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The U.S. Threat Assessment Process and Oversight for Biological Research at NBACC

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CISSM Working Paper

December 2007

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19 December 2007 Draft

ABSTRACT

The US Department of Homeland Security finished its first bioterrorism risk assessment in January 2006. That and the upcoming 2008 assessment employs a probabilistic risk assessment methodology designed to guide prioritization of ongoing biodefense-related research, development, planning and preparedness. The methodology and the scientific work it subsequently identifies as necessary have generated some discussion about both its design and consequence. This paper clarifies the current debate, describes the current processes in place, and identifies issues that merit further discussion.

INTRODUCTION

Biodefense encompasses an enormous range of activities that necessarily require policymakers to make trade-offs when allocating time, effort, and funding. Threat characterization is one controversial piece of the effort due to insufficient public information about how requirements are generated and how it is performed, and also in part because of widely divergent estimates as to the potentially harmful consequences of such scientific investigations as currently practiced. The Department of Homeland Security (DHS) created the National Biodefense Analysis and Countermeasures Center (NBACC) to perform threat characterization research as part of its mission to understand the biological threat to the US. A review of the issues that have accompanied the creation of NBACC and a description of the threat characterization process as it is currently practiced is presented here. In this way, a more informed discussion can proceed.

DHS presented the NBACC concept in 2003. In 2004, a Biodefense Knowledge Center was created within DOE's Lawrence Livermore National Laboratory. At Fort Detrick, a new NBACC facility is under construction that will house the National Bioforensic Analysis Center and the Biological Threat Characterization Center when it is completed in 2008. This will be a part of the National Interagency Biodefense Campus. The mission of 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 terrorism.[1]

[1] Testimony of Penrose 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) as cited in Dana A. Shea, "The National Biodefense Analysis and Countermeasures Center: Issues for Congress," *CRS Report for Congress* (15 February 2007). See also, "Battelle Wins Contract to Operate National Biodefense Analysis & Countermeasures Center," Battelle News Release (20 December 2006): downloaded from www.battelle.org.

In 2004, a detailed slide presentation described the kinds of threat assessment work that was intended for the proposed NBACC facility.[2] These included the acquisition, growth, modification, storage, stabilization, packaging and dispersal of classical, emerging, and genetically engineered pathogens. All work was originally intended to be classified. Soon after, the White House presented its biodefense strategy in which four major areas were outlined: Threat Awareness, Prevention and Protection, Surveillance and Detection, and Response and Recovery.[3] One critical element of the US biodefense policy is the periodic assessment of the biological weapons threat. To do this, the directive required a "continuous, formal process for conducting routine capabilities assessments to guide prioritization of our on-going investments in biodefense-related research, development, planning, and preparedness."

DHS submitted its first bioterrorism risk assessment to the White House on January 31, 2006. It was a classified document. Battelle, who in December 2006 won the contract to operate the NBACC facility at Fort Detrick, completed the first bioterrorism assessment in nine months. It was a first attempt to apply a probabilistic risk assessment (PRA) methodology for estimating bioterrorism risk.[4] As such, it incorporated only the infectious dose and mortality rate for agent parameters and limited data quality matrices.[5] The 2008 assessment will employ more extensive data quality matrices and include new agent-specific parameters and incorporate new scenarios such as the impact of the worried-well. In addition, while the 2006 assessment incorporated a single "test" enhanced agent (a multi-drug resistant bacterium), in the future additional enhanced agents are planned, including advanced agents, such as those that may be synthesized *de novo* in a laboratory.[6]

The risk assessment helps to determine biodefense-related research. Concerns about the kinds of work that is being pursued at NBACC under conditions that are largely kept secret started a debate about whether the US should be involved in such secret work at all and particularly in the aggressive way articulated.[7] Many experts in the biodefense field have raised concerns about BWC compliance by the US in general and the possibility for emulation of the current US biodefense work by other countries.[8]

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[2] George Korch, "Leading Edge of Biodefense – the National Biodefense Analysis and Countermeasures Center", Proceedings, Military Entomology – Its Global Challenge, 2004 DoD Pest Management Workshop, Naval Air Station, Jacksonville, Florida, February 9-13, 2004.

[3] The White House, *Biodefense for the 21st Century* (Washington, DC: April 28, 2004).

[4] See NJ McMillan et al., "An end-to-end quantitative approach for estimating bioterrorism risk," Abstract submitted to the Society for Risk Analysis Annual Meeting 2007. Downloaded from http://birenheide.com/sra/2007AM/program/singlesession.php3?sessid=M4-I.

[5] Department of Homeland Security, "2008 DHS Bioterrorism Risk Assessment: Thoughts and Impressions from the NAS Interim Report," presentation to the Committee on Methodological Improvement to the Department of Homeland Security's 2006 Bioterrorism Risk Assessment (10 February 2007).

[6] Department of Homeland Security, "2008 DHS Bioterrorism Risk Assessment: Thoughts and Impressions from the NAS Interim Report," presentation to the Committee on Methodological Improvement to the Department of Homeland Security's 2006 Bioterrorism Risk Assessment (10 February 2007).

[7] Milton Leitenberg, James Leonard, Richard Spertzel, "Biodefense crossing the line," *Politics and the Life Sciences* 22, no. 2 (17 May 2004): 2-3.

[8] See John Steinbruner, "In the Name of Defense," *The New Scientist* (25 November 2006): www.newscientist.com; Christian Enemark, "United States biodefense, international law, and the problem of intent," *Politics and the Life Sciences* 24, no. 1-2 (19 July 2006): 32-42; Peter Aldhous and Michael Reilly, "Bioterror Special: Friend or Foe?" *The New Scientist* no. 2573 (14 October 2006); Lois R. Ember, "Testing the Limits," *Chemical and Engineering News* 83, no. 83 (15 August 2005): 26-32; Laurie Goodman, "Biodefense cost and consequence,"

The key issue being debated is what kind of biodefense work the US should be pursuing and the conditions under which that work should be performed. Some have argued that greater transparency is necessary for both in order to provide reassurance and greater scientific rigor.[9] However, while it is acknowledged that reassurance about the defensive intent and methodological credibility of US biodefense research is important and beneficial, there are also significant risks from making some investigations and research results known.[10] What the current debate can benefit from is historical perspective: these issues have circulated since the start of the US bioweapons program in World War II. While still unresolved, past experience can shed some light on our biodefense choices and consequences.

Threat assessment today incorporates estimates of enemy capability and intention, estimates of effects of biological agents, estimates of response capabilities, and potential effects of modified agents based on scientific or technological feasibility. This approach – and the assumptions that are inherent in it – has a relevant historical record.

Threat Assessment and Past US BW Work

From its beginning in World War II, US biodefense efforts included threat assessments to inform and guide its research efforts (1942 – 1969). After President Nixon terminated the US offensive program, USAMRIID continued the medical biodefense effort without a concomitant scientific threat assessment effort (1969 – 1990s). This generated some critiques that the US biodefense effort was neither properly focused nor prepared to meet novel threats made possible by enormous advances in biotechnology. The presumption throughout is that biological threat assessments can help indicate what biodefense research and preparedness is necessary. What kinds of information are necessary for threat assessment has shifted over time as have strategies to address the perceived threat. Throughout the history of the US biodefense effort there has been tension between scientific arguments for greater transparency and security requirements for greater secrecy.

The need for the US to perform its first biological threat assessment arose during World War II when the original presumption[11] that biological weapons were potentially powerful, but too unmanageable for standard military operations was revisited. In 1940, the consensus of the US National Institute of Health (NIH) and the US Chemical Warfare Service (CWS) was that

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The Journal of clinical Investigation 114, no. 1 (1 July 2004): 2-3;; Jonathan Tucker, "Biological Threat Assessment: Is the Cure Worse Than the Disease?" *Arms Control* today 34, no. 8 (October 2004): 13-19; and Mark Wheelis and Malcolm Dando, "Back to Bioweapons?" *Bulletin of the Atomic Scientists* (January/February 2003): 41-45.

[9] John Steinbruner and Stacy Okutani, "The Protective Oversight of Biotechnology," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 2, no. 4 (December 2004): 273 – 280.

[10] 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* 3, no. 4 (2005): 295-308.

[11] L.A. fox, "Bacterial warfare: the use of biologic agents in warfare," *The Military Surgeon* 72: 189-207, 1933 (reprinted in *The Military Surgeon* 90, no. 5 (May 1942)).

biological weapons were most useful as sabotage weapons.[12] However, the US Army Surgeon General pressed for the development of countermeasures to possible enemy BW weapons. This stated need for better defenses prompted the US to establish a BW committee within the US National Academy of Sciences (NAS) to look at the *whole* issue of biological warfare, "to survey the present situation and the future possibilities."[13]

The BW committee that was formed existed for less than a year but in that short time overcame the major obstacle to military investment in BW: "Biological Warfare is regarded as distinctly feasible…The majority of the authors conclude that biological warfare is entirely possible, even probable, and that in the future, its use will be governed by the likelihood of military effectiveness rather than by any moral considerations or international agreements."[14]

In addition, the BW committee articulated an important presumption: "it is obvious that preparation for defense necessitates a knowledge of the offense and, if this knowledge is not available from experience, it must come from the results of careful investigation."[15] This perspective was shared by the UK: "My instructions are that H.M. Government feels that (1) a study of offense is an essential preliminary to the study of defense, (2) offensive studies are valueless until they are taken to a stage of complete realism."[16]

That is, the concept of fully investigating the offense as necessary *a priori* to effective development of defenses became established for biological weapon threat assessment. Once it was accepted that biological warfare was probable – regardless of the basis for this decision – attention focused on characterizing likely effects. Threat assessment therefore did not need to incorporate estimates of likelihood of use, but could instead focus on estimates of biological and strategic effects. This is an important leap in logic. It likely reflected the paucity of useful information from the intelligence community about the nature of the actual BW threat attributed to Japan and Germany during World War II. However, as the basis for planning, it was flawed and led to activities that were unnecessary in hindsight.

The US BW committee performed a wide-ranging, largely theoretical assessment of every candidate agent as to its possible methods of producing a harmful effect on man, animals, plants,

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[12] The progress report prepared by CWS (August 28, 1939) is cited in "Progress Report No. 54: Biological and Bacteriological Warfare" (August 15, 1941), National Academies of Science Archive: Committees on Biological Warfare Series 1, Box 1: "Organization and Administrative Liaison: 1941-1942." The NIH opinion is reported in a Letter from R.E. Dyer, Chief, Division of Infectious Diseases, NIH to The Surgeon General, USPHS, Bethesda, Maryland, December 16, 1940. National Academies of Science Archive: Committees on Biological Warfare Series 1, Box 1: "National Institute of Health: 1941."

[13] "Conference on Biological Warfare" (August 20, 1941), National Academy of Sciences Archive, Committees on Biological Warfare Series 1, Box 1, "Beginning of Program."

[14] E.B. Fred, Chairman, "Report of the W.B.C. Committee" (February 19, 1942). National Academy of Sciences Archive, Committees on Biological Warfare Series 1, Box 2, "Report: February 1942."

[15] E.B. Fred, Chairman, "Report of the W.B.C. Committee" (February 19, 1942). National Academy of Sciences Archive, Committees on Biological Warfare Series 1, Box 2, "Report: February 1942."

[16] Paul Fildes, "Organization of B.W. in the United Kingdom," (November 10, 1942), National Academy of Sciences Archive, Committees on Biological Warfare Series 4, Box 5: "U.S.-U.K. Cooperation: 1942-1944."

and food supplies.[17] The appendices to the 1942 report are exhaustive discussions of the range of microbes that could be made into a threat and possible methods for their use. It is possible to characterize US threat assessment work at that time as depending largely on estimates of two factors: the first is likely effect (as discussed in the 1942 report) and the second is technological feasibility.

Technological (or scientific) feasibility is the second major criteria in threat assessments at the time because the US and UK lacked solid evidence about their adversary's BW programs. The US and UK assumed that any technological or scientific progress they were exploiting was, logically, likely already to have been applied by their adversaries. One intelligence estimate at the time concluded, "it is safe to assume that the Germans have made much further advances in the field of experimentation with anthrax and that they developed more advanced bombs and other methods for its dissemination."[18] This kind of concern about technological inferiority emerges regularly in historical documents of the time.

Based on information from the initial threat assessment, investment began in a limited civilian R&D program that moved quickly into total military control with a drive toward bioweapons production. By war's end the BW program alone had consumed over $44 million (approximately $500 million in 2006 dollars). It soon became apparent that the US and UK BW programs – like its nuclear program – was larger and far more sophisticated in comparison to Japanese or German investment in the same areas.

The only successful vaccine developed and produced during the war was the product of a joint US-Canadian effort. In 1941, rinderpest was of immediate concern. The first BW project approved and begun was for the production and storage of rinderpest vaccine – a wholly defensive project that lacked any modeling or elaborate modeling of potential effect as an offensive weapon. Within two years, a plant was established that maintained a stockpile of at least 5,000 doses of vaccine. In addition, researchers developed a new vaccine that could be manufactured more rapidly, induce immunity more swiftly, and could be dried without loss of potency for a long period of time. Only *after* these major issues of defense were overcome was there any consideration for a request to investigate the offensive potential of the rinderpest virus.[19] Rinderpest, however, was the exception: the offensive potential of other potential BW agents were studied either before or along with a defensive investigation. No bioweapons were produced by the US during World War II.

A brief reconsideration

The 1942 threat assessment had erred in two ways: it assumed the existence of enemy BW programs that it turned out Germany did not have. It also assumed investigation of similar agents and processes, but the Japanese were dropping plague-infested fleas (among other

[17] The first BW committee was named the WBC Committee and later renamed first the ABC Committee and then the DEF Committee.

[18] "Probable Biological Agents which may be Employed by the Enemy," (1 January 1944) in *Historical Report of the War Research Service, November 1944 – Final*. National Academy of Sciences Archive, Series 4, Box 5, Section II, 149.

[19] *Historical Report of the War Research Service, November 1944-Final.* National Academy of Sciences Archive, Committees on Biological Warfare Series 4, Box 5.

grotesque activities) and not developing anthrax bombs.[20] Furthermore, biological weapons were found to not be so readily feasible in fact. There were significant hurdles that had to be overcome.

Nonetheless, continuation and expansion of the program was urged by the CWS over the reluctance of many members of the same civilian scientific advisory group that had initially convinced a skeptical military to invest in a BW program. The scientific advisors did not have a sense from the military as to what they wanted from a biological weapon – how were they to design a biological weapon without knowing the applications for which they were intended? For their part, the military planners themselves did not know what they wanted because they wanted the scientists to first describe the potential uses for BW.[21] There was clearly a difference of opinion as to which was the cart and which the horse.

Furthermore, many scientists on the NAS committee believed that the US BW program should either be terminated or made a wholly medical defense issue.[22] Therefore, to determine a course of action going forward – and in the context of rapidly changing world events, a new committee in 1949 was asked to "undertake a full examination of all the technical and strategic possibilities of biological warfare."[23]

In its examination, the 1949 BW committee took a similar approach as the 1942 BW committee: first, it presumed US inferiority in BW development, "The United States, although it enjoys atomic superiority… does not necessarily possess a corresponding superiority in the field of biological warfare – in fact, the situation might be the reverse."[24] Second, it based its recommendations on theoretical estimates of the potential effectiveness of bioweapons (i.e. scientific possibility) and not known enemy capabilities. Their recommendation was largely for better medical and civilian defenses to protect the obviously vulnerable US cities.

A year later, the military decided to pursue a bioweapons capability. Rather than implementing recommendations for better defense, it adopted a strategy emphasizing punishment. Brigadier General William Creasy, head of R&D (CWS) and later the Chief, CWS, wrote in 1952, "although development of adequate protective measures against CBR attack is an important part

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[20] Sheldon Harris, *Factories of Death: Japanese Biological Warfare, 1932-1945, and the American Cover-up* (New York: Routledge, 2002).

[21] William B. Sarles, "Report on DEF Committee Meetings. June 17-18, 1946, National Academies of Science Archives, Committees on Biological Warfare, Series 5, Box 5: "Joint Security Control: 1944 – 1948."

[22] See the following: W. Mansfield Clark, Letter to Perry Pepper (25 June 1946), National Academies of Science Archives, Committees on Biological Warfare, Series 5, Box 6: "Meeting: Report & Follow-up: Jun 1946"; and Ernest W. Goodpasture, M.D., Letter to Perry Pepper (October 16, 1946), National Academies of Science Archives, Committees on Biological Warfare, Series 5, Box 5: "Advisory committee on BW 1946 – 1948"; and W.A. Hagan, Letter to Perry Pepper (4 July, 1946), National Academies of Science Archives, Committees on Biological Warfare, Series 5, Box 6: "Meeting: Report & Follow-up: Jun 1946"; and J. Howard Mueller, Letter to Perry Pepper (24 June 1946), National Academies of Science Archives, Committees on Biological Warfare, Series 5, Box 6: "Meeting: Report & Follow-up: Jun 1946."

[23] Letter from Secretary of Defense Forrestal to Dr. Caryl Haskins (16 March 1949), in *Report of the Secretary of Defense's AD HOC COMMITTEE on Biological Warfare* (11 July 1949), Papers of Harry S. Truman President's Secretary's Files, Harry S. Truman Library.

[24] *Report of the Secretary of Defense's AD HOC COMMITTEE on Biological Warfare* (11 July 1949), Papers of Harry S. Truman President's Secretary's Files, Harry S. Truman Library, 6.

of Chemical Corps work, the development of superior offensive potential is believed to be an even greater deterrent to potential aggressors."[25] The extended strategic implications of having bioweapons was not studied systematically until 1969, when detailed consideration by the Office of Strategic Assessment revealed the flaws of a deterrent strategy for BW – and even more the implausibility of effective military use.[26] It was a situation not unlike that for the Davy Crockett nuclear missile: the US developed a small nuclear weapon that worked, but one that could not be employed in any imaginable military scenario.

In the 1950s and 1960s, literally hundreds of tests were performed using live biological agents and biological simulants.[27] New production and testing facilities were created: five anticrop and eight antipersonnel agents were standardized.[28] The Directorate of Biological Operations was created at Pine Bluff Arsenal for production and storage of biological agents.

> Between 1954 and 1967, the facility produced the following biological agents and toxins: *Brucella suis*, *Francisella tularensis*, *Q fever rickettsia*, *VEE*, *Bacillus anthracis*, botulinum toxin, and staphylococcal enterotoxin. Bulk agents and antipersonnel munitions filled with these various agents and toxins were produced and stored at DBA as a deterrent capability.[29]

The US BW program was conducted in secret and much of its work remains classified – as is probably appropriate to the kinds of knowledge it generated about offensive BW potential.

By 1969, the US had an arsenal of biological weapons that included over one thousand pounds of dry, lethal anti-personnel agent (in addition to over 150,000 pounds of wet, anti-crop agent)[30] but few usable medical defenses – and a total lack of emergency preparedness for the civilian population despite hundreds of tests that demonstrated the vulnerability of cities to sabotage or strategic attack with biological weapons.[31]

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[25] William M. Creasy, "Research and Engineering Command," *Armed Forces Chemical Journal* v, no.4 (April 1952): 44, 46.

[26] Han Swyter, "Political Considerations and Analysis of Military Requirements for Chemical and Biological Weapons," *Proceedings of the National Academy of Sciences of the United States of America* 65, no. 1 (15 January 1970): 261-270.

[27] Department of the Army, *U.S. Army Activity in the U.S. Biological Warfare Programs*, Volume II (24 February 1977), Appendix E and Appendix F. See also, National Academy of Sciences, *Toxicologic Assessment of the Army's Zinc Cadmium Sulfide Dispersion* Tests (Washington, D.C.: National Academy Press, 1997).

[28] Interdepartmental Political-Military Group, "Annual Review of United States Chemical Warfare and Biological Research Programs as of 1 November 1970," downloaded from www.gwo.edu/~nsarchiv/NSAEBB/NSAEBB58.

[29] Department of the Army, *U.S. Army Activity in the U.S. Biological Warfare Programs*, Volume II (24 February 1977), D-2.

[30] See Memo for the President from Dr. Edward E. David (6 July 1970); White House Title Folder Vol. 1 (1969); Box 1; WHCF; SMOF David; Nixon presidential Matierials, National Archives; also, Interdepartmental Political-Military Group, "Annual Review of United States Chemical Warfare and Biological Research Programs as of 1 November 1970," Doc 24b downloaded from www.gwu.edu/~nsarchiv/NSAEBB/NSAEBB58.

[31] See Appendix E, U.S. Army, *U.S. Army Activity in the U.S. Biological Warfare Programs* (24 February 1977).

A Second Reconsideration

After 1969, when President Nixon unilaterally terminated the offensive BW program, there were two major changes to the way biodefense work was conducted: it operated without an offensive program (biological agent stockpiles and weapons were destroyed) and it operated at an unclassified status. The reasoning and historical sequence of events has already been recounted in some detail.[32] Essentially, bioweapons were determined to be ineffective military weapons for the US, and created a great deal of risk. Better, then, that the US renounce such weapons, provide reassurance, and encourage others to emulate. This led to US support for the Biological and Toxin Weapons Convention that was signed in 1972. Much information about past programs became publicly available: in the same year that the authoritative six-volume study was published, *The Problem of Chemical and Biological Warfare*,[33] the USSR launched its program to modernize and expand its bioweapons program and founded Biopreparat.[34]

While the USSR was busy applying the revolution in genetic engineering to bioweapons, the US worked on improving medical defenses, albeit at a much lower level of investment than the USSR. It is not at all clear based on publicly available documents which effort was more successful – whether heavy Soviet investments in novel bioweapons outran very modest US investments in novel therapies, discussed below.

Post-1969 Biodefense

Without an offensive program, the US biodefense effort was limited to information from the intelligence community and testing of experimental vaccines against known and emerging diseases of potential BW threat. Large, open-air tests in public areas ceased and modeling of potential consequence was not done. Instead, the US program limited itself largely to development of medical defenses and protective equipment for the US military against agents based on criteria that have not been published, but largely reflected concerns with classic BW agents and emerging infectious diseases like the filoviruses and hemorrhagic fever viruses. Because work was done in an unclassified setting, certain opportunities for international collaboration were pursued with beneficial effect.

Threat assessment types of work were limited at Ft. Detrick to determining whether an agent posed an aerosol threat – as a wet agent. It was not considered necessary to run tests with dry agents. Much of the work was, by its nature, dual use. These included aerosol stability tests, the identification of resistant strains, large-scale production of agents and toxins (and purification methods), and animal challenge tests to determine LD50s. However, no work was done to deliberately enhance virulence:

> Use of recombinant DNA procedures with pathogenic organisms and toxins is closely controlled at all locations, both within and outside the government. <u>Development of a more virulent strain of a pathogen is specifically prohibited</u>

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[32] Forrest Russel Frank, *U.S. Arms Control Policymaking: the 1972 Biological Weapons Convention Case*, Ph.D. Dissertation, Stanford University (November 1974), 124.

[33] Stockholm International Peace Research Institute, *The Problem of Chemical and Biological Warfare* (Stockholm: Almqvist & Wiksell, 1973).

[34] Discussion of new Soviet investment in 1973 is discussed in Ken Alibek with Stephen Handelman, *Biohazard* (New York: Random House, 1999), 41.

> under any circumstance, and is not the goal of any BDRP effort. In fact, BDRP uses of recombinant techniques are with the goal of producing a less virulent strain which may be more safely used in the laboratory or for vaccine development."[35]

Work performed was predominantly protective: threat assessment was done in the context of a medical therapy being developed and not simply to evaluate vulnerabilities. When aerosol stability tests were done without a candidate vaccine to test, these were in response to information from the intelligence community (e.g. T-2 mycotoxins after allegations of use).

USAMRIID spent the vast majority of its limited manpower and funding – approximately $23 million per year (in 2006 dollars) – on the development of vaccines and therapies to major biothreat agents.[36] As of 1969, only the anthrax and tularemia vaccines were considered to be both safe and effective against various forms of their respective diseases. (The licensed plague vaccine was safe but not effective against aerosolized *Yersinia pestis*). For all the other agents that had been weaponized, the vaccines in existence were known to induce unacceptably high levels of undesirable reactions, or unacceptable side-effects, or both.

The 1989 Biological Defense Research Program report stated, "While the detailed threat analyses provided by the intelligence community are classified, ALL WORK CONDUCTED UNDER THE BDRP IS UNCLASSIFIED. Those results which impinge on the national security may be classified in accordance with Army Regulation 380-86."[37] While not all work was published in the open scientific literature, publications out of USAMRIID rose from a few dozen in 1969 and 1970 to regularly around 100 in the 1980s.[38] Foreign scientists worked at USAMRIID and collaborative efforts resulted in new vaccines and field trials in other countries that enhanced confidence in the medical countermeasures developed at USAMRIID.

Today, the rationale for biological threat assessments is based on a need to prepare for the possibility of a terrorist attack. What is added to the new assessments is an estimation of the probability of a terrorist being able to acquire or produce a virulent pathogen. Modeling is important not so much for creating medical defenses, but to realistically characterize and thereby anticipate potential attack scenarios in order to organize a more effective response and identify areas where the threat can be mitigated.

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[35] U.S. Army Medical Research and Development Command (USAMRDC), *Biological Defense Research Program: Final Programmatic Environmental Impact Statement* (Frederick, MD: USAMRDC, 1989): 5-9. Emphasis is in the text.

[36] All information is derived from a review of the US Army Medical Research Institute of Infectious Diseases, *Annual Progress Report*, for the years FY1969- FY1990.

[37] U.S. Army Medical Research and Development Command (USAMRDC), *Biological Defense Research Program: Final Programmatic Environmental Impact Statement* (Frederick, MD: USAMRDC, 1989), 2-2. (The emphasis is in the text.)

[38] Stacy M. Okutani, *Structuring Biodefense: Legacies and Current Policy Choices*, Ph.D. Dissertation, University of Maryland (2007), 115.

Threat Assessments Present

The 2002 National Strategy for Homeland Security states that "the knowledge, technology, and materials needed to build weapons of mass destruction are spreading. These capabilities have never been more accessible and the trends are not in our favor."[39] US concern over bioterrorism intensified during the 1990s:[40] this concern was fed in part by actual attempts by groups like the Aum Shinrikyo to disperse biological agents and then validated by the 2001 anthrax letters.[41] Some classified threat assessment research was done after intelligence indicated possible activities by other state bioweapons programs.[42] When such US activities were revealed, it created concern about US compliance with its obligations under the BWC.

More recently, the US has invested heavily in biodefense. The vast majority of funding has gone to medical countermeasures through research administered through the Department of Health and Human Services. The NIAID biodefense research program at HHS began in 2002 – prior to a full and complete threat assessment. Its Strategic Plan continues to guide the implementation of a research and development program necessary to a biodefense effort.[43] For example, the criteria for agents included on Category A list was quickly determined to be: ease of dissemination (or transmission person-to-person); high mortality, with potential for major public health impact; possibility for causing public panic and social disruption; and may require special action for public health preparedness. Criteria for agents on the Category B & C lists reflect generally less potential for a severe impact on public health preparedness and disruption.

In addition to the NIAID tiered agent categories, the CDC and USDA have a list of Select Agents – both human, animal, and overlap pathogens that require compliance with certain rules for researchers who work with them. These lists are largely similar. The Department of Homeland Security added a third list of agents for its purposes. The DHS list is unlike the other lists in that it ranks the agents in some order of severity and incorporates intelligence information, making it not a pure consequence model. Nonetheless, there are a few agents at the top of the list (approximately six) that are reported to be significantly more worrisome than the remainder. The remainder of this article describes the process that generated the listing of ranked agents and the oversight processes that have developed. Inherent in this description is an attempt to understand what this method and its results have done to enhance understanding and preparedness for a bioterrorism threat?

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[39] The Office of Homeland Security, *The National Strategy for Homeland Security* (July 2002), 9.

[40] Susan Wright, "Terrorists and biological weapons: Forging the linkage in the Clinton Administration," *Politics and the Life Sciences* 25, no. 1-2 (March – September 2006): 57-115.

[41] Milton Leitenberg, "Assessing the Biological Weapons and Bioterrorism Threat," *Strategic Studies Institute monograph* (December 2005).

[42] Judith Miller, Stephen Engelberg, William Broad, *Germs: Biological Weapons and America's Secret War* (New York: Simon & Schuster, 2001).

[43] U.S. Department of Health and Human Services, NIAID Strategic Plan for Biodefense Research (February 2002), NIH Publication No. 03-5306. Downloaded from http://biodefense.niaid.nih.gov

NBACC and Bioterrorism Risk Assessment[44]

NBACC exists within the Science and Technology Directorate of the Department of Homeland Security. It performs both laboratory research and mathematical modeling for the assessment of the bioterrorism risk to the U.S. As a first step, an assessment was made of 28 human pathogens considered a likely threat to the US. These were ranked according to the threat they posed, according to both intelligence information and potential consequence. The first bioterrorism risk assessment, *Bioterrorism Risk Assessment 2006*,[45] was completed and delivered to the White House on January 31, 2006. It is a classified document and was therefore not reviewed for this paper. Another assessment will be completed in 2008 that will incorporate the economic effect of agricultural pathogens.

Agents were ranked according to two main criteria. The first was according to the classic characteristics of the agent (unenhanced, except for one agent where there was evidence that an antibiotic-resistant strain had already been created). The second criteria dealt with whether the agent was likely to be produced and disseminated by terrorists.

Batelle performed the assessment for NBACC based on the known characteristics of the agent. For the public health consequence modeling, numerous variables were incorporated, including agent selection, target selection, and production and dissemination methods. Based on the models, estimates of the range of an agent's risk was presented as broad confidence intervals for comparison. DHS adopted the PRA methodology "both as a mechanism for providing regular 'snapshots' of bioterrorism risk to the nation, and as a risk mitigation strategy evaluation tool for use by risk managers."[46]

Sensitivity studies were then performed to discriminate between consequences. There were three broad categories: high relative risk, moderate relative risk, and low consequence. Once the ranking of the 28 agents was completed, NBACC discussed the rationale for it with the Department of Health and Human Services (HHS). Because the risk assessment was assembled from numerous discrete criteria, it was possible to begin estimating what variables were "pushing" the ranking for each agent. This allowed for in-depth discussions with experts to debate the merits of the rank of each agent and, it is believed, enhanced the credibility of the overall assessment.

That is, the process of ranking the 28 major human pathogens was refined through repeated interactions with experts who themselves had to reassess what they understood about the agents. Those who conducted the assessment attempted in every instance to support every assertion with scientific documentation so that the assessment was grounded in experimentation. Sometimes what was accepted as true lacked a published scientific basis.

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[44] Okutani interview with NBACC official, April 2007.

[45] *Bioterrorism Risk Assessment. 2006*. Biological Threat Characterization Center of the National Biodefense Analysis and Countermeasure Center. Washington, DC. Cited in The National Research Council, *Interim Report on Methodological Improvements to the Department of Homeland Security's Biological Risk Analysis* (Washington, DC: National Academies Press, 2007).

[46] McMillan, NJ et al., "An end-to-end quantitative approach for estimating bioterrorism risk," Abstract for a panel proposed for the SRA 2007 Annual Meeting, "Risk 007: Agents of Analysis." Downloaded from www.sra.org.

However, because of the second criteria – likely terrorist use – the NBACC assessment is not a pure consequence model like the one the NIH used in creating it list of agents (A,B,C). For this information, the NBACC assessment drew from information from the intelligence community that necessarily required the final assessment to be classified. Scenarios were estimated based on potential terrorist capability: from proliferation from a state-sponsored program through a highly-funded organization, to terrorists working in cells or as lone actors.

However, because there were some significant uncertainties regarding some intelligence information and estimates of terrorist activities, the model was run twice: once with the intelligence and expert information and once without (i.e. assuming that the terrorist groups had access to all the agents). This was done to ensure that the value of the information the US had was not discounted and also that it would not unduly influence the outcomes.[47]

The final model can be updated with new information or to test a variety of assumptions. It is possible to "dial in" or "dial out" parameters such as acquisition methods, effects, types of attacks, etc. A range of situations can be modeled in order to estimate effect. In this way, the relative risk of a variety of terrorist actions can be estimated. In so doing, important knowledge gaps were identified. Part of NBACC's mission is to reduce these knowledge gaps in order to improve the accuracy of the estimates in its risk modeling. This is where the crux of concern about NBACC's work is centered.

NBACC annually has somewhere between 35-50 research projects underway annually. The vast majority of the budget has been spent on traditional agents. However, a small amount of time has been spent looking at enhanced and emerging agents in order to assess the potential usefulness of such to a bioterrorist. At this point, NBACC is developing a strategy for dealing with advanced agents.

Some projects are "born classified" if they draw upon information from an intelligence source. Other projects can be classified if it reveals a significant vulnerability to the nation or a system.

Classification does not imply compartmentalization, however. If research reveals a vulnerability and a remedy is identified, that information is not concealed. Rather, such information is quickly provided to the US department who can implement any adjustments to address the threat in a discrete way. That is, the defense can improved without widespread knowledge of the vulnerability identified. In one case, for example, a threat to the US water supply was identified that could be readily addressed with a change to certain standards (e.g. temperature settings). That that information was given to the Department of Agriculture and a simple revision to accepted standards is issued without needing to publicize the rationale or nature of the threat detected.

Internal Scientific Review[48]

The scientific review process occurs through three basic levels of effort. The first is the project identification. This begins with the work of the Biothreat Risk Assessment that is performed

[47] Okutani interview with government consultant (October 2007).
[48] Okutani interview with DHS official. (May 2007)

every two years by the BTCC (described above). The BTRA model estimates the threat from identified biothreat agents using seventeen different nodes to populate a computational analysis. There are many subject matter experts involved in this process. Knowledge about agents and their growth and stability properties are gathered. Finally, a literature review (open-source) is done to know what is understood about the agents. If there are gaps in knowledge, these are then made into a scientific question that can be answered. By the time a project is identified, there is a scientific vetting system in place.

The second step is to identify the objectives. These are questions that will address and improve the risk assessment. This has a major impact on the threat assessment. The threat assessment, after all, drives the funding for countermeasures.

The last step is the search for proposals. Specific researchers with expertise in the subject area are sought who can work with Category A select agents; who have a track record in working with such agents, and who, preferably, are affiliated with a government institution (e.g. FDA/USDA/HHS) it is easier to move funding to another government institution rather than a private entity. That does not exclude private institutions, as NBACC has worked with some private institutions with a history or technologies able to work with threat agents.

A Broad Agency Announcement is made and proposals are then reviewed as they are received. Researchers who participate in the working groups that review proposals are not allowed to review their own project or those in competition with theirs.

NBACC conducts an internal scientific review to evaluate proposals for weakness, methodology, fit with the mission space, appropriateness to the mission stated, and whether it fills a knowledge gap or otherwise bridges known information. If a project passes this stage of review and is accepted, a second, external review is performed by the American Institute of Biosciences. They perform an independent evaluation with scientific and technical experts. AIB comments on the scientific merit of the work and the workplan.

DHS also takes steps to ensure that projects are performed under appropriately certified facilities and conditions. DHS performs site inspections of facilities that they work with. Within DHS, the Science and Technology Group re-checks the facilities' documentation to ensure compliance with all applicable regulations (animal use, human use, recombinant work, etc).

The vast majority of work is not classified unless classification is determined to be appropriate. A small number of projects come classified because the information comes from the intelligence community. Finally, results of a research project can be classified if they reveal a vulnerability.

External Scientific Review

There are three recent processes that have been created to provide external – meaning, non-departmental – scientific review of the NBACC work.. The first is the National Academy of Sciences board that was stood up in 2006 to review the BTRA methodology. The second is the Scientific and Technical Advisory Council (STAC) created in 2007 by Batelle that reviews all

NBACC work. The third is a new interagency review group created by Presidential Directive and is a "For Office Use Only" document (Appendix 1 to HSPD-10).

DHS presented its 2006 methodology to the National Academy of Sciences. In 2006 an interim NAS report was given to DHS[49], to which comments were received[50]. A final draft of the NAS recommendations is being circulated and may eventually become available for public review if it passes the DHS security review. As already discussed, the NAS review is limited to an examination of the methodology used and not its findings.

The STAC was created in 2007 in order to provide some independent scientific review of the work at NBACC, in particular the Biothreat Characterization Center. It reflects, in part, a desire to reassure scientists working on NBACC projects and in part to assure others that such are scientifically rigorous. The STAC members were not publicly announced and any release of their names requires the consent of their affiliated institutions. The STAC members review projects and can indicate whether they have concerns or if a project raises a perception of concern, but do not have authority to recommend changes.[51]

Finally, there is a new interagency review group that was created by Presidential Directive in the middle of 2007. Little is known about the group – either its membership or processes – because the document was not publicly circulated. Its purpose is to provide a more independent review process than that done by scientific groups internal to DHS or to any other department.

Compliance Review

On August 26, 2005, Secretary Chertoff issued Management Directive System Number 6300, "Compliance with, and inplementation of, arms control agreements." The Directive "provides policy and responsibilities for Department of Homeland Security implementation of arms control agreements of the United States Government and compliance with them." It applies to all organizational entities within DHS and those US National Laboratories, universities, and private contractors directly engaged in work to support DHS at the federal level. The term "arms control agreements" applies to "all legally and politically binding arms control measures to which the United States is a Party or a signatory." This includes confidence building measures.

According to the directive, "All relevant research, development, and acquisition projects shall be assessed for arms control compliance at inception, prior to funding approval, whenever there is significant project change, and whenever in the course of project execution an issue potentially raises a compliance concern." Such compliance will be carries out in such as way so as to avoid compromise of national security information.

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[49] The National Research Council, *Interim Report on Methodological Improvements to the Department of Homeland Security's Biological Risk Analysis* (Washington, DC: National Academies Press, 2007).

[50] Department of Homeland Security, "2008 DHS Bioterrorism Risk Assessment: Thoughts and Impressions from the NAS Interim Report," presentation to the Committee on Methodological Improvement to the Department of Homeland Security's 2006 Bioterrorism Risk Assessment (10 February 2007).

[51] Okutani interview with government consultant (October 2007).

For this purpose, a Compliance Review Group (CRG) was established within DHS to review all BW and CW countermeasures activities. The CRG is chaired by the Deputy Secretary, DHS and the Under Secretary for Science and Technology, John Vitko, is the Executive Secretary. The other members of the CRG are the General Counsel and the Under Secretary for Policy (and any others as appropriate).

As of July 2007, the CRG has met four times since its inception and has reviewed hundreds of DHS projects.[52] The Deputy Secretary reviews and approves compliance determinations of the CRG on behalf of the Secretary, DHS. However, if there is no agreement within the CRG, the Chair "shall recommend to the Secretary a treaty compliance determination, including any dissenting views of CRG members, or of other Department subcomponents and agencies that have equities in the matter. The Secretary will provide guidance or compliance determination on such issues."[53]

The Executive Secretary to the DHS CRG shall "ensure that any issue that reasonably raises a compliance concern is brought to the CRG for a compliance determination."[54] The Management Directive explicitly directs the heads of DHS subcomponents and agencies to "coordinate with the Executive Secretary of the CRG before taking any action, including but not limited to research, tests, development, exercises, and operations, that could reasonably raise an issue of DHS compliance with an arms control agreement." If any activity raises any doubt about compliance, counsel should be sought.

To carry out project reviews, a Compliance Assurance Program (CAP) office was created within the Under Secretary for Science and Technology. The CAP office requires that every project leader submit a Project Summary and complete a BWC Checklist. The Project Summary requires the following: the Title, Rationale, Objective, and Status of the project and a brief description of the scientific and technical approach, the names of any toxic chemicals, biological select agents and toxins, or novel reagents used in the project, and the types, quantities, and disposition of any dissemination means used as well as a rationale for their use.

The BWC Checklist is a list of twenty-two questions that fall into five categories. The first seven questions are taken from the NSABB Criteria for Identifying Dual Use Research of Concern. There are two questions regarding the agents used – whether select agents or the generation or use of recombinant or synthetic DNA are involved. Two others regarding intent are derived from Article I of the BWC. There are four questions about the facilities and equipment used and seven about the project's purpose.

There is both a legal review of the information submitted and a review to identify aspects of a project that might foster *perceptions* of concern. Those who participate in the CAP reviews are intelligence analysts, economists and microbiologists. These assessors are totally independent of those doing the work being reviewed and those who perform the scientific reviews.

[52] Okutani nterview with consultant, May 9, 2007.
[53] DHS, Management Directive Number 6300 (August 26, 2005).
[54] DHS, Management Directive Number 6300 (August 26, 2005).

The CAP organizes the projects to be reviewed by the CRG into three categories. Category 1 includes those projects that pose no compliance concern in the opinion of the analysts, CAP, and the office of General Counsel within the Science and Technology Directorate. Essentially, this means the project did not trigger any of the NSABB criteria and no dual-use issues were identified. These projects are described in a two or three paragraph summary in a read-ahead book.

Category 2 projects are those that might reasonably raise perceptions of compliance concern, but do not trigger any NSABB criteria. Those projects that pose significant dual-use issues, data generated on critical vulnerabilities, or those that involve studies of biological agent production or dissemination are included. Such projects are summarized in a read-ahead book and also briefed to the CRG at the meeting.

Category 3 projects are those that might reasonably raise the perception of a compliance issue by involving a NSABB "experiment of concern" criteria or involving types and quantities of biological agents that could raise questions about intent and purpose or experimental equipment, procedures, or activities that could raise questions about intent and purposes. Such projects are briefed to the CRG by the Program Manager and Compliance Officer and require CRG member signatures. At any point, the CRG can classify a project.

Issues for Consideration

Research Methodology

There are two major potential concerns over application of the PRA to the bioterrorist threat. First, it may not be appropriate for estimating terrorist motivation. The PRA was largely designed to estimate and combine probabilities for mechanical systems – and therefore the outcomes of any particular intervention could be known with a high degree of confidence. By contrast, estimates by even the most seasoned experts of terrorist group intentions and methods regarding BW inevitably involves a high degree of uncertainty. Rather than using a PRA approach an estimating likelihood of every decision-making stage, it may be more useful to apply a game theoretical approach to this part of the Bioterrorism Threat Assessment.[55]

Second, DHS has not run its model against known historical events. It would be useful to know how well it compares with the past activities of the Aum Shinrikyo or Rajneesh cults in order to have greater confidence in it.

In addition, the DHS model ranks agents according to estimates of severity of consequence. Integral to this assessment is some reasonably reliable model of the epidemiology of disease. For this, ever more precise estimates of lethal doses of agents (LD_{10} or even LD_1) is said to be required. There is at least some room to wonder whether such data (and the experiments required to generate that information) is really necessary: is our understanding of disease dynamics sophisticated enough to benefit from this kind of precision?

[55] Personal discussion (September 2007).

Oversight

As discussed above, the scientific and legal oversight of DHS biodefense research is notable for the level of internal scrutiny involved. Every program is reviewed and every PI must certify that there is no intention of violating the terms of the BWC. In itself, this is tremendously commendable. In addition, submitting the Bioterrorism Risk Assessment methodology to an independent scientific review committee of the National Academies also ensures a greater degree of scientific rigor. However, the NAS committee's mandate is limited to an evaluation of the methodology itself and not the findings or conclusions. Furthermore, there is some concern that while Batelle may develop a reasonable model, the significant benefits of doing so under a cooperative, open environment where every hypothesis can be tested is rebuffed. That is, the Risk Assessment is likely to be sound, but perhaps not optimal.

What is less clear about the oversight process is how the research requirements are generated from the risk assessment model. This is important because in principle, many enhanced characteristics could be theoretically tested for its consequence, but not all are truly feasible. Furthermore, while advancements in science and technology may indicate potential avenues for enhancing agent properties, how likely is its actual application by a terrorist group? The concern is that we will, by assuming that others perceive similar possibilities, push the technology in a way no one else has and thereby expand the threat space. This was indeed the case during and after World War II.

The lesson of the US BW program from 1942 – 1969 is that uncertainty prompts excessive reaction. If future directions are based on potential capabilities, this can lead to an exaggeration of the threat.

Transparency

There are processes in place that increase internal transparency – i.e. the government has a greater awareness of what kinds of research activities are being pursued. However, that has not translated into a significant level of external transparency. Those outside the government and the processes it created know little about what is being done, by whom, and with what purpose in mind.

The highly-esteemed former Commander of USAMRIID, David Huxsoll, ran a very transparent medical research effort in the 1980s:

> An open, transparent biomedical defense program is the only type of program that truly supports US national policy, which is based on the provisions of the BWC. If the medical defense program were shrouded by secrecy of any degree, it would be incompatible with program acceptance, execution, and accomplishment. Selective openness is unacceptable: being "open" or "transparent" implies access to information relating to all stages of the research and development cycle. I also firmly believe that a laboratory of institute that can lay claim to internationally recognized scientific excellence has an open program. Transparency is the responsibility of everyone who has any connection with the issues, either as part of his job, or as a consulting expert (whether

scientifically recognized or self-appointed). In other words, transparency is everybody's business.[56]

The unclassified status allowed foreign scientists to work at USAMRIID and also for US researchers to cooperate on international projects to test new therapies and vaccines that aided both foreign countries where diseases were endemic and the US biodefense research program. A few examples are noted below:[57]

- A new vaccine for Argentine Hemorrhagic Fever was developed under a UN Development project, jointly conducted by USAMRIID and Argentine investigators. The live, attenuated Junin vaccine was taken to final product in 1982 in compliance with vaccine requirements for the US and Argentina. Researchers also tested ribavirin, an antiviral, in a field trial against AHF.
- During outbreaks of Lassa fever in Liberia in the late 1980s, human immune plasma was harvested from recovering patients and used to treat infected ones. In the process, USAMRIID collected several hundred high-quality Lassa-immune plasma units for future treatment of the disease.
- USAMRIID leadership in filovirus research and international collaboration led to a "comprehensive, collaborative research program organized with the Institut Pasteur and implemented in the Central African Republic. The innovative international program, a pioneering first, allowed previously separate and independent laboratory and field efforts to be combined, closely integrated, and efficiently focused on Ebola and Marburg viruses."[58]

It is difficult to imagine USAMRIID scientists being given permission by foreign governments such as China to administer experimental US drugs to their citizens if those drugs came out of a classified US biodefense program. It is not even possible to imagine non-US citizens from certain countries being allowed to work within the US biodefense program today after the restrictions imposed by the PATRIOT act on researchers and international collaborations.

This decision to keep all work under the BDRP unclassified came despite the 1979 Sverdlovsk anthrax release, reports of deaths from T-2 mycotoxins in Southeast Asia, and other reports indicating the existence of biological weapons programs in other states. Therefore, in the midst of revelations of an evolving threat, a deliberate choice was made to operate the US Biodefense program under basic transparency rules and to retain the defensive focus of its work.

Conclusion

The U.S. government created the NBACC to better understand – and develop countermeasures to – biological threats to the US homeland. Can a state with advanced capabilities and a past

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[56] David L. Huxsoll, "Narrowing the Zone of Uncertainty between Research and Development in Biological Warfare Defense," in Raymond A. Zilinskas, ed., *The Microbioilogist and Biological Defense Research: Ethics, Politics, and International Security* (New York: The New York Academy of Sciences, 1992): 177-191.

[57] See Okutani, *Structuring Biodefense*, 116-117.

[58] Commander's Forward, USAMRIID, *Annual Progress Report FY1986* (Frederick, MD: USAMRIID), ix-x.

offensive program credibly perform secret biodefense work without generating adverse and competitive reactions among other states – and emulation by aggressive non-state groups? This is a fundamental question because the threats the US will face – and must therefore prepare for – will likely share the essential features of those generated by biological weapons: dual-use, widely available materials and methods that can be used for mass destruction by small groups or possibly even individuals.

For those concerned with national security and foreign policy, there are few more pressing issues than this, as both the conceptual and operational practices required to meet asymmetric threats to the US must develop at a pace commensurate with the evolving danger. One path forward is to examine whether reassurance about the non-aggressive nature of a state's activities is possible when preparing defenses. As a theoretical construct, reassurance is not well-understood nor well-defined. It is likely, however, that it will prove fundamental to our future security.

To prevent actors from crimes that cannot be punished – and therefore from which they cannot be credibly deterred – the US must not rely solely on being better prepared to respond and ever more vigilant. To do so is inherently impractical. Rather, the US must begin finding new ways to both provide reassurance to other states and to be reassured where trust is warranted. Doing this may require building innovative networks built on transparency and regular signaling. If the US can work actively in this way, it may be able to both delve deeper into the activities of groups of greatest interest and greatest threat and perhaps manage to diminish the threat itself.

Appendix 1: CWC and BWC Compliance

Project Summary – Template

- Project Title,
- Project Rationale. Please provide a clear statement regarding why the project needs to be undertaken (e.g. describe the specific foreign threat or technological capability that it is intended to understand, counter, etc., and/or the U.S. vulnerability it is intended to overcome, and whether it is based on any specific open source or intelligence information).
- Its objective (e.g. to determine, to develop, to improve, to better understand, to support development of, etc.)
- A brief description of the scientific/technical approach,
- Status (underway on-hold, completed),
- The names of any toxic chemicals*, biological select agents and toxins (as defined by 42 CFR §73.3 and §73.4), or novel reagents used in the project,
    - A statement regarding precise quantities (for chemicals and toxins only)
    - The method of production (e.g. laboratory quantities produced in cultures, etc.) or where they were obtained, and
    - Their disposition (e.g. consumed by experimentation, archived, decontamination/destroyed etc.)
- The types, quantities and disposition of any dissemination means (spraying devices, vectors, etc.) used in the project, as well as the rationale for their use.

*As defined in Article II of the Chemical Weapons Convention: *Any chemical which through its chemical action on life processes can cause death, temporary incapacitation or permanent harm to humans or animals. This includes all such chemicals, regardless of their origin or of their method of production, and regardless of whether they are produced in facilities, in munitions or elsewhere*.

Appendix 2: Biological Weapons Convention (BWC) Checklist

Section 1: BWC Screening Criteria

NSABB Criteria for Identifying Dual Use Research of Concern (July 2006 draft)

Is the project intended to enhance the harmful consequences of a biological agent or toxin.

Is the project intended to disrupt immunity or the effectiveness of an immunization without clinical and/or agricultural justification?

Is the project intended to confer to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent toxin, or facilitate their ability to evade…

Is the project intended to increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin?

Is the project intended to alter the host range or tropism of a biological agent or toxin?

Is the project intended to enhance the susceptibility of a host population?

Is the project intended to generate a novel pathogenic agent or toxin, or reconstitute an eradicated or extinct biological agent?

Agents

Does or will the project involve work with biological select agents or toxins?

Does or will the project involve the generation or use of recombinant or synthetic DNA?

Intent

Is or will the project be involved in any way with the development, production, stockpiling, transfer, acquisition, retention or possession of any biological agent, toxin, or delivery system for use as a weapon?

Does or will the project involve the transfer or weapons, equipment of means of delivery for BW agents or toxins?

Facilities and Equipment

Does or will the project include the use of a high or maximum biosafety containment laboratory (BL-3 or BL-4 lab)?

Does or will the project include the use of bioreactors or fermentors? If so, please describe the use in the Project Summary.

Does or will the project include the use of an aerosol test chamber? If so, please describe the use in the Project Summary.

Are any dissemination means (e.g. spraying devices, vectors, etc.) included in the project? If so, please describe the types, quantity and rationale for their use in the Project Summary.

Purpose

Does or will the project involve laboratory research for biological agent threat characterization and/or trials for countermeasures against such agents?

Does or will the project involve paper studies or modeling, without laboratory research on agents or toxins?

Does or will the project involve the development of biological agent detection or surveillance systems?

Does or will the project involve developing decontamination means?

Does or will the project involve the development of individual or collective protection systems?

Does or will the project involve the creation of vaccines or other medical countermeasures for humans/animals?

Does or will the project involve the use of microorganisms for the prevention of disease in humans or animals, for diagnostic reagents, or for use with biocontrol agents or plant inoculants?