

Bio & Terror Bible

EXPOSING THE COMING BIO-TERROR PANDEMIC

BIOTERRORBIBLE.COM: When a major bio-terror attack and subsequent pandemic hit the United States of America, it will most likely be executed from behind the scenes by [Ezekiel Emanuel](#), soon to be known as the “Doctor of Death”. As it currently stands, the city of [Chicago appears to be bio-terror target #1](#) with Ezekiel’s brother [Rahm Emanuel](#) in the power position of mayor. Both Emanuel brothers are dual U.S. and Israeli citizens whose father is a known Zionist terrorist who conducted attacks for the [terror state of Israel](#) who will likely provide the pathogens for the future bio-terror attack.

Israel is the only modern nation that has not signed the 1972 [Biological Weapons Convention](#) (refusal to engage in offensive biological warfare, stockpiling, and use of biological weapons). Israel is also the only modern nation that has signed but not ratified the 1993 [Chemical Weapons Convention](#) (refusal to produce, stockpile and use chemical weapons). Should a future biological terror attack hit America or any other nation, the state of Israel and its citizens will be prime suspects.

The following government and non-government agencies, institutions and organizations also appear to be intimately involved in some aspect of the upcoming bio-terror attack: [BARDA \(Biomedical Advanced Research and Development Authority\)](#), [CDC \(Center for Disease Control\)](#), [Center for Biosecurity of UPMC](#), [EIS \(Epidemic Intelligence Service\)](#), [INTERPOL \(International Criminal Police Organization\)](#), [NBACC \(National Biodefense Analysis and Countermeasures Center\)](#), [NIAID \(National Institute of Allergy & Infectious Diseases\)](#), [NIH \(National Institutes of Health\)](#), [OBFS \(Organization of Biological Field Stations\)](#), [USAMRICD \(U.S. Army Medical Research Institute of Chemical Defense\)](#), [USAMRIID \(U.S. Army Medical Research Institute of Infectious Diseases\)](#) and the [WHO \(World Health Organization\)](#).

Title: Biomedical Advanced Research And Development Authority

Date: 2012

Source: [Wikipedia](#)

Abstract: The Biomedical Advanced Research and Development Authority (BARDA), within the [Office of the Assistant Secretary for Preparedness and Response](#) in the U.S. Department of Health and Human Services, provides an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies.

BARDA manages the procurement and advanced development of medical countermeasures for chemical, biological, radiological, and nuclear agents, as well as the advanced development and procurement of medical countermeasures for pandemic influenza and other emerging infectious diseases.

Requirements Setting

Medical countermeasure requirements in BARDA provide a solid foundation for establishing advanced development and acquisition programs that support the overarching ASPR mission of reducing the adverse health effects of public health emergencies, including those caused by pandemic influenza, CBRN threat agents and emerging diseases. These requirements are critical to establishing programs to meet our preparedness goals. They also create incentives for industry participation and shape the market for countermeasure products.

Requirements for medical countermeasures for CBRN threats are defined with input from stakeholders across the federal government within the structure of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). Once established, these requirements drive BARDA advanced development and acquisition programs, as well as research, development, and acquisition efforts in HHS. CBRN medical countermeasure requirements are consistent with the planning and prioritization expressed in the HHS PHEMCE Implementation Plan for CBRN Threats.

Pandemic Influenza requirements are defined by strategic objectives established in the National Strategy for Pandemic Influenza and the HHS Pandemic Influenza Plan.

Advanced Research and Development

From its inception, BARDA has been committed to creating a robust and dynamic pipeline of medical countermeasures through advanced development of new and improved medical countermeasures. The goal of medical countermeasure development is to provide multiple product candidates in each program to both account for attrition in medical countermeasure development and to establish multi-product/multi-manufacturer portfolios for sustainability and redundancy.

BARDA medical countermeasures include vaccines, antimicrobial drugs, therapeutic products, diagnostics and non-pharmaceutical medical supplies and devices for public health medical emergencies including chemical, biological, radiological, and nuclear threats, pandemic influenza and emerging infectious diseases. BARDA currently has three programs dedicated to overseeing the advanced development of these medical countermeasures: Chemical, Biological, Radiological, and Nuclear (CBRN); pandemic influenza; and emerging infectious diseases. BARDA's Influenza and Emerging Diseases Division is in the planning phase for its Emerging Infectious disease program. This program will, when stood up, support the advanced development of vaccine, therapeutic and diagnostic medical countermeasures that address emerging disease threats.

Integrated National Biodefense Medical Countermeasures Portfolio

Integrated National Biodefense Medical Countermeasure Portfolio "One-Portfolio Approach." The Department of Defense (DoD) and HHS each identify medical countermeasure requirements to address their different missions and focus. DoD's focus is on protecting the armed forces prior to exposure, whereas HHS's focus is on response to threats to the civilian population after exposure in a CBRN event. However, there are areas of common requirements or interest where medical countermeasure candidates, resources and information can be appropriately shared to maximize opportunities for success in the development of medical countermeasures for the highest priority threats. BARDA, in partnership with other HHS and DoD partners, is leading an Integrated National Biodefense Medical Countermeasure Portfolio to leverage resources and programs across the agencies that develop and acquire CBRN medical countermeasures to more effectively address the broad range of common threats and requirements. Members of this Integrated Portfolio include BARDA, biodefense programs in NIAID and other Institutes of NIH, and multiple elements of the DoD Chemical and Biological Defense Program

Stockpiling Programs

The [Pandemic and All Hazards Preparedness Act](#) (PAHPA) established BARDA as the focal point within HHS for the advanced development and acquisition of medical countermeasures to protect the American civilian population against Chemical, Biological, Radiological, and Nuclear (CBRN) and naturally occurring threats to public health.

BARDA's stockpiling efforts are focused on building reserves of critical countermeasures as they emerge from Advanced Development. Stockpiling contributes to preparedness in two ways.

1. Stockpiled medical countermeasures directly support readiness, as the stockpiled products can help to mitigate the effects of an event or outbreak.
2. Establishment of the stockpile helps to ready suppliers to meet the increased demands that an event will bring about, becoming practiced in the production and delivery of products.

BARDA's acquisitions for the stockpile are not one-time events, complete upon the approval/licensure of a product. Rather, programs are structured to include incremental milestone acquisitions during late stage development, to make available products still in development that may increase preparedness in an event, pending Emergency Use Authorization. Furthermore, we aim to establish stockpiling milestones to address long term commitments post-licensure.

CBRN Stockpiling Programs

In FY 2004, Congress appropriated \$5.6 billion to the [Project BioShield](#) Special Reserve Fund (SRF) to support the Project BioShield goal of acquiring CBRN medical countermeasures over a 10-year period. BARDA has used these funds to support major acquisition programs leading to procurement of medical countermeasures against top priority threats.

Pandemic Influenza Stockpiling Programs

Using funds from the Pandemic Influenza Emergency Supplemental Fund, BARDA is leading the nation toward the vaccine and antiviral stockpile goals for preparedness for pandemic influenza.

Manufacturing and Infrastructure Building

Ensuring the availability of medical countermeasures for public health emergencies is central to BARDA's mission. This includes ensuring that manufacturing infrastructure is sufficient to support the production of required products, in a manner that is timely, reliable and cost effective.

BARDA is taking several approaches to bringing online the necessary infrastructure for medical countermeasure manufacturing. We are supporting the construction of new facilities as well as retrofitting existing facilities for maximal capacity and flexibility. We are also exploring the use of multiproduct manufacturing facilities to provide flexibility and surge capacity. So that we are able to rapidly provide countermeasures in the dosage forms required for use in the field, we are establishing a network of formulation/fill-finish manufacturers for emergency production and distribution. BARDA is also exploring the creation of centers of excellence for the development and production of non-commercial products, with assistance from industry partners.

Advancing Innovation

The Pandemic and All Hazards Preparedness Act (PAHPA) charges BARDA to support innovation to reduce the time and cost of medical countermeasures and product advanced research and development. This is to be accomplished through development of technologies that assist the advanced development of countermeasures, investment in research tools and technologies, and research to promote strategic initiatives including rapid diagnostics, broad spectrum antimicrobials, and vaccine manufacturing technologies.

We see this innovation mandate as an opportunity to work with our partners (including NIH, DoD, CDC, industry, and academia) to create new ways to "make medical countermeasure better." Examples of this approach to innovation could include the development of animal models to support efficacy testing, immune modulation and other broad-spectrum approaches, immunity assessment, and analytical (potency) assays.

An example of innovation from the Pandemic Influenza program is BARDA's Mix and Match study, assessing various combinations of antigens and adjuvants to obtain a more robust immune response. BARDA plans to support similar initiatives, leveraging technology platforms and products from multiple companies. PAHPA provided an important "antitrust" authority that is used to facilitate cooperation among companies for whom such cooperation would otherwise be difficult to accomplish.

BARDA's Strategic Science Team helps bring innovation to our programs. This team is the focal point for discussions with the creators of new technologies, ideas, and products. Together with the program managers, they seek ways to integrate innovative science into the development and production of medical countermeasures ([Wikipedia, 2012](#)).

Title: BARDA To Exercise Option On Botulism Antitoxin

Date: June 6, 2011

Source: [Bio Prep Watch](#)

Abstract: The Biomedical Advanced Research and Development Authority, the agency within the U.S. Department of Health and Human Services that administers biodefense stockpiling contracts, will exercise options under a botulism antitoxin supply contract with Cangene Corporation.

The options are expected to generate \$61 million in additional revenue over the next few years for Cangene, one of Canada's first and largest biopharmaceutical companies. The delivery schedule for the botulism antitoxin will be extended to 2018 for the approximately 80,000 doses that remain.

By exercising the options, the total contract value for Cangene rises from \$362 million to \$423 million, for which Cangene has already recognized approximately \$200.1 million.

"This is an extremely positive step," Michael Graham, acting president and CEO of Cangene, said. "Not only does this significantly increase the total revenue value of this contract, it also indicates that BARDA is adopting a strategy of extending these types of contracts to replenish supplies of biodefense products. As the supplier for three products in the U.S. Strategic National Stockpile, that's an indication we are happy to see. It also provides for a consistent addition to our revenue stream for the next seven years."

In addition to the botulism antitoxin, the company has also introduced two other items to the U.S. Strategic National Stockpile – an anthrax immune globulin and a vaccinia immune globulin, which counteracts certain complications that can occur from smallpox vaccination ([Bio Prep Watch, 2011](#)).