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The National Biodefense Analysis and Countermeasures Center: Issues for Congress

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Summary

The construction of the National Biodefense Analysis and Countermeasures Center (NBACC), with an estimated construction cost of $128 million, will be the first Department of Homeland Security laboratory specifically focused on biodefense. Its programmatic contents and component organization are unclear, as conflicting information has been provided during each of the past three budget cycles. Congressional oversight of programs, especially those performed in federal facilities for homeland security purposes, is considered key to maintaining transparency in biodefense. Policy issues which may interest Congress include funding for the construction of the NBACC facility, transparency of research activities performed through the center, and the potential for duplication of effort between the Department of Homeland Security and other federal agencies. This report will be updated as circumstances warrant.

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The National Biodefense Analysis and Countermeasures Center: Issues for Congress

Oversight of federal research and development in biodefense is an area of international interest, as only defensive research activities are allowed under the Biological and Toxin Weapons Convention. Congressional oversight of programs, especially those performed in federal facilities for homeland security purposes, is considered key to maintaining transparency in biodefense. The Department of Homeland Security (DHS) and the Department of Health and Human Services (HHS) play leading roles protecting civilians against biological weapons. The Department of Homeland Security has requested and received appropriated funding for the construction of the National Biodefense Analysis and Countermeasures Center (NBACC), a biodefense facility dedicated to homeland security activities. This facility, the first DHS laboratory focused on biodefense, has drawn the attention of Congress, arms control experts, and others. This report will outline the organizational structure of NBACC, describe its mission, and report the funding DHS has received for construction of its facility. It will then discuss policy issues such as funding for NBACC facility construction, oversight of NBACC research, and the potential for duplication of federal effort between NBACC and other agencies.

Organizational Structure

Resources for the National Biodefense Analysis and Countermeasures Center are provided through the Department of Homeland Security's Science and Technology Directorate. NBACC research programs are funded as part of the Biological Countermeasures portfolio, while construction of the NBACC facility is listed separately.

Descriptions of the organizational structure of NBACC are conflicting. In 2003, the FY2004 DHS budget justification and testimony by Assistant Under Secretary Albright before the House Select Committee on Homeland Security stated that four centers would comprise NBACC: the Biothreat Assessment Support Center, the Biodefense Knowledge Center, the Bioforensics Analysis Center, and the Bio-Countermeasures Testing and Evaluation Center.[1] In 2004, the FY2005 DHS budget justification and testimony by Assistant Under Secretary Albright before the House Select Committee on Homeland Security stated that NBACC would be

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[1]Dr. Albright also stated that the Plum Island Animal Disease Center would execute some NBACC programs. Testimony of Dr. Penrose C. Albright, Assistant Under Secretary for Science and Technology, Department of Homeland Security, before the House Select Committee on Homeland Security, October 30, 2003.

comprised of three organizational units: the Biodefense Knowledge Center, the National Bioforensic Analysis Center, and the Biological Threat Characterization Center.[2] The Biological Threat Characterization Center appeared to encompass both the Biothreat Assessment Support Center and the Bio-Countermeasures Testing and Evaluation Center. In 2005, the FY2006 DHS budget justification and testimony by Under Secretary McQueary before the House Committee on Science refer to NBACC as having two component parts: the National Bioforensic Analysis Center and the Biological Threat Characterization Center.[3] The Biodefense Knowledge Center now appears to not be part of the NBACC facility, though it may still be part of the NBACC program. As part of the federal biodefense research and development network, NBACC will also coordinate and collaborate with other entities, such as the Plum Island Animal Disease Center, the National Institutes of Health, and the United States Army Medical Research Institute for Infectious Disease (USAMRIID).

Programs undertaken by NBACC are currently conducted through partnerships and agreements with federal and private institutes.[4] The two NBACC facility components identified in the FY2006 DHS budget are in interim facilities pending construction of the NBACC laboratory building at Ft. Detrick, MD. The National Bioforensic Analysis Center (NBFAC) is housed at USAMRIID, located in Ft. Detrick, MD, and operates as a joint federal effort, including representatives of DHS, the Federal Bureau of Investigation, and the Army.[5] The NBFAC is currently receiving, handling, and performing forensic analysis on biological samples.[6] The other component center, the Biological Threat Characterization Center (BTCC), eventually will be located with the National Bioforensic Analysis Center in the new NBACC laboratory.

The third potential component, the Biodefense Knowledge Center (BKC), was dedicated on September 10, 2004, and is located at the Department of Energy's Los Alamos National Laboratory. Whether this center will continue as an independent center or be brought into the NBACC in unclear. The BKC will draw on the expertise of scientists at Lawrence Livermore National Laboratory and three additional national laboratories: the Pacific Northwest National Laboratory, Sandia National Laboratories, and Oak Ridge National Laboratory. Three Department of Homeland Security University Centers of Excellence, located at the University of Minnesota, the University of Southern California, and Texas A&M University, will

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[2]Testimony of Dr. Penrose C. Albright, Assistant Under Secretary for Science and Technology, Department of Homeland Security, before the House Select Committee on Homeland Security, June 3, 2004.

[3]Testimony of Dr. Charles E. McQueary, Under Secretary for Science and Technology, Department of Homeland Security, House Committee on Science, February 16, 2005.

[4]*FY2006 Budget Justification*, Science and Technology Directorate, Department of Homeland Security.

[5]Testimony of Major General Lester Martinez-Lopez, Commanding General, U.S. Army Medical Research and Materiel Command, before the House Committee on Veterans' Affairs, August 26, 2004.

[6]*FY2006 Budget Justification*, Science and Technology Directorate, Department of Homeland Security.

also collaborate with the Biodefense Knowledge Center.[7] The BTCC and the BKC are developing "material threat" assessments and formal risk assessments of pathogens of interest.

The programs within NBACC, as well as the construction of the NBACC facility, are part of the Biological Countermeasures portfolio of the DHS Science and Technology Directorate. The appropriated funding for this portfolio in FY2005, not including NBACC construction costs, is $362.65 million; $35 million was appropriated for NBACC facility construction.[8]

Mission

The mission of the National Biodefense Analysis and Countermeasures Center is to understand current and future biological threats; assess vulnerabilities and determine potential consequences; and provide a national capability for conducting forensic analysis of evidence from bio-crimes and terrorism.[9] The missions of the component parts of NBACC support this overall NBACC mission.

The BKC's mission has multiple parts. One is to provide scientific assessments and information to the Homeland Security Operations Center regarding potential bioterrorism events.[10] Another is to be a repository of biodefense information, including genomic sequences for pathogens of concern, the existence and location of vaccines, bioforensics information, and information about individuals, groups, or organizations that might be developing these pathogens. Finally, the BKC will aid in assessing potential bioterrorism agents as "material threats" for the purpose of the Project Bioshield countermeasure procurement process.[11]

The NBFAC was designated in Homeland Security Presidential Directive 10, *Biodefense for the 21st Century*, as the lead federal facility to conduct and facilitate

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[7]Lawrence Livermore National Laboratory, "Department of Homeland Security Under Secretary to Dedicate New Biodefense Knowledge Center," *Press Release*, September 10, 2004.

[8]*FY2006 Budget Justification*, Science and Technology Directorate, Department of Homeland Security.

[9]Testimony of Dr. Penrose C. Albright, Assistant Under Secretary for Science and Technology, Department of Homeland Security, before the Senate Committee on Health, Education, Labor, and Pensions, February 8, 2005.

[10]The Homeland Security Operations Center collects and analyzes information from multiple sources to help deter, detect, and prevent terrorist acts. The HSOC provides real-time situational awareness and monitoring, coordinates incidents and response activities, and issues advisories and bulletins concerning threats to homeland security. Department of Homeland Security, "Fact Sheet: Homeland Security Operations Center (HSOC)," *Press Release*, July 8, 2004.

[11]In order for a countermeasure to be procured using Project BioShield funds, the DHS Secretary must determine that a "material threat" requiring such a countermeasure exists. For more information on Project BioShield, see CRS Report RS21507, *Project BioShield*, by Frank Gottron.

the technical forensic analysis and interpretation of materials recovered following a biological attack.[12] NBFAC conducts analysis of evidence from a bio-crime or terrorist attack to attain a "biological fingerprint" in order to identify perpetrators and determine the origin and method of attack. In fulfillment of this mission, NBFAC is developing forensic tools, methods, and strain repositories for pathogens of concern.

The BTCC will conduct studies and laboratory experiments designed to address gaps in understanding current and future biological threats, assess vulnerabilities, conduct risk assessments, and determine potential impacts. Types of studies and experiments to be performed include assessing potential biothreat pathogens, developing strategies for defeating genetically engineered pathogens, and expanding current capabilities in testing non-human primates exposed to biological aerosols.[13]

Policy Issues

Funding for NBACC Facility Construction. The total construction cost for the NBACC facility has been determined by DHS to be $128 million. A contract to build the facility is scheduled to be granted in FY2005.[14] Construction is projected to be finished in FY2008. Funds for this construction were appropriated in FY2003-FY2005. See **Table 1**. No NBACC construction funds were requested by DHS for FY2006, and DHS states that no additional resources are required for construction of the facility.[15] At the end of FY2004, the Science and Technology Directorate as a whole carried over $21.3 million as unobligated funds. All other appropriated funds appear to have been reprogrammed into other program elements. In FY2005, $35 million was appropriated for NBACC construction.

Table 1. Funding for NBACC Construction

(Dollars in thousands)

FY2003 Appropriated	FY2003 Actual	FY2004 Appropriated	FY2004 Actual	FY2005 Appropriated	FY2006 Request
5,000	1,600	88,000	4,319[a]	35,000	0

Source: DHS Budget Justification FY2006

[a] This value is not consistent through the FY2006 budget justification. On p. 65, approximately $4.3 million is given as the amount obligated, while on p. 42, only $0.4 million is stated as obligated. The higher value has been used here.

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[12]This activity is conducted in support of the lead federal agency as determined by the National Response Plan.

[13]Presentation by LTC George Korch, *Leading Edge of Biodefense - The National Biodefense Analysis and Countermeasures Center*, at the Department of Defense Pest Management Workshop, February 2004.

[14]Testimony of Dr. Penrose C. Albright, Assistant Under Secretary for Science and Technology, Department of Homeland Security, before the Senate Committee on Health, Education, Labor, and Pensions, February 8, 2005.

[15]*FY2006 Budget Justification*, Science and Technology Directorate, Department of Homeland Security.

Since no additional funds have been requested for the construction of the NBACC facility, and previously appropriated funds appear to have been used for other purposes, it is unclear what funds will be used to construct the NBACC facility in future years. One possibility is that funds will be reprogrammed from other program elements into construction costs for the NBACC facility. Another possibility is that future costs for other program elements have been offset through use of funds appropriated for NBACC construction, and that future funding for these costs will be used in the construction of the NBACC facility. A third option is that future budget requests will contain requests for additional appropriations for NBACC construction.

Public Oversight of NBACC Research. Arms control experts and other stakeholders have raised concerns about the research to be performed by NBACC at the Ft. Detrick facility. They assert that the research being undertaken might violate or might be interpreted as violating the Biological and Toxin Weapons Convention.[16] The Department of Homeland Security states that research performed by the Department is solely for defensive purposes, will be in accord with treaty obligations, and will be published, to the maximum extent possible, in the open scientific literature.[17] Some research activities performed by the BTCC and the NBFAC, however, either in interim facilities or at the to-be-constructed NBACC facility, may be classified in nature.[18]

Some agencies use institutional biosafety committees (IBCs) as a mechanism for overseeing compliance issues.[19] In order to assess federally funded extramural research and development programs which have potential dual-use capabilities, the Department of Health and Human Services has established the National Science Advisory Board for Biosecurity, a board whose duties include providing expert advice on ways to minimize potential misuse of dual-use research. The IBCs are seen as a mechanism for implementing at the institutional level the recommendations developed by the NSABB. The DHS has stated that an IBC will be established on site, but it is unclear what role the IBC will have in assessing research programs. The primary purpose of an IBC is to ensure that recombinant DNA research follows the NIH *Guidelines for Research Involving Recombinant DNA Molecules*. IBCs are required by NIH guidelines to seat community members on the committee, in

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[16]Milton Leitenberg, James Leonard, and Richard Spertzel, "Biodefense Crossing the Line," *Politics and the Life Sciences*, Vol. 22, (2003).

[17]U.S. Department of Homeland Security and Army Garrison, Fort Detrick MD, *Final Environmental Impact Statement - Construction and Operation of the National Biodefense Analysis and Countermeasures Center (NBACC) Facility by the Department of Homeland Security at Fort Detrick, Maryland*, December 23, 2004. See also Justin Rood, "DHS Germwar Research Bugs Nonproliferation Watchdogs," *CQ Homeland Security*, September 24, 2004 and David Ruppe, "Proposed U.S. Biological Research Could Challenge Treaty Restrictions, Experts Charge," *Global Security Newswire*, June 30, 2004.

[18]U.S. Department of Homeland Security and Army Garrison, Fort Detrick MD, *op. cit*.

[19]While IBCs are responsible for oversight of recombinant DNA research, these responsibilities need not be so restricted. Department of Health and Human Services, National Institutes of Health, *Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)*, April 2002.

addition to scientists and safety officials from the institution. The NIH guidelines are requirements for recipients of NIH funding regarding recombinant DNA techniques, but other institutions are encouraged to follow the NIH guidelines.[20]

The degree to which the research programs of NBACC are transparent and actively overseen may become an area of Congressional interest. The establishment of an IBC at NBACC may provide a potential public oversight mechanism, reassuring the local community and others with respect to the research being performed at NBACC. Some have assailed the utility of the IBCs though, asserting that the IBCs often do not provide effective oversight of research facilities where they are established.[21]

Biosafety Level 4 Construction. The NBACC facility will include laboratory space at the highest level of biosafety containment, Biosafety Level 4 (BSL-4). The volume of laboratory space at the BSL-4 level has historically been small, with federal facilities available at the CDC in Atlanta, GA and at USAMRIID in Fort Detrick, MD. Federal efforts are increasing the available BSL-4 laboratory space. The National Institute of Allergy and Infectious Disease (NIAID) has funded the construction of two new BSL-4 facilities, one at the University of Texas Medical Branch at Galveston and one at the Boston University Medical Center.[22]

The increase in BSL-4 laboratory space is likely to result in a corresponding increase in the number of scientists trained in the techniques required to handle contagious, deadly pathogens. Some posit that such an increase will lead to further dissemination of information regarding biothreat agents, possibly to scientists who oppose the United States.[23] Others argue that the increase in BSL-4 laboratory facilities and trained scientists will lead to a more robust biodefense capability, providing more rapid breakthroughs in pathogen identification and countermeasure development.[24]

The construction of a DHS BSL-4 facility dedicated to threat characterization has raised community fears with regard to potential pathogen leakage, theft, or loss, and possible indirect health impacts.[25] Similar concerns have been raised regarding

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[20]Department of Health and Human Services, National Institutes of Health, *Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)*, April 2002.

[21]The Sunshine Project, *Mandate for Failure - The State of Institutional Biosafety Committees in an Age of Biological Weapons Research*, October 4, 2004.

[22]National Institute of Allergy and Infectious Diseases, "NIAID Funds Construction of Biosafety Laboratories," *Press Release*, September 30, 2003.

[23]Eileen Choffnes, "Bioweapons: New Labs, More Terror?" *Bulletin of the Atomic Scientists*, Vol. 58, September/October 2002.

[24]For a representative argument, see testimony of Dr. Anthony Fauci, Director, NIAID, NIH, before the Subcommittee on Bioterrorism and Public Health Preparedness, Senate Committee on Health, Education, Labor and Pensions, February 8, 2005.

[25]Scott Shane, "With Biodefense Plan, Fear of Repercussions," *The Baltimore Sun*, April 29, 2004. See also public comments in U.S. Department of Homeland Security and Army (continued...)

the construction of the NIAID BSL-4 facilities.[26] Others assert that such a release is unlikely, given the high safety requirements of a BSL-4 facility.[27]

Coordination with Department of Health and Human Services. When the Department of Homeland Security was formed, most programs addressing medical countermeasures to biological threats remained under the authority of the Department of Health and Human Services (HHS). Other programs addressing nonmedical countermeasures, such as those funded by the Department of Energy, were transferred to the Department of Homeland Security.[28] With the establishment of the NBACC, research and development activities in areas being pursued by the BTCC will be closely related to those performed through HHS.[29] Coordination of effort between HHS and DHS may be a topic of Congressional interest.

The DHS Secretary is charged with coordinating homeland security research and development activities across the federal government. If this charge is accomplished effectively, there may be good coordination of the two programs. For example, basic and applied research and development could be performed through HHS, and advanced development and testing could be performed through DHS. On the other hand, if coordination is ineffective, there may be significant potential for overlap and duplication of effort.

Location of the BKC at a Non-Department of Homeland Security Facility. Congress may also have concerns about the establishment of the BKC at a Department of Energy National Laboratory, rather than at a DHS facility. The feasibility study performed for NBACC identified several potential routes for the construction of NBACC. A phased approach, in which the BKC was initially formed outside of the Ft. Detrick facility and then incorporated into the facility at a later date, was one route identified. Whether such a phased approach is under consideration, how the information and experience located in the BKC at Lawrence Livermore National Laboratory would be transferred to the Fort Detrick facility, and whether such a phased approach should be undertaken are unresolved questions.

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[25](...continued)
Garrison, Fort Detrick MD, *op. cit*.

[26]Frank James, "Anti-bioterror Labs Raise Risk to U.S., Critics Say; Accidents, Costs Cited as 14 Are Planned for Nation," *Chicago Tribune*, December 5, 2004

[27]U.S. Department of Homeland Security and Army Garrison, Fort Detrick MD, *op. cit*.

[28]P.L. 107-296, Section 302.

[29]For example, research on genetic modification of model systems for pathogens has been funded by NIAID. See G. Chaudhri, V. Panchanathan, R.M. Buller, et al., "Polarized Type 1 Cytokine Response and Cell-mediated Immunity Determine Genetic Resistance to Mousepox," *Proc. Natl. Acad. Sci. USA*, Vol. 101, June 15, 2004, pp.9057-62.