. "A lot of it, they just find overwhelming".

One might argue that the paperwork headaches are worth it if they keep our samples of deadly pathogens secure (especially after an affair like [the Bruce Ivins case](#), in which the longtime Army researcher ~~was convicted for~~ was the lead suspect in the 2001 anthrax attacks before [he died in 2008 in an apparent suicide](#)). But biodefense policy expert Vickie Sutton told [Nature](#) that the Patriot Bioterrorism Preparedness acts aren't securing out lab supplies of ebola and anthrax—they're just slowing down our own knowledge about them.

For example, regulations require researchers to create an inventory of each sample of a select agent and to document any changes. A missing test tube would draw immediate attention from the US Centers for Disease Control and Prevention, says Sutton. But the system does nothing to prevent the use of samples withdrawn from a live culture to seed a new culture. "You could every day be giving this agent out to someone," she says. "It's nonsense" ([Discovery, 2010](#)).