# Chapter 1

# Introduction

In the mid-1990s, growing concerns about the threat posed by biological weapons began to catch the attention of policymakers throughout the United States government. The 1993 bombing of the World Trade Center suggested that a new species of terrorist might aim to inflict large numbers of civilian casualties on US soil, and would not shrink from using unconventional weapons.[1] Worries about the proliferation legacies of state-sponsored biological weapons programs in Iraq and the former Soviet Union increased with the Japanese cult Aum Shinrikyo's deadly release of sarin nerve gas in the Tokyo subway system in 1995, prompting many US leaders to herald a new era of catastrophic terrorism by non-state actors.[2] On November 16, 1997, during renewed tensions over Iraqi weapons inspections, then-Secretary of Defense William Cohen brandished a 5-pound bag of sugar on *This Week* to illustrate the amount of anthrax bacilli necessary to kill half the population of Washington, DC. The policy community issued studies about the reality of the biological, chemical, and nuclear terrorism threat that ranged from guarded concern to the apocalyptic. As a group of experts in epidemiology and infectious diseases began compiling technical updates on potential biological weapons (BW) such as anthrax for use by healthcare professionals,[3] a trio of former intelligence and defense officials announced that the "danger of weapons of mass destruction being used against America and its allies is greater now than at any time since the Cuban missile crisis of 1962."[4]

These cumulative warnings – framed in a series of 1995 Senate hearings, numerous press conferences and talk show appearances, publications in scientific and policy journals, and hundreds, if not thousands, of articles and books in the popular media – certainly convinced many Americans, as well as

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[1] A concise review of contemporary arguments for and against the likely use of biological weapons by "professional terrorists who have associated themselves with nationalist-religious causes such as pan-Islamic identity" can be found in editor Jonathan Tucker's introduction to *Toxic Terror: Assessing Terrorist Use of Chemical and Biological Weapons* (Cambridge, Mass.: MIT Press, 2000), 9-12. In Chapter 11 (page 185) of the same volume, John V. Parachini examines the implications for chemical terrorism in the case study of "The World Trade Center Bombers (1993)."

[2] Amy E. Smithson and Leslie-Ann Levy. *Ataxia: The Chemical and Biological Terrorism Threat and the US Response.* (Washington, DC: The Henry L. Stimson Center, 2000), 1.

[3] Thomas V. Inglesby, et al., "Anthrax as a biological weapon," *Journal of the American Medical Association,* No. 281 (12 May 1999), 1735.

[4] Ashton B. Carter, John Deutch, and Philip Zelikow, "Catastrophic Terrorism: Tackling the New Danger," *Foreign Affairs* No. 77 (November/December 1998), 80.

their leaders, that chemical and biological weapons threatened their security at home and abroad.[5] Although only one instance of biological terrorism within the US had been documented – by a religious cult that contaminated restaurant salad bars in an Oregon community with *Salmonella typhimurium* in the hope that the resulting food-poisoning epidemic would incapacitate voters and change the outcome of a local election – the number of "hoax" letters threatening exposure to anthrax and other agents soared.[6] Emergency responses to these suspected biological attacks revealed unevenness in treating potential victims, reflecting varied policies and practices among the federal agencies assigned responsibility for managing the consequences of biological terrorism.[7]

Presidential Decision Directive 62, announced in 1998, updated US counterterrorism strategies by focusing on stronger and more coordinated federal preparedness for attacks against the civilian population with unconventional weapons, including biological agents.[8] Congress passed legislation designed to bolster local preparedness for the use of weapons of mass destruction in 1996, and legislation intended to "improve, enhance or expand the capacity of national, State and local public health agencies to detect and respond effectively to significant public health threats, including major outbreaks of infectious disease, pathogens resistant to antimicrobial agents and acts of bioterrorism" in 2000.[9] Despite the appearance of political momentum and public support, civilian biodefense efforts still received relatively limited funding: the Department of Health and Human Service's bioterrorism preparedness and research budget for fiscal year 2000 totaled just less than $278 million, and about $271 million in fiscal year 2001.[10],[11] Awareness might have been heightened, but the national biological security strategy remained fragmented among agencies and entities with competing priorities.

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5 A 1998 survey by the Chicago Council on Foreign Relations found that 76% of participants viewed chemical and biological terrorism as a "critical threat" to US interests. The percentage increased to 86% following the fall 2001 terrorist attacks and anthrax assaults. Worldviews 2002: Public Opinion and Foreign Policy. (Chicago: Chicago Council on Foreign Relations 2002), 16. The survey summary can be found at http://www.worldviews.org/detailreports/usreport.pdf (accessed August 2004).

6 W. Seth Carus, *Bioterrorism and Biocrimes*, (Washington, DC: Center for Counterproliferation Research, National Defense University, 1998 [2001 Revision]), 7 and 109-156.

7 Leonard A. Cole, *The Anthrax Letters: A Medical Detective Story* (Washington, DC: Joseph Henry Press, 2003).

8 An unclassified abstract of Presidential Decision Directive-62 (PDD-62), "Protection Against Unconventional Threats to the Homeland and Americans Overseas," dated 22 May 1998, can be found at http://www.ojp.usdoj.gov/odp/docs/pdd62.htm (accessed August 2004).

9 The Defense Against Weapons of Mass Destruction Act of 1996 (Title XIV of Public Law 104-201, passed 23 September 1996), also known as the Nunn-Lugar-Domenici Amendment, authorized a program to train and equip first responders in 120 cities to confront terrorist threats. The Public Health Threats and Emergencies Act (Title X of Public Law 106-505, passed 13 November 2000) authorized funds to revitalize the Centers for Disease Control and Prevention (CDC) and expand a CDC plan to improve state and local readiness for disease outbreaks, various education and assessment programs, and an interagency working group on public health and medical consequences of bioterrorism.

10 US Department of Health and Human Services Fact Sheet, "HHS Initiative Prepares for Possible Bioterrorism Threat," 18 May 2000.

## BIOSECURITY POST-9/11: A NEW SENSE OF URGENCY

Active efforts to prepare for the possibility of biological terrorism began immediately in the wake of the terrorist attacks of 11 September 2001, and the public health system leapt to full alert with the first of the eventual 22 cases of confirmed or suspected anthrax contracted through deliberately contaminated mail addressed to media offices and political figures in Florida, Washington, and New York.[12] The efforts of clinicians and public health professionals to identify and treat suspected cases, offer appropriate prophylaxis to the potentially exposed, and accommodate thousands of additional scares and hoaxes severely strained laboratory and disease surveillance resources at the local, state, and federal level, revealed communication gaps (including initial failures in explaining the unfolding health crisis credibly to the public), and generally raised concerns about the nation's ability to respond to a more catastrophic act of biological terrorism.[13] The direct and indirect costs of the anthrax incidents have not yet been completely totaled, but the costs of remediating contaminated postal facilities in New Jersey and the District of Columbia, as well as the Senate Hart Building and other parts of the Capitol complex, have alone been estimated in the hundreds of millions.[14]

In response to the attacks, Congress dramatically increased funding (more than 10-fold) for domestic biodefense, including more than $1 billion designated annually for the last three years to cooperative agreements administered through the Centers for Disease Control and Prevention (CDC) to upgrade state and local laboratory capacity and communications networks, and through the Health Resources and Services Administration (HRSA) for local hospital preparedness.[15] The budget for biodefense research and vaccine development at the National Institute of Allergy and Infectious Diseases (NIAID, part of the National Institutes of Health, or NIH) climbed from $53 million in fiscal year 2001 to

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[11] Ari Schuler, "Billions for Biodefense: Federal Agency Biodefense Funding, FY2001-FY2005," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* No. 2(2) (2004), 86.

[12] Daniel B. Jernigan, et al., "Investigation of bioterrorism-related anthrax, United States 2001: Epidemiologic findings," *Emerging Infectious Diseases* No. 8(10) (October 2002), 1019.

[13] *Bioterrorism: Public Health Response to Anthrax Incidents of 2001*, Report GAO-04-152, (Washington, DC: General Accounting Office, October 2003).

[14] Scott Shane, "Clean Up of Anthrax Will Cost Hundreds of Millions of Dollars," *The Baltimore Sun* (18 December 2002).

[15] Ari Schuler, "Billions for Biodefense."

more than $1.6 billion in fiscal year 2004.[16] Portions of two laws, the USA PATRIOT Act and the Bioterrorism Prevention Act of 2002, expanded existing controls on access to "select agents," those pathogens deemed to pose a high risk to public safety if made into biological weapons.[17] Together, the two laws defined classes of restricted persons to be denied access to such agents in domestic laboratories[18], created a registry system for laboratories and individuals carrying out select agent research in the US, and imposed criminal penalties for possession of such agents for reasons other than "bona fide" research. Various regulatory agencies, most notably the new Department of Homeland Security (DHS), have developed new or expanded science and technology programs aimed at accelerating the availability of biological countermeasures. In fact, the majority of highly visible new biodefense programs, such as the $5.6 billion Project Bioshield,[19] focus on domestic preparedness and countermeasures, although the administration's unclassified statement on "Biodefense for the 21st Century" declared that

> Preventing biological weapons attacks is by far the most cost-effective approach to biodefense. Prevention requires the continuation and expansion of current multilateral initiatives to limit the access of agents, technology, and know-how to countries, groups, or individuals seeking to develop, produce, and use these agents.[20]

Despite this display of commitment to preventing the proliferation and use of BW, and funding for countermeasures to mitigate loss of life and health should such measures fail, the future of a sound national biological security policy remains far from assured. Political will alone will not be sufficient to overcome the many challenges that the public health, bioscience, intelligence, law enforcement, and

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[16] Ibid.

[17] Title II of The Public Health Security and Bioterrorism Prevention Act of 2002, Public Law 107-188 (12 June 2002) and The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct terrorism (USA PATRIOT) Act, Public Law 107-56 (26 October 2001). Pathogens that might cause catastrophic harm if successfully weaponized are assigned to the "select agent list" according to criteria codified in Title 42 (Part 73) of the Code of Federal Regulations; responsibility for updating the list and supervising the use of such agents is held by either the CDC (for pathogens that could be used to target humans) or the US Department of Agriculture (for pathogens that could infect plants or animals of agricultural importance).

[18] "Restricted persons" as defined by the Patriot Act and the Bioterrorism Prevention Act collectively, include individuals who have been indicted or convicted of crimes punishable by imprisonment for more than one year, fugitives from justice, illegal aliens, dishonorably discharged servicemembers, any "unlawful user of any controlled substance," anyone who has been "adjudicated as a mental defective" or committed to any mental institution, any national of a country deemed by the Secretary of State to support terrorism, anyone who has committed or can be "reasonably suspected" of terrorist crimes, and anyone who can be "reasonably suspected" of association with an organization that engages in terrorism or of being "an agent of a foreign power."

[19] Project Bioshield promises an estimated $6 billion over 10 years to encourage development of diagnostic tools, drugs, vaccines, and other countermeasures to potential biological weapons threats by private industry. ("President Bush signs Project Bioshield Act of 2004," White House press release, 21 July 2004. Available at http://www.whitehouse.gov/news/releases/2004/07/20040721-2.html (accessed August 2004).

[20] "Biodefense for the 21st Century," White House fact sheet, 28 April 2004. Available at http://www.whitehouse.gov/homeland/20040430.html (accessed August 2004).

security communities face in working together over the long term. These diverse communities must develop a shared vocabulary as well as a seamless strategy; their success will rely heavily on the integration of appropriate science, technology, and health (STH) expertise at every level of biological security policy development and implementation.

## Biosecurity Policy Challenges

First, strategies will have to keep pace with staggering advances in abilities to understand and manipulate biological processes. Rapid advances in the biosciences mean that previously benign microbes could be transformed into pathogens, circumventing the controls on select agents that lie at the heart of current domestic security efforts. Advances in functional genomics, synthetic biology, and nanotechnology may soon yield revolutionary therapies and environmental panaceas, but might also be subverted for malicious purposes to make novel biological weapons.

The dissemination of tools and techniques through international collaborations and a burgeoning global biotechnology industry mean that inherently dual-use technologies – those critical to either legitimate biological research and development or weapons production, whose intended use cannot be distinguished on a technical basis – would be incredibly onerous, if not impossible, to contain through the traditional export control-based paradigm. Development of a technically sound national and international biosecurity strategy that prevents or detects bioweapons development based on program intent, rather than merely content, requires new approaches to governing biotechnology transfers.[21] Despite US insistence that member states of the Biological Weapons Convention (BWC) pass national legislation to prevent biological terrorism as an alternative to the compliance protocols that it rejected in 2001, the World Health Organization's guidelines for international biosecurity standards will not be released until next year, and mechanisms for encouraging or enforcing compliance with such standards have not been selected.

The reaction of the public and the bioscience community itself to new domestic biosecurity measures has been decidedly mixed. Although few scientists object to the idea of improving physical and personnel security for deadly pathogens, opinions on the efficacy and impact of the new "select agent rules" stemming from the PATRIOT Act and the Bioterrorism Prevention Act range widely. Certainly, the regulations have come with a financial cost for universities, and productivity and legal concerns for researchers stemming at least in part from perceived zealousness in implementation by federal law

[21] Jean Pascal Zanders, "Biotechnology Transfers for Peaceful Purposes," Presentation to the UN Secretary's Advisory Board on Disarmament Matters (1 July 2004).

enforcement.[22],[23] Some fear that the windfall in funding for basic biodefense research will disappear in the future if discoveries fail to meet policymakers' expectations, and that other necessary infectious diseases research may suffer as a result of a skewed research portfolio.[24] Others believe that $1.7 billion federal budget slated for the construction of new high-level pathogen containment laboratory spaces (including biosafety level 4 laboratories, where pathogens for which no cures exist can be handled) far exceeds both the existing shortfall in such facilities and the available number of qualified workers.[25] Plans announced by NIAID to construct such laboratories at several universities have raised concerns about a concomitant increase in incidents such as laboratory-acquired infections, and the balance between secrecy to preserve national security and the community's right to know about possible safety risks.[26] Some scientists also fear that the new government emphasis on security contradicts standing US policy to protect basic research findings from information control whenever possible, and worry that open publication of peer-reviewed basic research findings, the fundamental mechanism by which scientists build upon and verify each others' work, might be endangered directly by categorizing the results of a federally funded research project as "sensitive but unclassified," or indirectly through restrictive clauses in new government grants.[27]

## BRINGING SCIENCE, TECHNOLOGY, AND HEALTH EXPERTISE INTO THE BIOSECURITY POLICY PROCESS

To understand the nuances of many biological security policy questions, decision-makers require not just lucid explanations of technical capabilities and feasibilities, but insights into the culture of science. Historically, few channels have connected the agencies and advisory bodies charged with developing and implementing security policies and the rich reservoir of bioscience and biotechnology expertise in the US Several high-level commissions on terrorism preparedness launched prior to the

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[22] Diana Jean Schemo, "After 9/11, Universities are Destroying Biological Agents," *The New York Times,* (17 December 2002).

[23] Joanne Chan, "Issue Brief: Select Agent Rules (updated)" in "Science and National Security in the Post-9/11 Environment," (Washington, DC: The American Association for the Advancement of Science, 2003) available at http://www.aaas.org/spp/post911/brief_archive/agents/ (accessed August 2004).

[24] John Dudley Miller, "Bioterrorism Research: New Money, New Anxieties," *The Scientist* No. 17(7) (7 April 2003), 52.

[25] John Dudley Miller, "US Government Launches Biolab Building Spree," *The Scientist* No. 18 (10) (24 May 2004), 48.

[26] Laura H. Kahn, "Biodefense Research: Can Secrecy and Safety Coexist?" *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* No. 2(2) (2004), 81.

[27] Ryan Ricks, "Issue Brief: Sensitive but Unclassified Information (updated)," in "Science and National Security in the Post-9/11 Environment," (Washington, DC: The American Association for the Advancement of Science, July 2004), available at http://www.aaas.org/spp/post911/sbu/index.shtml (accessed August 2004).

terrorist attacks of fall 2001 highlighted the critical roles of science and technology (S&T) in preventing acts of catastrophic terrorism, and advocated efforts to address the threat of BW proliferation and use.[28] Although these commissions (particularly the Hart-Rudman Commission[29]) encouraged domestic investment in both research and education to expand the pool of available STH expertise, they prized the tools that science might yield, rather than advocating stronger integration of such expertise into the security policy process.

Two committees composed of eminent scientists convened by the National Research Council (NRC) asked how STH expertise might instead improve strategies to prevent BW use. In 2002, the National Academies convened a self-initiated study spurred by the desire to determine how US S&T capabilities could be best put to use in combating terrorism; the report observed that the "S&T resources are in one set of agencies and the homeland-defense missions in another," and that the "technical nature of the threats" demanded STH capabilities throughout the government in order to develop a coordinated S&T strategy.[30] A report by an NRC committee studying ways to prevent the destructive application of biotechnology recommended stronger and sustained ties between the life sciences, national security, and law enforcement communities.[31] Both recognized the difficulties in accomplishing this, and suggested a variety of organizations, contracting mechanisms, and advisory boards to fill the need for guidance on specific technical issues. Neither report offered an easy mechanism for engaging appropriate STH expertise in every stage of biological security policy development and implementation.

## Study Design and Methods

In order to capitalize on current enthusiasm for stronger ties between the security and bioscience communities, those familiar with both must find ways to match the demand for STH expertise in Congress and the Executive branch agencies and bodies charged with preventing BW threats with the

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[28] The report of the Gilmore Commission that most directly addresses health/biological issues is the "Third Annual Report to the President and the Congress," (Washington, DC: The Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction, 15 December 2001), which can be found at http://www.rand.org/nsrd/terrpanel/terror3-screen.pdf. *Countering the Changing Threat of International Terrorism*, (Washington, DC: The National Commission on Terrorism, June 2000), also called the "Bremer Commission Report," can be found at http://www.mipt.org/bremerreport.asp (accessed August 2004).

[29] *Road Map for National Security: Imperative for Change*, (Washington, DC: the US Commission for National Security/21st Century, 31 January 2001), 30. Can be found at http://www.cfr.org/pdf/Hart-Rudman3.pdf (accessed August 2004).

[30] Committee on Science and Technology for Countering Terrorism, *Making the Nation Safer: The Role of Science and Technology in Countering Terrorism,* (Washington, DC: National Academies Press, 2002)

[31] Committee on Research Standards and Practices to Prevent the Destructive Application of Biology, National Research Council, *Biotechnology Research in an Age of Terrorism* (Washington, DC: National Academies Press, 2003). The report is frequently referred to as "The Fink Report," after Committee Chair Dr. Gerald Fink.

most appropriate sources of such expertise. This report attempts to identify strategies for, and obstacles to, successfully completing this task, and to deepen understanding of science-based decision-making in the national security context, in theory and practice. Its findings rely heavily upon the knowledge and experiences described by a group of technical experts, decision makers, and science policy professionals during a series of roundtable discussions on "Science, Technology, and Health Expertise in the National Biological Security Policy Process," hosted by the Henry L. Stimson Center with the support of the Carnegie Corporation of New York.

Participants met in sessions intended to concentrate on the perspectives of three distinct communities: 1) the governmental and non-governmental organizations that serve in advisory capacities to government bodies, providing technical analysis, science policy guidance, or resident science and technology fellows; 2) homeland security, disaster response, and domestic law enforcement; and 3) intelligence, defense, and foreign relations.[32] Participants (see Acknowledgements) brought a wealth of experiences to the table, frequently wearing the multiple hats of their past and current roles in each discussion. Each group was asked to consider the same series of central questions, in addition to potential case studies and questions tailored to the group's specific interests:

1. What science, technology and health (STH) data and resources do the Federal entities that formulate biosecurity policy, and experts within them, identify as essential to the policy process?
2. Where and how do these entities consistently seek STH expertise deemed necessary?
3. How much internal STH expertise resides in agencies with operational security missions, and how is it used in both technical and general policy processes?
4. How have various offices/agencies "engineered the science into the system?"
5. Given infinite resources, what would the "wish list" for STH expertise available to the agencies charged with biological security look like?

The discussions considered the term "biological security policy" broadly, addressing issues related to technology transfers and proliferation threats, biodefense research and countermeasures,

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[32] Session 1, held 9 June 2004, focused on how decision-makers seek such expertise from "traditional" sources of science and science policy information – including science and technology fellows, professional societies, non-governmental policy organizations, academic centers, and official governmental science policy advisory bodies – and if and how these demands have changed in the post-9/11 world.

Session 2, held 21 June 2004, addressed the specific needs of the homeland security and law enforcement communities, including where and how relevant agencies seek expertise deemed necessary.

Session 3, held 23 June 2004, examined experiences in international security at the State Department, HHS, and within the intelligence community, including how internal expertise is used in both technical and general policy processes.

biosecurity measures aimed at controlling access to select agents, and the ability of advisors to address more narrowly defined technical questions. Each group (except the first) reviewed and commented upon the conclusions of the previous sessions before beginning the discussion. All subsequent observations offered by roundtable participants were derived from transcripts of the proceedings. In order to allow broader participation and encourage frank discussion, all comments have been quoted without attribution to any specific speaker, as per the agreement of the participants.

Over the last decade, many influential reports have considered pathways and obstacles to effective incorporation of S&T analysis into government decision-making, including an entire series by the Carnegie Commission on Science, Technology, and Government. The inescapable features of this general policy landscape, as well as the challenges particular to the life sciences, will be considered in Chapter 2. Chapter 3 addresses the current environment for S&T expertise in biological security policy development and implementation, while Chapter 4 discusses barriers to its successful incorporation, as well as unmet needs and new strategies.