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 2011. 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: $1B Effort Yields No Bioterror Defenses
Date: January 17, 2011
Source: Boston.com

Abstract: The Pentagon is scaling back one of its largest efforts to develop treatments for troops and civilians infected in a germ warfare attack after a $1 billion, five-year program fell short of its primary goal. Even the heavy infusion of research cash and a unified effort by university labs and biotech companies from Boston to California were insufficient to break through limitations of genetic science, according to government officials and specialists in biological terrorism.

Instead, the Pentagon's next $1 billion for the Transformational Medical Technologies program will focus on better ways to identify mutant versions of Ebola, Marburg, and other deadly viruses. Those are among the genetically modified agents that officials fear could be used by terrorists or rogue states against urban or military targets.

The continued flow of money, even with the shift in strategy, should help Massachusetts and other states retain jobs and research labs focused on this arena.

"There is tremendous potential for further development of a biodefense subcluster in the state,'' said James D. Rooney, vice president of the Massachusetts High Technology Council.

Among Bay State firms that have received contracts under the germ warfare effort is Worcester-based Microbiotix. Representatives from Microbiotix did not respond to requests for comment.

The new strategy represents a return to the drawing board for an ambitious program conceived after the Sept. 11 terrorist strikes and subsequent mailing of anthrax to members of Congress and media organizations — events that helped US military planners realize that the nation lacked adequate defenses against bioterrorism.

Scientists initially set out to develop new medicines capable of attacking viruses that might be altered by terrorists to make them more deadly. But after more than 50 research projects by more than 100 contractors — including biotech firms, pharmaceutical companies, and universities, including several in the Boston area — only two experimental medicines have shown promise. And even those are far from being ready for limited clinical tests, according to project officials.

“They are trying to come up with new medical technologies that are more difficult to develop,’’ said Crystal Franco, a specialist at the Center for Biosecurity at the University of Pittsburgh Medical Center who specializes in biological defense policy. “They are really trying to push the envelope.

Another hurdle in the government’s effort: such treatments cannot be tested in human clinical trials, which are typically required for Food and Drug Administration approval, because it is unethical to expose people to deadly virus in such a study, requiring animals with similar traits as humans to serve as surrogates.

Alan S. Rudolph, director of science and technology at the Defense Threat Reduction Agency, said in an interview that the agency will now focus more attention on ways of identifying new pathogens. That research could lay the groundwork for further advances in the development of antidotes that could eventually win FDA approval.

The new focus of the program will be making a “cadre of investments that are able to take an unknown sample that may contain different agents, and be able to determine very quickly what is in there,’’ Rudolph said. “It is our intent to continue to grow this capability.’’

He added the ultimate goal will still be to someday develop therapeutic remedies that could treat someone infected with any number of deadly viruses — what the Pentagon called “one size fits all’’ or “one drug, many bugs.’’

In addition to Ebola and Marburg, some of the potential biological threats on the Pentagon’s target list are Lassa, Sabia, Machupo, and Junin, especially modified versions designed to cause more severe symptoms of hemorrhagic fever that are more resistant to traditional drugs.

The difficulty in developing medicines so far, however, demonstrates how much more research is needed, say biological warfare specialists.

It turns out it is easier to modify a germ or virus for an offensive threat than it is to develop an effective defense, they said.

“The offensive capabilities outrun the defensive capabilities as the march of biology continues,’’ said Richard J. Danzig, a former Navy secretary and noted expert on bioterrorism who sits on the Pentagon’s high-level Defense Policy Board.

“The theory behind [the program] was these same advances should empower the defenses,’’ he said. “I think that intuition is worth exploring and investing in, but it is easier to conceive than to execute.’’

Margaret Kosal, an assistant professor at Georgia Tech who worked on the program between 2006 and 2007, said “there is a fundamental need for basic science. The low-hanging fruit has all been picked.’’

One Pentagon contractor involved in the program who was not authorized to speak publicly put it more bluntly: “We’re years away from any reasonable FDA certification, let alone production.’’

Franco said the project’s hurdles also highlight the need for ongoing taxpayer-investment commitments from government, to encourage private-sector focus on such technologies that will generate little in sales, compared to, say, cholesterol and diabetes treatments.

“These are not going to be blockbuster drugs,’’ said Franco. “It is different when the government is your only market. There needs to be incentives for companies to participate, to take it on for the public good’(Boston.com, 2011).

Title: Pentagon Retools Bio-Effort After $1 Billion Flop
Date: January 18, 2011
Source: Wired

Abstract: It was supposed to come up with antidotes for pathogens that terrorists might use for a mass-casualty bio-attack. But after spending over $1 billion during the last five years, the Pentagon's Transformational Medical Technology initiative can barely develop drugs ready for a clinical trial. That's why the officials tasked with running it are setting their research-subsidy targets much lower.

In a shift, the Defense Threat Reduction Agency's science and technology chief tells the *Boston Globe* that the bio-initiative will now invest money on early detection of new pathogens. That puts about another $1 billion worth of Pentagon cash closer to where science is, rather than throwing money at crash programs for undeveloped antidotes. Ultimately, the Pentagon wants to develop multi-pronged vaccines that can resist a variety of biological agents — what it calls "One Drug, Many Bugs." But that's a long way off: step one is understanding how those sicknesses develop.

The *Globe* reports that the program has hit one snag after another. Out of nearly 50 research programs, only two (unspecified) efforts to neutralize pathogens like Ebola and Marburg have shown promise, and they're not ready for clinical trial. Making matters worse for the program, the Food and Drug Administration doesn't allow experimenting on people, so Transformational Medical Technology would have to make do with animal surrogates.

It's also become something of an object of fun within the military's chem-bio community. Our pal Jason Sigger lamented the program's inability to come up with a lightweight, portable Tricorder-like bio-detection device. The office tasked with coming up with one still sought to buy a Cadillac, one networked into troops' communications system and that can also detect chemical weapons. "All they need to do is warn the individual that there's a bad bug nearby," Sigger wrote.

But don't expect the Pentagon to steer away from far-out bio-medical research. In 2009, Darpa wanted to create a bank of "universal immunity donor cells" to head bio-outbreaks off at the pass. More recently, in September, it doled out over $5 million so Arizona State University could experiment with growing vaccines with the aid of tobacco plants. "I don't know if we can pull this off, but I think this basic idea might work," one of the ASU researchers shrugged when the grant was announced.

Still, according to the *Globe*, if the military wants to speed up the day when it can deliver mass antidotes for a host of bio-threats, it's got to subsidize pharma companies' research in areas that won't yield the next generation of lucrative "blockbuster drugs." Bio-defense expert Crystal Franco of the Center for Biosecurity tells the paper, "It is different when the government is your only market. There needs to be incentives for companies to participate, to take it on for the public good." That is, until someone figures out how to make Viagra stop anthrax (Wired, 2011).

Title: S. 1814 CRS Summary
Date: November 7, 2011
Source: CRS

Abstract: National Disaster Medical System Act - Amends the Public Health Service Act to: (1) authorize appropriations for providing for the Assistant Secretary for Preparedness and Response and the operations of the National Disaster Medical System for FY2012-FY2016, and (2) authorize the Secretary of Health and Human Services (HHS) to determine and pay claims for reimbursement for health-related social services, other human services, and auxiliary services to respond to the needs of victims of a a public health emergency directly or by contract providing for payment in advance or by way of reimbursement (CRS, 2011).

Title: Bill To Strengthen Biopreparedness Introduced
Date: November 17, 2011
Source: Bio Prep Watch

Abstract: Four U.S. senators recently introduced a bill to help prepare the nation for the threat of a bioterror terror attack or a newly emerging pandemic.

Senators Richard Burr (R-North Carolina), Tom Harkin (D-Iowa), Mike Enzi (R-Wyoming) and Bob Casey (D-Pennsylvania) introduced the Pandemic and All-Hazards Preparedness Act Reauthorization Bill of 2011 as a bipartisan effort to ready the nation for a range of medical emergencies that could arise as a result of a chemical, biological, radiological or nuclear attack, according to PoliticalNews.me.

“The threats facing our nation are serious and we must address them accordingly,” Burr said, PoliticalNews.me reports. “The American people expect us to do all that we can to prevent an attack and, if one should occur, be fully prepared to respond, including having safe and effective medical countermeasures readily available. While key progress has been made since PAHPA was signed into law, more work remains to be done.”

The original legislation, passed in 2006, took steps to organize how the federal government would respond to an attack or new pandemic in partnership with state and local governments. The U.S. response to the H1N1 pandemic has since provided lessons that have been integrated into the reauthorization bill.

“This legislation redoubles our efforts to protect the American people by strengthening our existing programs and making targeted improvements in areas in which we know we must do better, including ensuring that our nation’s medical countermeasure enterprise reflects and is prepared to respond to modern-day threats,” Burr said, according to PoliticalNews.me (Bio Prep Watch, 2011).

Title: H.R.2405 CRS Summary
Date: December 7, 2011
Source: CRS

Abstract: Pandemic and All-Hazards Preparedness Reauthorization Act of 2011 - Amends the Public Health Service Act to revise and reauthorize appropriations for public health preparedness activities, including activities related to: (1) tracking the initial distribution of federally purchased influenza vaccine in an influenza pandemic, (2) state and local public health and medical preparedness and response, (3) improving hospital surge capacity, (4) expanding the capabilities of the Centers for Disease Control and Prevention (CDC) to respond effectively to bioterrorism and other public health emergencies, and (5) the operations of the National Disaster Medical System.

Reauthorizes appropriations for the special reserve fund for the procurement of security countermeasures. Allows 30% of such fund to be used by the Biomedical Advanced Research and Development Authority (BARDA) to coordinate the acceleration of advanced research and development of countermeasures and qualified pandemic or epidemic products.

Extends the time under which specific technical data or scientific information that is created or obtained during such advanced research and development is exempt from disclosure under the Freedom of Information Act (FOIA).

Authorizes the Secretary of Health and Human Services (HHS) to determine and pay claims for reimbursement for services provided during a public health emergency.

Amends the Pandemic and All-Hazard Preparedness Act to extend provisions granting an antitrust exemption for meetings related to countermeasures or pandemic or epidemic products.

Expands the duties of the Assistant Secretary for Preparedness and Response to include: (1) stockpiling and distributing qualified countermeasures, security measures, and qualified pandemic or epidemic products; (2) identifying gaps, duplication, and other inefficiencies in public health preparedness activities and the actions necessary to overcome these obstacles; and (3) leading the development of a coordinated Countermeasure Implementation Plan.

Gives the Assistant Secretary authority over and responsibility for BARDA.

Amends the Federal Food, Drug, and Cosmetic Act to require the Secretary: (1) to accelerate the development, stockpiling, approval, and licensure of countermeasures and qualified pandemic or epidemic products; (2) initiate a program of frequent scientific feedback and interactions regarding the process of developing each security countermeasure; and (3) develop a written regulatory management plan for each security countermeasure (CRS, 2012).