The National Biodefense Analysis and Countermeasures Center: Issues for Congress

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Summary

The mission of the National Biodefense Analysis and Countermeasures Center (NBACC) 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 bio-terrorism. The NBACC is operational, with a program office and several component centers occupying interim facilities.

A laboratory facility dedicated to executing the NBACC mission and to contain two NBACC component centers is being built at Fort Detrick, Maryland, as part of the National Interagency Biodefense Campus. The laboratory facility, with an estimated construction cost of $141 million, will be the first Department of Homeland Security laboratory specifically focused on biodefense. Its programmatic contents and component organization appear to be evolving, as conflicting information has been provided during previous 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 that may interest Congress include the operation of the NBACC facility as a federally funded research and development center, transparency and oversight of research activities performed through the center, and the potential for duplication and coordination of research effort between the Department of Homeland Security and other federal agencies.

This report will be updated as circumstances warrant.

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As Congress perform oversight in the 110th Congress, biodefense research, biosecurity, and the activities of the Department of Homeland Security (DHS) in this area may become of interest. As DHS continues its activities in biological threat assessment, the 110th Congress may have a unique perspective into these federal forensics and research programs.

Transparency and oversight of research and development in biodefense is an area of international interest, as development of biological weapons is prohibited under the Biological and Toxin Weapons Convention. Congressional oversight of federal programs, especially those performed in federal facilities for homeland security purposes, is considered to play a key role in ensuring transparency. The DHS and the Department of Health and Human Services (HHS) have leading roles in protecting civilians against biological weapons. The National Biodefense Analysis and Countermeasures Center (NBACC) is a program office within the DHS Science and Technology Directorate that funds biodefense research and other activities. The mission of the NBACC program 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.

DHS has requested and received appropriated funding for the construction of a biodefense facility dedicated to homeland security activities and overseen by the NBACC program. This facility, the first DHS laboratory focused on biodefense, has drawn the attention of Congress, arms control experts, local community groups, 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 select 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.

Funding and Organizational Structure

Funds for NBACC programs are provided through the DHS Science and Technology Directorate. Activities funded include both intramural and extramural efforts. The programs within NBACC, as well as the construction of the NBACC facility, have been reported as part of the Science and Technology Directorate's Biological Countermeasures portfolio. The NBACC program currently conducts research through partnerships and agreements with federal and private institutes.[1]

To provide a unique home for research overseen by the NBACC program, DHS is constructing an NBACC laboratory at Fort Detrick, MD as part of the National Interagency Biodefense Campus. Funds for the laboratory, estimated to cost $128 million, have been appropriated over FY2003-2005. Construction commenced on the NBACC facility in June 2006.

The NBACC facility is operated as a federally funded research and development center (FFRDC).[2] The U.S. Army Medical Research Acquisition Activity, acting as the contracting authority for DHS in this instance, released a Request for Proposals (RFP) for the operation of the NBACC facility.[3] On December 20, 2006, DHS announced that Battelle National Biodefense

[1] *FY2006 Budget Justification*, Science and Technology Directorate, Department of Homeland Security, available online at http://ucop.edu/research/homelandsecurity/documents/STFY2006CJ2022005Final1.pdf.

[2] See 70 *Fed. Reg.* 41777 (July 20, 2005).

[3] The RFP closed on May 15, 2006. The NBACC request for proposals can be found online at http://www-usamraa.army.mil/pages/announce/NBACC/index.htm.

Institute had been awarded the NBACC management contract.[4] Similar to the Department of Energy National Laboratories, the NBACC facility is a government-owned, contractor-operated facility where the contract operator manages the facility and provides the technical expertise and program execution to support DHS's needs.[5]

The identity of the NBACC facility component centers has evolved since the facility's conception. Different information has been presented to Congress through various DHS testimony and documentation over the course of this evolution. In 2003, the FY2004 DHS budget justification and testimony by DHS Assistant Under Secretary for Science and Technology Albright stated that four centers would comprise NBACC: the Biodefense Knowledge Center (BKC), the Bioforensics Analysis Center, the Biothreat Assessment Support Center, and the Bio-Countermeasures Testing and Evaluation Center.[6] In 2004, the FY2005 DHS budget justification and testimony by Assistant Under Secretary Albright stated that NBACC consisted of three organizational units: the Biodefense Knowledge Center, the National Bioforensic Analysis Center (NBFAC), and the Biological Threat Characterization Center (BTCC).[7] In 2005, the FY2006 DHS budget justification and testimony by DHS Under Secretary for Science and Technology McQueary refer to the NBACC facility as having two component parts: the National Bioforensic Analysis Center and the Biological Threat Characterization Center.[8] This two center configuration is reportedly the final configuration for the NBACC facility.[9]

The two NBACC component centers identified in the FY2006 DHS budget, the Biological Threat Characterization Center and the National Bioforensic Analysis Center, are operating in interim facilities pending construction of the NBACC laboratory building.[10] The BTCC has ongoing activities in a number of government and private laboratories. The NBFAC is housed at the United States Army Medical Research Institute for Infectious Disease (USAMRIID), located in Fort Detrick, MD, and operates as a joint federal effort, including representatives of DHS, the Federal Bureau of Investigation, and the Army.[11] The NBFAC is currently receiving, handling, and performing forensic analysis on biological samples.[12]

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[4] Department of Homeland Security, "DHS Awards Management Contract for National Biodefense Analysis and Countermeasures Center," *Press Release*, December 20, 2006.

[5] Department of Homeland Security, Science and Technology Directorate, Office of Research and Development, *Draft Solicitation for a National Biodefense Analysis and Countermeasures Center (NBACC) Operating Contract for the Department of Homeland Security*, May 31, 2005.

[6] 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.

[7] The Biological Threat Characterization Center appeared to encompass both the Biothreat Assessment Support Center and the Bio-Countermeasures Testing and Evaluation Center. 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.

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

[9] Personal Communication with DHS staff, November 14, 2006.

[10] Testimony of Dr. John Vitko, Jr., Director, Biological Countermeasures Portfolio, Department of Homeland Security, before the House Committee on Government Reform, Subcommittee on National Security, Emerging Threats, and International Relations, June 14, 2005.

[11] 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.

[12] *FY2006 Budget Justification*, Science and Technology Directorate, Department of Homeland Security, found online at http://ucop.edu/research/homelandsecurity/documents/STFY2006CJ2022005Final1.pdf.

Apparently conceived as part of the NBACC facility, the Biodefense Knowledge Center was dedicated on September 10, 2004, and is located at the Department of Energy's Lawrence Livermore National Laboratory. This center operates as an independent center though its work is closely coordinated with that of the NBACC facility centers. While funding for the BKC originates from within the Biological Countermeasures portfolio, the BKC is funded independently, not as a component of the NBACC program.[13] The BKC draws 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, also collaborate with the Biodefense Knowledge Center.[14]

The NBACC facility is to be part of the federal biodefense research and development network. As such, its activities are to be coordinated with those of other network members, including the Plum Island Animal Disease Center, the National Institutes of Health (NIH), and USAMRIID.

Missions of Component Centers

The mission of the NBACC program 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.[15] Each of the NBACC facility component centers executes a piece of this overall program mission. Also, the Biodefense Knowledge Center appears to collaborate with these centers to assist them in meeting mission goals.

The Biological Threat Characterization Center is to conduct studies and laboratory experiments designed to find and address critical gaps in understanding current and future biological threats, assess vulnerabilities, conduct risk assessments, and determine potential impacts.[16] An apparent goal of this program is to provide a science-based assessment of possible biological threats, focusing on those pathogens deemed by the Centers for Disease Control and Prevention to have the potential for high consequence. Types of research to be performed in characterizing biological threats include, but are not limited to, investigating potential biothreat pathogens, studying pathogen stability and viability, and assessing lethality through dose/response studies.[17] An earlier presentation on NBACC program activities also included developing strategies for defeating

[13] Both the BKC and the NBACC program are part of a larger threat characterization activity within DHS. Personal Communication with DHS staff, November 14, 2006.

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

[15] 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.

[16] For example, DHS has contracted with Battelle to compute and assess the risks of death, morbidity, and direct economic costs related to release of one of 28 pathogens. National Research Council, Board on Mathematical Sciences and Their Applications, Committee on Methodological Improvements to the Department of Homeland Security's Biological Agent Risk Analysis, *Interim Report on Methodological Improvements to the Department of Homeland Security's Biological Agent Risk Analysis*, online at http://www8.nationalacademies.org/cp/projectview.aspx?key=48682.

[17] Department of Homeland Security, *Broad Agency Announcement BAA 05-2*, February 2005.

genetically engineered pathogens, and expanding current capabilities in testing non-human primates exposed to biological aerosols.[18]

The National Bioforensic Analysis Center was designated in Homeland Security Presidential Directive 10 (HSPD-10), *Biodefense for the 21st Century*,[19] as the lead federal facility to conduct and facilitate the technical forensic analysis and interpretation of materials recovered following a biological attack.[20] The NBFAC conducts analysis of evidence from a bio-crime or terrorist attack to obtain a "biological fingerprint" in order to identify perpetrators and determine the origin and method of attack. Consequently, when housed in the NBACC facility, the NBFAC would provide the federal government with a centrally coordinated, validated bioforensic analysis facility.[21] To meet this mission, NBFAC is developing forensic tools, methods, and strain repositories for pathogens of concern.[22]

The Biodefense Knowledge Center supports NBACC facility component centers and has its own functions and missions. One is to provide scientific assessments and information to the Homeland Security Operations Center regarding potential bioterrorism events.[23] 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 aids in assessing potential bioterrorism agents as "material threats" for the purpose of the Project Bioshield countermeasure procurement process.[24] The BTCC and the BKC jointly make these assessments.

Policy Issues

NBACC Facility Construction and Operation

The total construction cost for the NBACC facility has been determined by DHS to be $141 million, a $13 million increase from the initially requested $128 million.[25] Original funds for the

[18] 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.

[19] Executive Office of the President, The White House, *Biodefense for the 21st Century*, Homeland Security Presidential Directive 10, April 28, 2004.

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

[21] Department of Homeland Security, *Broad Agency Announcement BAA 05-2*, February 2005.

[22] On January 12, 2007, NBFAC was accredited to the ISO 17025 quality management standard for testing and calibration laboratories, establishing the technical competence and ethical behavior of laboratory staff, well-defined procedures, and uniformity in test report and certificate contents. For more information, see online at http://www.bnbi.org/.

[23] 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.

[24] In order for a countermeasure to be procured using Project BioShield funds, the DHS Secretary must determine that a "material threat" from a particular agent exists. For more information on Project BioShield, see CRS Report RS21507, *Project BioShield: Purposes and Authorities*, by (name redacted).

[25] DHS attributes the increase in cost as generally due to increases in materials and construction expenses, rather than to a shift in scope or scale. Personal communication with DHS staff, September 22, 2006.

construction were appropriated in FY2003–FY2005. The additional $13 million were reprogrammed from other portfolios.[26]

Construction began in June 2006 and is projected to be finished in FY2008. Community response to the NBACC facility construction has been mixed. The construction of the NBACC facility, along with new laboratory space for other federal agencies, at the Fort Detrick site has been identified as beneficially spurring investment and development in the surrounding area.[27] Some local advocates and citizen groups have protested the construction of the NBACC facility though.[28] They cite concerns regarding security, safety, and secrecy surrounding the facility.[29]

The DHS operates the NBACC facility as an FFRDC, overseen in a manner akin to the Department of Energy National Laboratories. The NBACC FFRDC contractor has the responsibility for enacting the projects and program developed by the NBACC program office. This includes bringing the existing interim centers into the new NBACC facility, when constructed, and continuing those activities currently ongoing, such as the biological risk assessment process.

Oversight of NBACC Research

The degree to which the research programs of the NBACC program and component centers are transparent and actively overseen may become an area of Congressional interest. Two factors have contributed to an increased focus by biosecurity advocates on NBACC research activities: the degree to which classified research may be performed by the NBACC program and the extent and quality of review for compliance with the Biological and Toxin Weapons Convention (BWC). Because of the potential for classified research to be performed at the NBACC facility, some biodefense experts have identified the lack of transparency as problematic for international relations and treaty compliance.[30] Other experts assert that such issues of transparency can be dealt with so long as a process for review and compliance with applicable treaties is developed and maintained. These issues and the Department's efforts to address these factors are described below.

[26] The construction contract for the NBACC facility is reportedly a fixed cost, contractor's liability contract, where the contractor is liable for any additional costs above those agreed upon in the contract. Thus the $141 million is described by DHS as a ceiling above which the total cost to DHS may not rise. Personal Communication with DHS staff, November 14, 2006.

[27] Greg Barrett, "Frederick County Gets Popular, Pricey," *Baltimore Sun*, March 3, 2006; Ike Wilson, "Frederick, MD City Official Says Economic Development Is Gaining Strength," *Frederick News-Post*, March 17, 2006; and Dana Hedgpeth, "Moving Up the Corridor; Frederick County Enjoys a Boom in Office-Building Development," *Washington Post*, May 15, 2006.

[28] Erika Check, "Locals Rally to Combat Biodefense Labs," *Nature*, August 30, 2006.

[29] See, for example, Nelson Hernandez, "Protesters Decry Fort Detrick Expansion; Planned Biodefense Campus Called Environmental Threat at Frederick Rally," *Washington Post*, June 6, 2005; Fredrick Kunkleand, "Fort Detrick Neighbors Jittery Over Expansion; Bioweapons Work Possible, Some Fear," *Washington Post*, February 27, 2005; and "Fort Detrick's New 'Mayor' Aims to Be Good Neighbor," *Associated Press*, August 3, 2005.

[30] Lois R. Ember, "Testing the Limits," *Chemical and Engineering News*, August 15, 2005.

Classified Research

Some research activities performed by the BTCC and the NBFAC, either in interim facilities or at the to-be-constructed NBACC facility, may be classified in nature.[31] The NBACC facility is being constructed in such a manner that the entire building can be certified as a Sensitive Compartmented Information Facility (SCIF).[32] The FFRDC contractor operating the NBACC facility must be capable of providing employees cleared at the Top Secret/Sensitive Compartmented Information (TS/SCI) level.[33] The balance of classified and unclassified activities will change depending on agency need and future planning. Thus, the extent to which the capability to perform classified research will be utilized is undetermined.[34]

Initially, only a portion of the NBACC facility may operate under classified circumstances, with this amount increasing or decreasing depending on evolving research priorities. The NBACC FFRDC RFP provides some expectations for the FFRDC contractor's future capabilities though, stating:

> The Government has estimated final operations work force at 120 people, with virtually all of them (>95%) requiring TS/SCI clearance. The offerors are expected to propose a strategy and commensurate workforce for initial operations and transition. The Government estimates that 20-25% of the Contractor's workforce during initial operations will require TS/SCI clearances. The Government estimates that >40-60% of the Contractor's workforce during transition will require TS/SCI clearances.[35]

Requiring that virtually all of the NBACC FFRDC workforce be eligible for, and eventually possess, clearance for classified information may provide advantages over requiring only a sub-section of the workforce to obtain requisite clearance. One advantage may be increased flexibility in workforce management given changing workload. Another may be an increased ability to generate synergy between research skills and knowledge due to a larger pool of qualified researchers able to converse about a particular problem.[36]

Conversely, some experts are concerned about the potential proliferation of dual-use research results and biological techniques specific to such sensitive research topics.[37] They argue that as

[31] Department of Homeland Security, *Request for Information*, February 25, 2005, and 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.

[32] Joby Warrick, "The Secretive Fight Against Bioterror," *Washington Post*, July 30, 2006.

[33] U.S. Army Medical Research Acquisition Activity, *Solicitation for A National Biodefense Analysis and Countermeasures Center Operating Contract, a Federally Funded Research and Development Center for The Department of Homeland and Security, Amendment 3—Questions & Answers*, HSHQDC-06-R-00017, April 24, 2006. This solicitation closed May 15, 2006.

[34] Personal communication with DHS staff, September 22, 2006.

[35] U.S. Army Medical Research Acquisition Activity, *Solicitation for A National Biodefense Analysis and Countermeasures Center Operating Contract, a Federally Funded Research and Development Center for The Department of Homeland and Security, Amendment 3—Questions & Answers*, HSHQDC-06-R-00017, April 24, 2006. This solicitation closed May 15, 2006.

[36] Personal communication with DHS staff, November 14, 2006.

[37] The phrase "dual-use" has many definitions. This report defines "dual-use" as "research with legitimate scientific purpose that may be misused to pose a biologic threat to public health and/or national security." This definition parallels that found in the charter of the National Science Advisory Board for Biosecurity. Department of Health and Human Services, *National Science Advisory Board for Biosecurity Charter*, March 4, 2004.

more scientists are trained and brought into biological threat assessment studies, the risk of diversion of material, information, or scientific technique to others may increase. While acknowledging that the use of security background checks can reduce this risk, they assert that this risk can not be eliminated.[38]

Compliance and Oversight

Some arms control experts and other stakeholders have raised concerns about the research to be performed by NBACC at the Fort Detrick facility. They assert that the research being undertaken might violate or might be interpreted as violating the Biological and Toxin Weapons Convention.[39] While research activities may uphold both the letter and the spirit of the BWC, international observers may lack confidence in, or harbor suspicions about, those research activities being performed.[40]

Strong internal oversight and review of these research activities may allay some of these concerns or suspicions. As put by Petro and Carus,

> Thus, any federal program that focuses on threat characterization research will likely require strict administrative guidelines and procedures to ensure that all activities are legally compliant.[41]

The DHS asserts such a strong review process exists, as an internal process to the Department.[42] The DHS has developed and implemented a management directive regarding compliance with arms control agreements.[43]

Adhering to this directive, DHS has established both a compliance assurance program office and a Compliance Review Group to determine whether the NBACC research activities are in compliance with the BWC, among other duties.[44, 45] The Compliance Review Group is composed of senior DHS officials, including those with oversight of pertinent research areas. The

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[38] Jonathan B. Tucker, "Biological Threat Assessment: Is the Cure Worse Than the Disease." *Arms Control Today*, October, 2004.

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

[40] James B. Petro and W. Seth Carus, "Biological Threat Characterization Research: A Critical Component of National Biodefense," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, Vol. 3, Number 4, December, 2005.

[41] James B. Petro and W. Seth Carus, "Biological Threat Characterization Research: A Critical Component of National Biodefense," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, Vol. 3, Number 4, December, 2005.

[42] Joby Warrick, "The Secretive Fight Against Bioterror," *Washington Post*, July 30, 2006.

[43] Department of Homeland Security, *Compliance with, and Implementation of, Arms Control Agreements*, Management Directive 6300, August 26, 2005. This management directive applies to all DHS components, including all entities directly engaged in work by DHS, and covers all applicable binding arms control agreements.

[44] An overview of the nascent compliance review process was presented in at the Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, Meeting of Experts, in Geneva, Switzerland from June, 2005. See online at http://daccessdds.un.org/doc/UNDOC/GEN/G05/619/03/PDF/G0561903.pdf?OpenElement.

[45] This office also determines whether research activities are in compliance with other pertinent treaties and regulations, such as the select agent regulations regarding pathogen possession and security. Personal communication with DHS staff, November 14, 2006.

compliance assurance program office has been established separately from the research program offices, so that reseach management and compliance oversight activities do not become conflated. Currently, all NBACC research activities are reviewed, and compliance determinations are made, before the research activities begin. If questions persist about whether a research activity may pose a compliance concern, the compliance assurance program office and the Compliance Review Group are empowered to require additional, clarifying information be presented before a compliance determination is made. Should the Compliance Review Group not reach consensus regarding a particular research activity, the final judgement is reportedly made by the DHS Secretary, who is obligated to ensure DHS activities are in compliance.[46]

While such an internal compliance review process may be robust, some arms control experts have been critical of compliance processes that remain entirely internal to a single agency. Such critics assert that interagency review, or review performed or coordinated through the White House, for example through the National Security Council or the Homeland Security Council, would provide greater expert input and further divorce the compliance review from the programmatic and budgetary aspects of a research program.[47]

Other possible mechanisms for review of potentially contentious research exist outside of the Department. To assess federal research and development programs that may have potential dual-use capabilities, the Department of Health and Human Services has established the National Science Advisory Board for Biosecurity. This board's duties include providing expert advice on ways to minimize potential misuse of dual-use research.[48] The NSABB is expected to generate guidance on assessing dual-use research through local oversight at research institutions. The NSABB was not given responsibility to view or assess classified research programs, so might be of limited utility in overseeing such research.

Transparency

Selective transparency in activities performed at the NBACC facility and funded by the NBACC program is considered both essential and difficult to enact. While the ability for outside observers to identify and understand the activities underway at the NBACC facility and funded through the NBACC program is deemed by some experts as key to maintaining international confidence in the US biodefense program, such openness must preserve the protection granted to information deleterious to national security.[49] It is difficult to determine what an appropriate balance is when weighing the potential release of information relating to national vulnerabilities against assuring others of the munificent focus of biodefense research.

[46] Personal communication with DHS staff, November 14, 2006.

[47] See, for example, Jonathan B. Tucker, "Biological Threat Assessment: Is the Cure Worse Than the Disease." *Arms Control Today*, October, 2004; and Milton Leitenberg, *Assessing the Biological Weapons and Bioterrorism Threat*, December 2005.

[48] For more information on the NSABB, see online at http://www.biosecurityboard.gov/. See also CRS Report RL33342, *Oversight of Dual-Use Biological Research: The National Science Advisory Board for Biosecurity*, by (name redacted).

[49] For example, see Jonathan B. Tucker, "Biological Threat Assessment: Is the Cure Worse Than the Disease?" *Arms Control Today*, October, 2004; and James B. Petro, Theodore R. Plasse, Jack A. McNulty, "Biotechnology: Impact on Biological Warfare and Biodefense," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, Vol. 1, No. 3, September, 2003.

How to best achieve needed transparency while preserving necessary information restriction is a matter of contention. Some arms control experts claim that openness in the US biodefense program should be held as the model for other countries. Other biosecurity experts assert that special care must be taken to assure that information that would disclose a potential vulnerability is not inadvertently released.

Once possible mechanism is the inclusion of local community members into the oversight process for NBACC research. In other areas of contentious biological research, local review boards, such as institutional biosecurity boards, have been used to oversee research activities. Typically, the primary purpose of an IBC is to ensure that recombinant DNA research follows the NIH *Guidelines for Research Involving Recombinant DNA Molecules*.[50] IBCs are required by NIH guidelines to seat community members on the committee, in addition to scientists and safety officials from the institution. IBCs have also been highlighted as possible mechanisms for implementation of NSABB recommendations. The DHS has stated that an IBC will be established at the NBACC facility, but it is unclear what role the IBC would have in assessing research programs. Inclusion of such persons may be problematic in light of the potential for classified or law-enforcement sensitive nature of some activities.

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 advocates 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.[51]

Another possible mechanism might be developing independent, external oversight of research activities, using scientific experts, possibly using members of the National Academies, to assess research programs.[52] The DHS has established an advisory committee through the National Academies to provide input into the NBACC research process.[53] The advisory committee's suggestion and activities have not, as yet, been widely discussed or publicized. Formalizing the committee input mechanism or more widely disseminating the results of the advisory committee's activities may be considered by critics as sufficient to allay transparency concerns.

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.[54] As such, they are committed to

[50] While IBCs are responsible for oversight of recombinant DNA research, these responsibilities need not be so restricted. The NIH guidelines are requirements for recipients of NIH funding regarding recombinant DNA techniques, but other institutions are encouraged to follow the NIH guidelines. Department of Health and Human Services, National Institutes of Health, *Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)*, April 2002.

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

[52] Lois R. Ember, "Testing the Limits," *Chemical and Engineering News*, August 15, 2005.

[53] While a standing National Academy of Sciences committee has been established to support the NBACC program's research, it provides scientific review, not review of policy or compliance matters. Personal communication with DHS staff, September 22, 2006. See also, Board on Army Science and Technology, Committee on Biodefense Analysis and Countermeasures, online at http://www7.nationalacademies.org/BAST/BAST_Biodefense_Analysis_Committee.html.

[54] 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 (continued...)

assessing and reducing biodefense vulnerabilities, adhering to scientific standards and practices, and exercising sufficient and appropriate levels of openness. The Department points to its robust internal compliance review process, the establishment of a standing advisory committee, and its plan to conduct much of its research in an unclassified manner as indicators that critics concerns are overstated.[55]

Prioritization of NBACC Research Activities

Another area of concern amongst the arms control community and increasingly within Congress is the lack of a clear research plan for NBACC programs or for the NBACC facility.[56] The research performed through the NBACC program is designed to fill in knowledge gaps regarding pathogens, test the effectiveness of biological countermeasures, and to assess the risk posed by new and future activities in biological science.[57] Such research will likely span both classified and unclassified areas.

Arms control experts have expressed concern that the research being considered at the NBACC facility may not be properly based on risk, but instead might be based on other characteristics, such as potential consequence or the ability of a nation state to develop such a weapon. These experts suggest that a more proper prioritization would focus on the capabilities of terrorists, rather than rogue nations. They also suggest that improper prioritization of research activities may lead to an arms race in the biodefense community, as scientists engaged in biodefense attempt to develop countermeasures to more dangerous pathogens developed in their own laboratories.[58]

Since the NBACC program deals with matters of homeland security, public oversight of its research activities might compromise homeland security. If that is the case, some advocates argue that a robust, prioritization and planning mechanism should be developed, so that the mechanism itself can be reviewed.[59] They argue that such an activity will bolster confidence that proper prioritization and planning activities will occur, even if the results of those activities are not available. Others might argue that such structures already exist and are in place, citing the array of advisory boards and committees available to DHS in developing strategic planning.[60] Since the

(...continued)

Ruppe, "Proposed U.S. Biological Research Could Challenge Treaty Restrictions, Experts Charge," *Global Security Newswire*, June 30, 2004.

[55] Personal communication with DHS staff, November 14, 2006.

[56] The Department of Homeland Security Science and Technology Directorate released a strategic plan and five-year research strategy that provides some insight into work that may be performed at the NBACC facility. While not explicitly delineating research done at the NBACC facility from other biological countermeasures research, it does identify thrust areas that support NBACC program components, such as a forensics program underpinning the NBFAC, and a threat assessment program, sustaining the BTCC and BKC. See online at http://hsc.house.gov/SiteDocuments/20070627105705-57451.pdf.

[57] Dr. Maureen McCarthy, Director, Office of Research and Development, Department of Homeland Security, *Public Comments at the Center for Strategic and International Studies*, October 31, 2005.

[58] David Ruppe, "Homeland Security Threat Priorities Draw Criticism," *Global Security Newswire*, November 2, 2005.

[59] A similar approach has been taken on a small scale with the Biological Risk Assessment required under Homeland Security Presidential Directive 10. The results of the risk assessment are classified, but the methodology is not and is open to review by the National Academies. See National Research Council, Board on Mathematical Sciences and Their Applications, Committee on Methodological Improvements to the Department of Homeland Security's Biological Agent Risk Analysis, *Interim Report on Methodological Improvements to the Department of Homeland Security's Biological Agent Risk Analysis*, online at http://www8.nationalacademies.org/cp/projectview.aspx?key=48682.

[60] For example, P.L. 107-296, the Homeland Security Act of 2002, established a Science and Technology Advisory (continued...)

efficacy of planning and prioritization is open to interpretation, developing appropriate metrics to assess this process may pose a challenge.

Biosafety Level 4 Construction

The NBACC facility is to include laboratory space at the highest level of biosafety containment, Biosafety Level 4 (BSL-4). Such laboratories are required for performing experiments using the most dangerous pathogens, like viral hemorrhagic fevers such as Ebola virus. The volume of BSL-4 laboratory space has historically been small, with federal facilities available at the Centers for Disease Control and Prevention 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 Diseases (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.[61] Additional BSL-4 laboratory space is proposed for the National Bio- and Agro-defense Facility.

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.[62] 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.[63]

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.[64] Similar concerns have been raised regarding the construction of the NIAID BSL-4 facilities.[65] The DHS and DOD assert that such a release is unlikely, given the high safety requirements of a BSL-4 facility.[66]

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Council for the Department of Homeland Security's Science and Technology Directorate. This advisory council dissolved in 2005. The Department also requested support from the National Academies in establishing a standing Committee on Biodefense Analysis and Countermeasures. For more information, see online at http://www7.nationalacademies.org/bast/BAST_Biodefense_Analysis_Committee.html.

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

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

[63] 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.

[64] Nelson Hernandez, "Protesters Decry Fort Detrick Expansion," *Washington Post*, June 6, 2005. 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 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.

[65] 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.

[66] U.S. Department of Homeland Security and Army Garrison, Fort Detrick MD, *Final Environmental Impact* (continued...)

Coordination with Other Federal Agencies

How the NBACC program and NBACC facility coordinate their efforts with other federal agencies may attract Congressional interest. 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). Most civilian programs addressing nonmedical countermeasures, such as those funded by the Department of Energy, were transferred to the Department of Homeland Security.[67] With the establishment of the NBACC facility, research and development activities in some areas being pursued by the BTCC would be closely related to those supported by HHS.[68] Results of such DHS research and development activities could also help inform and shape policy and research agenda in other departments. For example, the risk assessment activities undertaken by DHS could potentially aid in informing HHS strategic deliberations.[69]

The DHS Secretary is charged with coordinating homeland security research and development activities across the federal government. If coordination is well-managed, the effectiveness of research and development activities would be optimized. Results from DHS testing and evaluation of biological countermeasures, for example, might inform new research areas for HHS to support. On the other hand, if coordination is ineffective, significant overlap and duplication of effort may occur between agencies.

Additionally, effective coordination between the NBFAC and the Federal Bureau of Investigation (FBI) would be necessary for a prompt forensics response following a bioterrorism incident. The NBFAC has, in its interim space, completed processing of thousands of forensic samples in support of bioterror/biocrime cases for the FBI, acting as the lead federal facility for bioforensic analysis.[70] The FBI has entered into contracts with Department of Energy Laboratories to perform forensics and attribution activities for nuclear materials.[71] Lessons learned from these activities may lower barriers to effective interagency actions following a biological attack.

Some coordinative activities designed to leverage the NBACC facility capabilities are already underway. The DHS, acting through the Science and Technology Directorate, has entered into the Interagency Biomedical Research Confederation at Fort Detrick. This group consists of agencies and institutes engaged in medical or biotechnology research at Fort Detrick and also includes representatives from the National Institutes of Health, the Agricultural Research Service, the Centers for Disease Control and Prevention, and the Army Surgeon General. Through committees and subcommittees established under this interagency group, these participants attempt to

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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.

[67] The Homeland Security Act of 2002, P.L. 107-296, Section 302.

[68] 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.

[69] For an example of how current DHS risk assessment activities are to be used by HHS, see 71 *Fed. Reg.* 53,097–53,102 (September 8, 2006).

[70] Dr. Bernard Courtney, *National Biodefense Analysis and Countermeasures Center*, Presentation to the National Academies Committee on Methodological Improvements to the Department of Homeland Security's Biological Agent Risk Analysis, August 28, 2006.

[71] Jim Nesbitt, "SRS Lab Wins FBI Contract," *The Augusta Chronicle*, February 24, 2005.

coordinate work in scientific areas of mutual interest, so as to encourage efficient management, foster scientific interchange, and maximize research and development productivity.[72]

Interaction of the Biodefense Knowledge Center and NBACC 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 Fort Detrick facility and then incorporated into the facility at a later date, was one route identified. Another was the construction of the NBACC facility with the BKC integrated within it. The BKC was, instead, established separately at Lawrence Livermore National Laboratory, and now appears to be a center independent of the NBACC facility and NBACC program.

The BKC, in its data collection, analysis, and dissemination capabilities, appears to play a similar role to the NBACC program and facility. The degree to which information needs and gaps identified by one of the centers may be filled by the other center may rest heavily on internal communications and interactions. Efficient information sharing and planning may play a key role in maximizing the effectiveness of both centers.

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[72] For more information about the Interagency Biomedical Research Confederation at Fort Detrick, see online at http://www.detrick.army.mil/nibc/.