

# Bio Terror Bible

## EXPOSING THE COMING BIO-TERROR PANDEMIC

**BIOTERRORBIBLE.COM:** The following news and events are in respect to the field of bio-terror and pandemic related contracts 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 funding draconian bio-terror contracts in the wake of the 9/11 attacks.

**Title:** HHS Provides Funds For Hospital Bioterror Preparedness

**Date:** July 12, 2010

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

**Abstract:** The U.S. Department of Health and Human Services has announced that it will provide a total of \$390.5 million this month to help hospitals nationwide to strengthen medical capabilities.

The grants will increase the ability of hospitals and healthcare facilities to respond to the public health and medical impacts of any emergency, including bioterrorist attacks, natural disasters and disease outbreaks.

All states, including major metropolitan cities like Los Angeles and New York, will receive a portion of the funds through the federal Hospital Preparedness Program.

Specific goals of these funds will be to improve hospital communication systems, develop more reliable systems to track available hospital beds and to provide advance registration for volunteer health professionals. The money will also go towards funding processes for fatality management and hospital evacuations.

The Hospital Preparedness Program enhances the ability of hospitals and health care systems to prepare for and respond to bioterrorism and other public health emergencies.

During the past five years, HPP funds have also improved bed and personnel surge capacity, decontamination capabilities, isolation capacity, pharmaceutical supplies, training, education, drills and exercises.

Hospitals, outpatient facilities, health centers, poison control centers, EMS and other healthcare partners work with the appropriate state or local health department to acquire funding and develop healthcare system preparedness through this program ([Bio Prep Watch, 2010](#)).

**Title:** NIAID Awards \$46.3 Million In Vax Grants And Contracts

**Date:** September 1, 2010

**Source:** [Fierce Vaccines](#)

**Abstract:** The National Institute of Allergy and Infectious Diseases (NIAID) has awarded two grants to vaccine makers for anthrax and hepatitis B vaccines, respectively. Emergent BioSolutions received a contract worth up to \$28.7 million for its third generation anthrax vaccine. Dynavax Technologies, based in Berkeley, CA, received a portion of a five-year, \$17.6 million grant.

Emergent's new contract expands upon development efforts being conducted under a contract awarded in September 2008. The featured vaccine in the deal is a combination of the company's BioThrax vaccine and immunostimulatory VaxImmune. With this new contract, the potential funding from the U.S. government for this third generation anthrax vaccine candidate increases to more than \$58 million, according to a statement. Emergent has previously won contracts worth more than \$400 million for its anthrax vaccines, but the program seemed to be in trouble recently as [Congress considered axing \\$2 billion of Project Bioshield's \\$5.6 billion budget](#).

NIAID's other grant was awarded to Dr. Jacques Banchereau of the Baylor Institute of Immunology Research. Part of that grant will be spent on Dynavax Technologies' promising hepatitis B vaccine, Heplisav. After some initial issues, Heplisav has performed promisingly in trials.

"Heplisav...has already demonstrated an ability to protect certain patients, for example, the elderly and chronically ill who are normally less- or non-responsive to conventional vaccines," says Robert Coffman, Dynavax's chief scientific officer, in a release. "With this grant we have the opportunity to study the underlying mechanisms that affect a target population's ability to respond to immunization" ([Fierce Vaccines, 2010](#)).

**Title:** Emergent BioSolutions Inc. Signs Contract For Third Generation Anthrax Vaccine Candidate

**Date:** September 1, 2010

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

**Abstract:** Emergent BioSolutions Inc. has signed a contract for advanced development of its third generation anthrax vaccine candidate.

The contract, valued at up to \$28.7 million, was signed with the National Institute of Allergy and Infectious Diseases, an institute within the National Institutes of Health.

The third generation anthrax vaccine candidate is one of two such vaccines being developed as part of Emergent BioSolutions Inc.'s anthrax franchise, which consists of BioThrax in combination with CPG 7909, a novel immunostimulatory compound.

"Emergent applauds the U.S. government's commitment to protecting the nation against biological threats by supporting critical development of advanced vaccine and therapeutic candidates," Daniel J. Abdun-Nabi, president and chief operating officer of Emergent BioSolutions, Inc., said. "We believe our vaccine candidate addresses key criteria established by the government for a third generation anthrax vaccine. If successfully developed, we believe this product would strengthen the government's portfolio of biodefense medical countermeasures."

The four year development contract consists of a two year base that is valued at \$9.1. million. A milestone-based option increases the total contract value to up to \$28.7 million if exercised.

The base contract is meant to fund activities related to manufacturing and stability studies of Phase II clinical trial lots, process characterization and assay validation, and clinical trial preparation.

The Phase II clinical trial has an anticipated start date for the first quarter of 2012. Preliminary data is expected to be available in the second half of 2012 ([Bio Prep Watch, 2010](#)).

**Title:** General Dynamics Receives Contract For Bioagent Detection Systems

**Date:** September 13, 2010

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

**Abstract:** General Dynamics Armament and Technical Products has been awarded a \$30 million contract to produce joint biological point detection systems that will rapidly detect biological warfare agents.

The U.S. Army's Research, Development and Engineering Command Acquisition Center in Maryland awarded the biodefense firm the contract last month, officials said. The contract could have the potential value of up to \$300 million if all options are exercised, the officials said.

General Dynamics has supported the Army's Joint Biological Point Detection Systems program since 2001. Since that time, General Dynamics has delivered over 700 JBPDS units.

The JBPDS unit is a self contained instrument that is capable of rapidly detecting and identifying biological warfare agents. The JBPDS comes in several forms, ranging from a man-portable model to shelter-based, ship-based and trailer-mounted models, according to General Dynamics officials.

Bill Gural, vice president of detection systems, said he is excited about the contract.

"General Dynamics has and continues to deliver innovations that protect our troops and our country from evolving chemical, biological, and explosive threats," Gural said. "We look forward to continuing our work with the U.S. Army Research, Development and Engineering Command Acquisition Center for production of JBPDS."

General Dynamics Armament and Technical Product, headquartered in Charlotte, N.C., designs and produces high-performance armament systems, mobile shelter systems, and biological and chemical detection systems ([Bio Prep Watch, 2010](#)).

**Title:** Northrop Grumman Security Systems Among HHS Contract Winners

**Date:** September 21, 2010

**Source:** [U.S. Department of Health and Human Services](#)

**Abstract:** Eight contracts for products and technology to protect Americans awarded for \$55-\$100 million.

The U.S. Department of Health and Human Services' Biomedical Advanced Research and Development Authority (BARDA) announced the first eight contract awards under an initiative to help modernize and improve the nation's infrastructure for producing medical countermeasures that protect against natural and man-made biological threats.

The contracts help advance innovative tools and techniques that reduce the time and cost of development, testing, and production of medical countermeasures and that improve the safety, efficacy, and ease of use of these products. These contracts total \$55 million for the initial phase and up to \$100 million over three years.

Identifying innovative solutions to the challenge of preparing for and responding to public health emergencies is a key focus for BARDA under its authorizing legislation, the Public Health Service Act as amended by the Pandemic and All-Hazards Preparedness Act (PAHPA).

The importance of fostering innovation was strongly emphasized in *Public Health Emergency Medical Countermeasure Enterprise Review* released by HHS Secretary Kathleen Sebelius in August, which reviewed the federal government's system for producing medical countermeasures. The review found that

new technologies and approaches that allow the system to operate more efficiently are needed to overcome current bottlenecks and restrictions that can delay and limit an effective countermeasure response.

The eight contracts will support the development and evaluation of technologies that can apply to specific countermeasures, but may also have broader applicability and thus enhance the capabilities of the overall countermeasure infrastructure.

Recipients of the contracts are VaxDesign Corporation, Orlando, Fla.; PATH, Seattle, Wash.; Infectious Disease Research Institute (IDRI), Seattle, Wash.; Pfenex, Inc., San Diego; Novartis Vaccines and Diagnostics, Cambridge, Mass.; Rapid Micro Biosystems, Bedford, Mass.; 3M, St. Paul, Minn; and Northrop Grumman Security Systems, Baltimore, Md.

The contracts support the following innovations:

VaxDesign will further develop its MIMIC platform, an *in vitro* (test-tube-based) human immune system mimetic designed to accelerate evaluation of candidate and stockpiled vaccine safety and effectiveness by supplementing animal testing.

PATH will test multiple innovative formulation chemistries and strategies to increase the shelf-life of influenza vaccines, which has implications for the national vaccine stockpile as well as cold-chain requirements domestically and in developing countries.

IDRI will develop and evaluate innovative adjuvant formulations to enhance influenza vaccine immunogenicity and cross-protection to make them more effective against novel viral strains that may cause the next pandemic.

Pfenex will apply its innovative Pfenex Expression Technology Platform to the development of optimized bioprocesses for high yield production of a stable candidate anthrax vaccine.

Novartis Vaccines and Diagnostics will address a critical issue in the time required to begin manufacturing of influenza vaccine against a newly identified strain by investigating techniques for the rapid development of optimized influenza seed virus.

Rapid Micro Biosystems will address a critical issue in the time required for release of influenza vaccine after manufacturing by developing methods for accelerated sterility testing. Together, these improvements could shave weeks off the influenza vaccine manufacturing and product release schedule.

3M and Northrop Grumman will develop integrated diagnostic capabilities for rapid, high-throughput surveillance and molecular diagnostics.

In addition to fulfilling BARDA's mandate for innovation under the Public Health Service Act, several of these awards also directly address recommendations in the report from the President's Council of Advisors on Science and Technology on *Reengineering the Influenza Vaccine Production Enterprise*. Specifically addressed are technologies for influenza surveillance, seed virus generation, and sterility testing, as well as continued support of egg-based and adjuvant technology.

These contracts were awarded using a contracting tool called a broad agency announcement (BAA). The Innovations BAA solicits proposals for work in four broad categories of medical countermeasure development: technology to accelerate evaluation of candidate vaccines and therapeutics; formulation chemistry, protein stabilization, and vaccine delivery technology; innovative methods in bioprocess development and manufacturing; and methods and technology to advance development of diagnostic tests for rapid diagnosis of human infections.

A focus of the broad agency announcement is to identify “platform” technologies that have the potential to apply to multiple products and programs. Many technologies are first introduced to BARDA via its web portal, [www.medicalcountermeasures.gov](http://www.medicalcountermeasures.gov), and its TechWatch program, which provides an opportunity for external organizations to meet with the federal government to discuss their new and innovative medical countermeasure technologies.

These meetings provide the federal government with the latest information about emerging technology and inform strategic and programmatic planning for effective public health emergency response.

BARDA, within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services, provides a comprehensive integrated portfolio approach to the advanced research and development, stockpile acquisition, innovation, and manufacturing infrastructure building of the necessary vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products for public health medical emergencies including chemical, biological, radiological, and nuclear threats, and pandemic influenza, and emerging infectious diseases ([U.S. Department of Health and Human Services, 2010](#)).

**Title:** MRI Awarded Contract For Testing Of Chemical Weapon Protection System

**Date:** November 18, 2010

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

**Abstract:** Independent research organization Midwest Research Institute has been awarded an army contract to proceed with Phase IIa testing of their Individual Protection Ensemble Mannequin System.

The IPEMS will be used to test personal protection equipment against agents of chemical warfare.

The IPEMS consists of a free-standing, self-balancing robot that simulates human physiology and a chemical agent test facility. The mannequin will be dressed in IPE and tested in various simulated warfighter activities and environmental conditions in the presence of chemical agents.

The contract will allow MRI to fabricate and startup a novel test facility that can perform environmentally controlled testing on individual protection ensembles against the conditions of live chemical agent exposure.

“The IPEMS Critical Design Review was very successful and we are honored to add this project to MRI’s more than 40 years of experience in providing the U.S. Department of Defense with cutting-edge research, development, testing and evaluation in the areas of personal and collective protection, chemical and biological detection and decontamination,” MRI Senior Vice President and Director of Research Operations Thomas M. Sack said.

Phase I testing was completed in March 2010 and included the system’s design. Phase II will include the fabrication, building renovation, testing, procurement, assembly, installation and operator training of the system and will also include preparation of operating procedures and software development ([Bio Prep Watch, 2010](#)).