Bio Stat*

Funding of United States Biodefense Programme and Private Sector

In the United States, allocatations for biodefense research programme on genomics, diagnostics, and vaccine development has reached at $ 1.7 billion for the year of 2005.[1]

The National Institute of Allergy and Infectious Diseases (NIAID)[2] of National Institute of Health (NIH)[3] plays a significant role for running biodefense programme and funding drug companies for the production of biodefense medicines. The NIH is one of the world's leading medical research centre, comprised of 27 separate institutes and part of U.S. Department of Health and Human Services (HHS). It has been pursuing research on advancement of biomedical and behavioral sciences with the objective of research on disease, organ system, stage of development, and developing research tools. The NIAID has awarded a number of grants and contracts for the expansion of scientific research and development for biodefense research resources, product development, clinical and basic research. Most of its budget allocates through research project grants (RPGs) to the private sector industries.

The NIH budget has gone up consistently since 2001, when it was $ 42 million and by 2005 it is $ 107 million (Table 1). There is a greater emphasis on developing facilities for clinical testing of new vaccines for which a new facility *viz,* Regional Centres of Excellence for Biodefense and Emerging Infectious Diseases Research (RCEBEIDR) has also been

Table1: NIH funding for biodefense programme

Year	Funding (Million ($))
2001	42
2002	N.A.
2003	102
2004	106
2005	107

Source: - Fisburn (2005). Fisburn (2004). Wysocki (2005).

* Prepared by Bijaya Kumar Sahu, Researcher, RIS

Table 2: Combined HHS and DHS biodefense preparedness spending:

(Million ($))

Year	Biodefense preparedness spending
2001	294[1]
2002	300[1]
2003	404[2]
2004	502[3]

Note: - [1]Only HHS budget, [2] Combined HHS and DHS budgets and [3]Combined HHS and DHS budgets including Bioshield Project.
Source: HHS (2004)

established recently.

Another important agency is DHS, which provides network of organizations and institutions with the objective to secure biodefense and develop high level response plan. It has developed a framework 'Biological Countermeasures' as a strategic plan with high R&D budget of $ 407 million. DHS has received fund from government $ 2.5 billion in 2005 for the development of BioShield Project.[4]

The Department of Health and Human Services (HHS) is the principal agency for protection of health and provides essential human services and health insurance. Many HHS-funded services are provided at the local level by state or county agencies, or through private sector grantees. In addition to the services, the HHS programs provide for equitable treatment of beneficiaries nationwide, and the collection of national health and other data. HHS has spent around $ 5.6 billion over 10 years on biodefense drugs production under Bioshiled Project.[5] The HHS has also drawn plans to spend $ 97.1 million for the year 2006 to support specific targeted research activities, which need to develop radiological/nuclear ($ 47.1 million) and chemical ($ 50.0 million) countermeasures for different threats.

Private Sector Participation

NIH, over the years has successfully established linkage with private sector for diverse research projects through the RPGs. And most of the funding for RPGs comes from DHS and HHS through Bioshield Project. The main aim is to develop innovative technologies and product platform for valuation and validation of new products.[6] *Bavarian Nordic,* a multinational company largest funding of $ 171 million for smallpox vaccine. The company has developed *Imvamune,* a third-generation vaccine through the advanced clinical development programme (Table

3). The government has also given priority to private research through the cooperative research program and most of the companies like *Acambis, Vaxgen, Bioport, Avecia, Cerus* and etc. are working third generation anthrax and smallpox vaccine development. *VaxGen, Inc.,* a biopharmaceutical company engaged in development, manufacture and commercialization of anthrax, smallpox and Meningitis B vaccines awarded a contract of $ 878 million to provide 75 million doses of its recombinant anthrax vaccine for biodefense programme (Table 3).

The partnership program is intended to support the private sectors in all phases of product or technology development, which may help in the clinical trials, scale-up, production, regulatory requirements, etc. The conceptual framework of industries may differ but it may help for the identification of target technology. In these case NIAID plays vital role for the product development through public private partnership. The technology transfer, which is the pillar of innovation helps in terms of new product development for biodefense programme.

Table 3: NIAID major funding to private companies

Company	Location	Vaccine	Funding (Million ($))
Bavarian Nordic	Kvisrtgard, Denmark	Smallpox	171
Acambis	Cambridge, UK and Cambridge, Mass.	Smallpox	141
VaxGen	Brisbane, California	Anthrax, smallpox, and meningitis	877.5
Avecia	Manchester, UK	Anthrax	80
BioPort	Michigan, U.S.	Anthrax	122
AlphaVax	Research Triangle Park, North California	Vaccine against botulinum neurotoxins and equine encephalomyelitis	16.6
LigoCyte	Bozeman, Montana	Anthrax	4.6
PHRIm—	Newark, New Jersey	Infectious disease	2
Cerus Corp. (CERUS)	California	Anthrax	3.8
Corxia Corp. (CRXA)	Seatle, Washington	Infectious disease	11.6
DynPort	Frederick, Maryland	Tularemia	4.5

Note: - m— The Public Health Research Institute, New Jersey.
Sources: RIS based on Wysocki (2005), NIAID (2005), NIAID (2004), VexGen (2005) and www.biodefensestocks.com.

Endnotes

1 Wysocki Jr, 2005.

2 The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, conducts and supports much of the research aimed at developing new and improved medical tools against potential bioterrorism agents. It works on biodefense research programme, and launched several new initiatives to catalyze development of vaccines, therapies, and diagnostic tests.

3 The NIH is an agency of the U.S. Department of Health and Human Services and is the world's premier medical research institution, supporting more than 50,000 scientists at over 2,000 research universities, medical schools, teaching hospitals, independent research institutes and industrial organizations throughout the United States and the world.

4 BioShield, is a project under the guidance of the US Office of Research and Development Coordination (ORDC), was announced by President on 28 January 2003. The purpose of this project is to accelerate the process of research, development, purchase, and availability of effective countermeasures against agents of bioterrorism.

5 Wysocki Jr, 2005. Wysocki Jr. Bernard, (2005), 'Bioterror funding causes a strain', The Wall Street Journal, USA, Page 14-15,7th December.

6 NIAID has a Small Business Biodefense Grants Programme (SBBGP) to support for small business innovation research to stimulate technological innovation.

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