Case Study

Protecting Homeland: US Biodefence Programme Post 9/11

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Reports of the US secret biodefence activities surfaced in 2001 and questions were raised regarding the nature of the following programmes: Project Jefferson, Project Bacchus and Project Clear Vision. A modest estimate shows that the US government has spent or allocated over \$ 40 billion since 2001, till the fiscal year 2008.

Bioterrorism is (...) a threat to every nation that loves freedom. It's important that we confront these real threats (...) and prepare for future emergencies."

US President George W. Bush, 12 June 2002.

"Bioterrorism is a high consequence but low probability event." While the debate over this statement continues to dominate national security discourse across the world, the United States of America (US) has been aggressively pursuing biodefence strategy to thwart any kind of threat emanating from a biological pathogen or weapon. Ever since Anthrax spores reached the US government offices through postal mails, the annual government spending on biodefence programmes increased manifold. The government has spent a substantial amount of its resources over the past six years to prepare and to protect the nation against any bioterrorist attack. This paper aims to discuss, or rather document, the emergence and growth of various national biodefence programmes with special reference to the US biodefence programme.

Historically speaking, the biodefence programme in the US was initiated in 1969 when the then President Richard Nixon ordered the destruction of all bio-weapons stockpile and terminated the offensive bio-warfare programme, under the directive of National Security Decision Memorandum (NSDM 35 and NSDM 44). Both the Memorandums outlawed offensive bio-weapon and toxin programmes respectively and authorized biodefence activities. This led to the establishment of the US Army Medical Research Institute of Infectious Disease (USAMRIID) at Fort Detrick, Maryland, primarily to continue the development of

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vaccines and antibiotic research. Again, in the 1980s, under **Programmatic** late Environmental Impact Statement (PEIS) which covered biological pathogen research, testing and evaluation, the US government clarified that its biodefence programme does not include weaponization of biological pathogens, thus, professing transparency about its activities. However, there was a shift from the 'policy of relative openness to secrecy in the 1990s,' and the US biodefence programmes maintained a low profile. Reports of secret biodefence activities surfaced in 2001 and questions were raised regarding the nature of the following programmes: Project Jefferson, Project Bacchus and Project Clear Vision. The last two projects were undertaken by the Defense Threat Reduction Agency (DTRA) and the Central Intelligence Agency (CIA), respectively.

The US biodefence programme continued to remain covert until the advent of Project BioShield in 2003, which was pursued overtly with government sanctions. Project BioShield became a law in July 2004. Under the Project, efforts have been made to develop and make available effective drugs and vaccines to protect civilian population against any biological and chemical weapon attacks. This is a ten-year programme that aims to acquire medical countermeasures for civilian use, for which the administration appropriated \$6 billion for 10 years, to purchase countermeasures to achieve three primary objectives:

- to expedite the conduct of National Institutes of Health (NIH) research and development on medical countermeasures (drugs and vaccines) based on recent scientific discoveries;
- 2. to give Food and Drug Administration (FDA) the ability to make new treatments available in emergency situations by establishing a fast-track system of safety approval and regulation for pharmaceutical companies; and

3. to ensure that resources are available to pay for "next-generation" medical countermeasures (drugs and vaccines) for Strategic National Stockpile programme, formerly the National Pharmaceutical Stockpile (NPS).

According to one conservative estimate, the biodefence spending and allocations since 2001 have reached approximately \$40 billion mark. Arguably, an increasing vulnerability towards bioterrorism, intentional use of disease causing pathogens by 'lone wolves' and natural outbreaks of emerging and remerging infectious diseases post 9/11, prompted the Washington administration to devise plans to protect the civilian population at large. Hence, germinated the idea of protecting Americans from biological weapons. At least 18 Homeland Security Presidential Directives (HSPDs) have been passed since 2001 and among them, three are directly related to the country's overall biodefence efforts. They are: HSPD-8 on National Preparedness (December 2003), HSPD-10 on Biodefence for the 21st Century (April 2004) and HSPD-18 on Medical Countermeasures against Weapons of Mass Destruction (WMDs) (January 2007). The classified version of HSPD-10, which is conceived by the Homeland Security Council (HSC), elaborates the US biodefence strategy. It specifies the duties and roles of each federal agency involved in biodefence, including, Department of Health and Human Services, Department of Homeland Security.

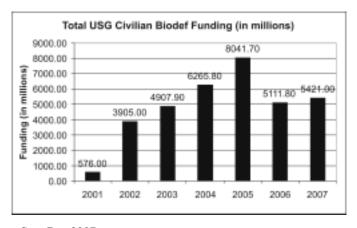
The unclassified version of HSPD-10 provides a comprehensive framework for the US biodefence programme; to protect America and Americans from any bio-terror attack in post 9/11 security environment. It out lines four essential pillars of overall US biodefence programme, with specific directives, namely:

 Set awareness with BW related intellegence, periodic vulnerability assessments and anticipation of future and emerging threats;

- 2. Prevention and Protection through interdiction and critical infrastructure protection;
- 3. Surveillance and Detection, which includes BW attack warning and attribution to ascertain the perpetrator and method of attack;
- 4. Response and Recovery with response planning, mass casualty care, risk communication, medical countermeasures, and decontamination.

Another major initiative is the BioWatch Programme under the Department of Homeland Security (DHS) for providing early warning of pathogen release with a series of pathogen detectors installed in various US cities along with Environmental Protection Agency (EPA)'s air quality monitors. Though it is not known exactly how many cities are covered under the BioWatch initiative, sources indicate that over 30 cities are presently covered and that it would soon cover another 90 cities. The BioWatch equipment is reportedly installed in the major cities of Philadelphia, New York City, Washington DC and Boston among others. The programme reportedly requested \$118 million in fiscal year 2005 to support and expand BioWatch, including development of improved monitors.

Figure-I Total Civilian BioDefence Funding (in Millions)

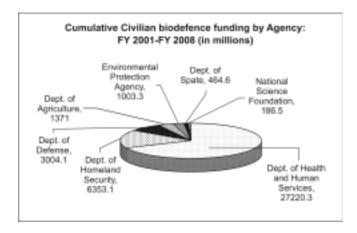


Largely, biodefence funding focuses on research and development, acquisition of medical countermeasures and protective medical equipment, surveillance, preparedness and environmental detection. Though there is no centralised resource for tracking civilian biodefence budgets and spending of over ten federal departments and agencies involved in this mammoth programme, a modest estimate shows that the US government has spent or allocated over \$40 billion since 2001, till the Fiscal Year 2008. The annual bioweapons related spending grew rapidly from Fiscal Year 2001 to Fiscal Year 2005 and reasonably decreased in subsequent years (See, Fig-I). Both, Department of Health and Human Services (DHHS) and Department of Homeland Security (DHS), are primarily responsible for civilian biodefence, and account for over 90 percent of budgeted funds. Among all the departments and agencies, DHHS topped the list of beneficiaries with \$27,220.3 million followed by the DHS with \$6,353.1 millions and Department of Defense (DoD) with 3,004.1 million. The DHHS funding is meant for its major constituent agencies and offices such as Food and Drug Administration (FDA), Resources Health and Services Administration (HRSA) and the Centers for Disease Control (CDC) among others. The CDC BioSurveillance initiative, a project to develop an early-warning system tracking the spread of dangerous biological agents, would receive a boost in Fiscal Year 2008. The other major agencies involved, namely Department of Agriculture, Environmental Protection Agency, Department of State and the National Science Foundation share approximately 3, 025.4 millions in this period (See Fig-II). In the Fiscal Year 2008, the outgoing Bush Administration has proposed an additional \$6.77 billion which is estimated to be \$550 million more than the amount that US Congress appropriated for Fiscal Year 2007.

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Figure-II

Cumulative Civilian BioDefence Funding FY 2001-FY 2008



These spending and infrastructural overhauling notwithstanding, many aspects of the biodefence programme has been criticized, especially the growing numbers of people involved in handling biological pathogens in sprouting biolabs and facilities around the country. One report stated that there are around 20,000 people working at 400 sites in the US, a ten-fold increase in research since 2001. These figures were given by the Sunshine Project which warned that all these biological defence efforts might produce an incident with greater consequences than an actual act of bioterrorism, either through an accident or by a deranged researcher. It cited cases of institutions carrying out research using live disease agents and the loopholes. Also, the group aired its reservations on the horizontal proliferation of biodefence programmes to other countries. Moreover, some US scientists, disputing the very premises and implementation of the biodefence spending,

think that through this stepped up biodefence efforts, large chunks of government funding diverted from research on 'pathogens that cause major public health problems (like Diabetes, Cancer and other life threatening most prevalent ailments) to obscure germs (Anthrax, hunta virus, Small pox, etc.) the government fears might be used in a bioterrorist attack'.

Criticism aside, it is reported that the U.S. Centers for Disease Control and Prevention has yet to develop a criteria for judging the success of various biodefence efforts underway in the US. Till now, there is no statistical proof to show that the money allocated for each federal department or agency is well spent and that the measures have been effective as well.

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