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SPEAKING DATA TO POWER:

SCIENCE, TECHNOLOGY, AND HEALTH EXPERTISE IN THE NATIONAL BIOLOGICAL SECURITY POLICY PROCESS

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Acknowledgments and Preface

This report could not have been produced without the generosity of a group of distinguished professionals who offered to carve hours from their demanding schedules to participate in roundtable discussions, grant detailed interviews, and review the observations distilled from their lively dialogues. Had they brought nothing to the table except their current credentials, they would have been formidable enough; their collective past experiences, spanning myriad governmental and non-governmental perspectives, made them legion. The opportunity to share their observations and insights was a privilege.

Participants, listed in alphabetical order and by affiliation at the time of the June 2004 roundtable series, included: Dr. Katherine Bliss, International Affairs Fellow, Office of International Health Affairs, US Department of State; Dr. Kerry Brenner, Senior Program Officer, Board on Life Sciences, the National Academies; Dr. Joseph Dudley, Senior Analyst, Biosecurity and Agriculture, the INTELLIBRIDGE Corporation; Dr. Gerald Epstein, Senior Fellow, Science and Security, Center for Strategic and International Studies; Dr. Barry Erlick; Ms. Nancy Forbes, Senior Analyst for Science and Technology, Strategic Assessments Center, CIA; Dr. Susan Ginsberg, Senior Policy Advisor, Science and Technology Directorate, US Department of Homeland Security; Dr. Elin Gursky, Senior Fellow for Biodefense and Public Health Programs, ANSER Institute for Homeland Security; Mr. Martin V. Hale, Special Assistant, Office of the Assistant Secretary for Public Health Emergency Preparedness, US Department of Health and Human Services; Dr. Jo Husbands, Director, Committee on International Security and Arms Control, the National Academy of Sciences, The National Academies; Dr. Gigi Kwik, Fellow and Assistant Professor of Medicine, University of Pittsburgh Medical Center, Center for Biosecurity; Dr. Jennifer Laird, Science and Technology Coordinator, Women in International Security, Georgetown University; Ms. Sina Lehmkuhler, Department of Homeland Security Graduate Fellow, US Department of Homeland Security; Dr. Sarah Lister, Specialist in Public Health and Epidemiology, Domestic Social Policy Division, Congressional Research Service; Dr. Stephanie Loranger, Biology Issues Director, Federation of American Scientists; Dr. Kristine Maxymiv, Intelligence Officer, Counterproliferation Support Office, Biological Warfare Assessments Division, Defense Intelligence Agency; Dr. Randall Murch, Research Staff Member, Science and Technology Division, Institute for Defense Analysis; Dr. Stephen Nelson, Associate Director for Science and Policy Programs, American Association for the Advancement of Science; Dr. Marc L. Ostfield, Bioterrorism Security Advisor, Office of International Health Affairs, US Department of State; Ms. Deborah Runkle, Senior Program Associate, Scientific Freedom, Responsibility and Law Program, American Association for the Advancement of Science; and Dr. Patricia Stein Wrightson, Senior Program Officer, Roundtable on

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Julie E. Fischer
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Abbreviations

AAAS	American Association for the Advancement of Science
BW	Biological weapons
CDC	Centers for Disease Control and Prevention
CIA	Central Intelligence Agency
DHS	US Department of Homeland Security
DOD	US Department of Defense
DOJ	US Department of Justice
DTRA	The Defense Threat Reduction Agency
FBI	Federal Bureau of Investigations
FFRDC	Federally Funded Research and Development Center
HHS	US Department of Health and Human Services
HS-ARPA	Homeland Security Advanced Research Projects Agency
NGO	Non-governmental organization
NSC	National Security Council
OSTP	Office of Science and Technology Policy
PCAST	President’s Council of Advisors on Science and Technology
S&T	Science and technology
STH	Science, technology, and health

Executive Summary

As the Manhattan Project and World War II wound together to mutually dependent ends, a small group of technically trained researchers found themselves standing astride the suddenly unclear borders of US science and security policy. Their contributions, and the federal commitment to continuing the productive association of industry, academia, and the Department of Defense into peacetime, created the template for an enduring (if not always cordial) relationship between science advisers and policymakers. Scientific and technological developments have since become integrated into every facet of diplomacy, defense, and daily life, making dependable systems for delivering useful scientific advice to decision makers even more critical to good governance. Over the last decade, many thoughtful reports have mapped possible paths between every level of political organization and credible, accessible sources of scientific and technical analysis. Nonetheless, determining when and how to incorporate science, technology, and health (STH) expertise into government decision-making remains a challenge, a particularly pressing one for the agencies involved in the national security policy process.

The dichotomous nature of scientific progress, with its ability to yield new weapons and new shields – sometimes based on the same technologies – vaulted into the public consciousness again following the terrorist events of September 11, 2001, and the subsequent anthrax assaults. Policymakers and the public found themselves confronted with the suddenly evident threat of biological terrorism and warnings of a sadly eroded public health infrastructure almost simultaneously. The U.S. Congress and the Executive branch have responded with dramatically increased funding and a raft of laws, regulations, directives, and new programs for biological defense and security. Despite this evidence of current political will, the public health, bioscience, intelligence, law enforcement, and security communities still face many challenges in working together to develop a long-term, effective commitment to preventing the proliferation and use of biological weapons. These diverse communities must develop a shared vocabulary as well as a seamless strategy; their success will rely heavily on the integration of appropriate STH expertise at every level of biological security policy development and implementation.

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, including relevant regulatory agencies, with the most appropriate sources. This report attempts to identify strategies for, and obstacles to, successfully completing this task. 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. Participants (see Acknowledgements and Preface) 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" – do personal relationships between resident science advisors suffice?
5. Given infinite resources, what would the "wish list" for STH expertise available to the agencies charged with biological security look like?

BIOLOGICAL SECURITY IN THE POLICY LANDSCAPE

New efforts to incorporate STH expertise into the national biological security policy take place against the broader background of science policy and politics. The low level of science literacy in the U.S presents a serious problem in communicating science and technology issues to policymakers and the public. Individual leaders in the executive and legislative branches have placed varying degrees of value on S&T policy advice as part of the political decision-making process, both reflecting and exacerbating occasional tensions between the political, science policy, and science communities. The influence and status of S&T advisors to the presidents have varied with each administration's distinct priorities, most dramatically in 1973 when President Nixon abolished the President's Science Advisory Committee out of frustration with perceived political disloyalty. The Office of Technology Assessment (OTA) provided Congress with nonpartisan, unbiased S&T policy analyses on the range of increasingly complex technical issues facing legislators from 1972 until it closed, a victim of budget politics, in 1995.

The legacies of such decisions and the current science policy climate affect decision-makers' openness and access to science policy advice. Although both the President's Council and OTA enjoyed high levels of credibility among technical experts and receptive policymakers, their well-merited reputations for offering politically neutral and competent S&T advice did not prove sufficient to save them during times of budget, organizational, and political turmoil. Conflicts between groups of scientists and political leaders, such as those recently played out publicly between science advocates and the Bush administration, can affect the receptivity of executive branch decision-makers to analyses that might be critical. The demise of OTA also left a vacuum that can be detected not only in uneven access to S&T analysis among members of Congress, but in the changing demands on remaining governmental and non-governmental policy analysis organizations. Legislators and their staffs depend increasingly on S&T experts within the NGO community, who may have different backgrounds, different sources of information, and possibly different organizational stakes in various issues.

The population of professionals who are "bilingual" in the vocabularies of research culture and government policy continues to evolve with the increasing number of fellowship opportunities and academic programs. The American Association for the Advancement of Science (AAAS) S&T Fellowship programs alone now counts about 1700 alumnae, with approximately one-third of each year's AAAS fellowship class electing to remain within the policymaking and policy analysis communities. S&T fellows, former fellows, and other scientists seeking what are often labeled "alternative careers" in policy have changed the baseline level of technical sophistication in the policymaking and policy analysis communities. Despite increased training opportunities, scientists willing to leave the laboratory bench for policy work still remain the exception rather than the norm, and may experience tacit or explicit disapproval from leaders in their academic institutions and fields. Although a relatively minor burden for tenured or otherwise senior researchers, the lack of career incentives for even more limited public service may discourage researchers earlier in their careers from volunteering to serve as technical experts.

WHAT DOES STH EXPERTISE LOOK LIKE?

Scientific expertise can take various forms, all of which fulfill the general task of providing an interface between the scientific community and decision-makers. These currently accepted forms for providing STH expertise in the national biological security policy process strongly influence when and how science policy information can be supplied. Such forms include:

- Standing advisory bodies to Congress, including the Government Accountability Office (GAO, formerly the General Accounting Office) and the Congressional Research Service (CRS), which have taken on an increasing number of technology-based studies with the demise of OTA;

- Standing advisory bodies to security and regulatory agencies, such as the Defense Advisory Board, the recently launched FBI Science and Technology Advisory Board, and the Department of Homeland Security (DHS) Homeland Security Science and Technology Advisory Committee;

- Issue-specific or ad hoc advisory bodies to security and regulatory agencies, which may be statutorily required by Congress, such as the Secretary's Council on Public Health Preparedness at the Department of Health and Human Services (HHS), or convened by the agencies themselves to gather information on a specific topic quickly;

- Professional societies, representing those who share specific technical training or working areas, have become a growing source of information on biodefense and biosecurity issues in the past three years;

- Non-profit, non-governmental policy organizations, which provide an increasing amount of biological security expertise to decision-makers through publications, briefings, testimony, and personal relationships with policymakers and their staffs, or to agencies through contracts;

- S&T fellowship programs, which introduce technical expertise directly into Congressional or Executive branch agency offices, simultaneously providing fellows with hands-on public policy experiences and government offices with resident scientists;

- The National Academies, the nation's premier source of independent S&T analyses, which convene workshops, administer fellowship programs, conduct educational outreach, and, most significantly carry out science policy studies (largely at the request of federal agencies, although the Academies can carry out self-driven studies); and

- Science advisors and in-house expertise, including those officially styled as S&T advisors (such as the new Senior Science and Technology Adviser to the Secretary of State, and technically trained professionals within Congressional offices and regulatory or security agencies whose roles includes providing S&T policy advice as part of a more complex job description.

THE DISTINCTIVE CHALLENGES OF BIOSECURITY

With increased scrutiny on and funding for bioterrorism prevention in the US, the number of individuals newly immersed in related preparedness and research efforts has ballooned concomitantly. Biodefense and biosecurity mandates command an increasing amount of time, attention, and resources from professionals in fields where such issues until recently remained peripheral, including public health, health care, biological and biomedical sciences, and agricultural and food safety. Reliance on a public health infrastructure composed largely of state and local assets has necessitated STH expertise at every level of government. Organizations that represent health professionals at the state and local level, professional societies representing researchers, and research universities have become stakeholders in biodefense and biosecurity issues.

The roles of the various Federal agencies charged with aspects of biodefense and biosecurity have also evolved since 2001 as a result of both major legislation (including the Bioterrorism Prevention Act) and a series of executive directives and agreements. Programs within the Departments of Defense and State have changed little, while increased funding has translated to a dramatic expansion of programs and offices within HHS. The Department of Agriculture has increased research, oversight, and security responsibilities, and the Environmental Protection Agency (EPA) has gained new responsibilities (with little budget accompaniment) for water security and remediation of contaminated buildings. The largest change of all included the 2002 creation of the Department of Homeland Security (DHS), which oversees operational, research and development, and policy missions related to biodefense and biosecurity within its Emergency Preparedness and its Science and Technology Directorates.

The legacies of heavily politicized nuclear threat issues and years of massive government-funded research projects fostered interaction between various groups of physicists, security policy analysts, and policymakers at every level. In contrast, many of the now-key players in biological security and defense have received a relatively recent introduction to the security concepts. Until quite recently, the community of biologists with any experience in studying biological weapons or defense against biological attacks, or who claimed strong ties to government policies in any way other than grant-making, remained fairly small. This historical schism between security issues, including those involving biological weapons, and the life sciences pervaded the policy analysis community as well.

Attitudes toward biosecurity issues in the biological research community may have been influenced by worries about visa issues, and – for those most intimately connected with biodefense research – the impact of the "select agent rules." Researchers who study pathogens now classed as select agents and their institutions have experienced uncertainty about the scope of the new rules, frustration with bureaucratic backlogs in processing registrations for laboratories and security risk assessments for individuals, and fears that criminal penalties might result from unintended compliance failures. Many select agent researchers also harbor concerns about self- or government-imposed controls on open publication in peer-reviewed journals of techniques that might prove useful in designing biological weapons, an extremely difficult set of criteria to define when almost all biological research falls into the inherently dual-use category. Although new biodefense research grants continue to draw researchers to the field, countering warnings that the logistics of compliance would have a chilling effect on all biodefense research, this influx has itself created a wave of new experts with varying degrees of experience in handling different pathogens.

STH ADVICE IN BIOLOGICAL SECURITY: THE CURRENT DEMAND

Experts necessary to providing sound science and science policy advice can be classified in three general tiers:

- Technical experts have scientific or professional training in a biological or biomedical discipline, including current acquaintance with cutting-edge research and real-world conditions. These subject matter experts can serve on advisory committees (such as the standing advisory boards, ad-hoc or issue-specific committees, or National Academies panels), or be recruited to address specific questions by government agencies or programs, but most likely serve as advisors briefly before returning to the research environment.

- Technical policy advisors with specific expertise have technical training as well as practical experience in a specific biological or biomedical field. These (mostly mid-career) scientists rely upon their research expertise and experience in providing guidance for operational and analytical missions within government agencies, as well as intra- or inter-agency planning. Technical policy advisors sometimes have greater policy leverage as scientifically credible liaisons to interagency working groups than they do as available sources of expertise within home agencies, where they may be somewhat isolated by a stove-piped organizational structure.

- Science policy professionals have technical training and credentials which confer credibility among both researchers and government decision-makers, but focus on broader science and science policy issues. They may rarely (or never) rely upon their original areas of narrow technical expertise, but rather make use of their dual familiarity with researchers and research culture and the policy environment and its demands to connect decision-makers with the most appropriate types of STH expertise when needed, in an accessible and useable form.

Identifying technical experts in biodefense and biosecurity often proves more difficult than simply seeking a distinguished publication record or academic reputation -- a scientist may be a world expert on the natural history of a specific pathogen but have little or no knowledge of existing data on that pathogen's behavior in weaponized form (such as a deliberately released aerosol). "Expert exhaustion" can pose a problem, especially during a crisis or a period of intense policy debate, when the number of technical experts with reliable credentials and adequate free time can prove unequal to the demand. Although both technical experts and technical policy advisors should obviously have specific expertise in the programs that they guide, participants acknowledged that this is not always the case, and that the decision-makers who rely upon them may not distinguish between scientific disciplines at all.

INCORPORATING STH EXPERTISE INTO DECISION-MAKING

Reports or publications in which science and science policy advice are presented can take several forms: specific technical analysis or broad science policy, open or closed (produced for use within a specific organization with no outside distribution), anticipatory or reactive, self-driven by an organization or solicited by request, and evidence-based or estimate-based – that is, relying upon incomplete evidence and past experiences to draw "best guesses."

Integration of STH expertise in most agencies and organizations may depend upon informal personal networks rather than a systemized approach. The likelihood that STH expertise enters the process through a more formal mechanism may reflect the value that high-level administrators place on science policy advice, the history of advisory mechanisms within the organization, or a combination of both. In-house S&T expertise does exist in intelligence and federal law enforcement agencies, but the organizational components of the programs with a technical or research and development focus tend to be segregated from the offices that make decisions on broader policy issues. Getting scientists "out of the ghetto and into the main office" requires placing a small core of science policy professionals at multiple levels throughout the organization, rather than just within programs or offices that concentrate on technical or research issues; ensuring that at least some of these science policy professionals are integrated into the staff that fulfills policy and planning functions in a systemized way; creating credible scientific leadership within the agency, with adequate resources and authority stemming directly from the head of the program or organization; and educating senior decision-makers to recognize the relevance and value of STH expertise early in the decision-making process through internal and external outreach.

The National Science Advisory Board for Biosecurity (NSABB) offers a potentially successful model for incorporating policy recommendations made by STH experts into the national biological security policy process. The National Academies initiated a study called Biotechnology Research in an Age of Terrorism (also known as the "Fink Report" after its chair, Dr. Gerald Fink), a self-driven, anticipatory, largely evidence-based open report on broad science policy issues, prior to the anthrax assaults of fall 2001 with the support of the Sloan Foundation and NTI. The resulting report outlined several steps in a new system for overseeing inherently dual-use biotechnology research (which might result in knowledge or tools that could be applied equally to legitimate research and development or the production of biological weapons). One recommendation included creating the NSABB, which was realized when the Secretary of HHS announced the charter of the NSABB in March 2004. Although decision-makers did not adopt every recommendation of the Fink report, they did charge the NSABB specifically with addressing most of its recommendations. Thus, a comprehensive anticipatory report's operational recommendations on science policy have been translated into at least the launch of a structure intended to ensure that appropriate STH expertise goes into development of particular regulatory and oversight structures, based on a set of policy recommendations that outlined specific courses of action.

SURMOUNTING THE BARRIERS

A constant influx of fresh perspectives, born of active communication between technical experts, science policy professionals, and experts in security and law enforcement issues will be required to prevent the first reactions to a domestic biological attack from becoming entrenched and unyielding dogma. Although some decision-makers, STH technical policy advisors, and science policy professionals have developed personal networks to exchange STH information, whether many of these fairly new S&T advisory mechanisms for biodefense and biosecurity issues will prove robust enough to survive the comings and goings of individual personalities remains unclear in a still-evolving policy environment.

Classification and secrecy issues

A barrier with both practical and conceptual aspects facing the S&T policy community lies in access to classified materials and potential application of classification (or the vague "sensitive but unclassified" label) to basic research publications, stemming from a relatively small population of bioscientists accustomed to secrecy issues and cultural differences between the bioscience and intelligence and law enforcement communities on the desirability of open information. A relatively easily accomplished task involves increasing accurate perceptions of the nature of classification and secrecy in science and science policy analyses within the community of potential biodefense experts. The converse involves enabling STH experts to push back against reflexive rather than productive classification by the intelligence community, a more challenging task. Accomplishing this task would require outreach within the S&T community as well as to the intelligence and law enforcement agencies to establish a clear message on when classification of biodefense and biosecurity information might prove counter-productive, and to provide willing expertise where possible to help make informed decisions on restricting information. Approaches include creating formal channels for continuing feedback between scientists and policy or intelligence analysts after workshops or studies have been concluded, rather than relying on groups of academic experts who "operate in a vacuum, present ideas, and then go away."

Deepening the Pool of Experts

A lack of encouragement or mentoring for those interested in science policy options, especially for professionals considering a policy career but not yet ready to "leave the fold," and the nature of tenure demands for those scientists who would like to contribute time to public service without leaving their laboratories for a prolonged period can limit the pool of technically trained science professionals both interested and willing to participate in the national biological security policy process to either quite senior scientists or those who have given up professional recognition within their disciplines for the less tangible rewards of a science policy career. Further investigation is needed to characterize the demand for career development programs for scientists with an interest in public service and science policy who might not be ready for or interested in a year-long fellowship commitment, and to seek methods to make short-term commitments to public service a "career builder" for academic researchers. A potential method for introducing researchers interested in public service, but not necessarily eager to leave the laboratory entirely, to policy concepts could come in the form of a curriculum to develop non-technical communications skills. Finally, attention should be paid to reforming the categories of post-training career choices deemed as indicators of successful service for former recipients of federal pre-doctoral or post-doctoral training grants, and to encourage accurate estimates of the population of S&T policy professionals by encouraging professional societies and government organizations that examine career choices within the larger community of S&T research professionals to include science policy career options among the choices available.

Reliance on Interagency Expertise

One aspect of providing STH expertise articulated by some participants reflected a bias that might not be intuitive to policy analysts in the NGO community: a tendency for government decision-makers to seek technical information, when necessary, from other government sources. Successful intra- and interagency exchange of STH expertise can result from formal mechanisms for consulting on particular issues, or as a result of the "Rolodex Effect," in which science policy professionals or technical science advisors deliberately cultivate relationships with decision-makers in order to provide an obvious source of STH expertise when necessary. Building a strong core of internal STH expertise depends, in part, upon the availability of professionals with the appropriate skills and knowledge, and the commitment of the organization's leadership to fostering integration of S&T professionals into the decision-making process. Lessons in determining the most effective methods of encouraging interagency sharing of appropriate STH expertise may be drawn from the examples of interagency working groups, temporary assignments of employees from one agency to another, and "virtual committees" of experts representing different programs and agencies that have been favored by the intelligence community. A growing body of STH expertise on biodefense and biosecurity issues now resides in the NGO community; for it to be accessed, such organizations must build trust with government decision-makers, possibly through adopting a reliable system for quality assurance in technical reports.

Building a Better Study

Core expertise in biodefense and biosecurity studies – those who study pathogens, infectious diseases, and potential countermeasures – is critical but not enough to provide relevant STH advice. Cross-disciplinary working groups and advisory committees that include experts in sociology, anthropology, political science, and other social sciences in addition to biology and security allow decision-makers to consider biosecurity issues in a richer context. The demise of OTA has left significant gaps in two specific areas: reports designed to provide insights on (sometimes politically controversial) technical issues for a public constituency, and anticipatory reports allowed the luxury of taking the long view. The previously cited Fink Report on dual-use biotechnologies provides one example of an anticipatory study conducted by the National Academies; only about 20% of the projects conducted through the National Academies receive funding from a non-federal source. Financial resources are needed to help policy analysis organizations, including the National Academies, produce studies that can anticipate, rather than merely respond to, serious biodefense and biosecurity policy issues before political pressures or events demand immediate actions.

Cementing Scientific Leadership

Developing and supporting scientific leadership within government agencies and programs, ideally in the form of a senior science advisor, constitutes a critical step in securing both adequate in-house expertise and institutional receptivity to STH advice. Without authority, permanence, and sufficient resources, the science advisor can end up being "a cheerleader for science," whose most effective possible role is "trying to connect disparate agencies and perspectives as opposed to being an advisor and influencing how science is driven." Lessons might be drawn from early successes in establishing a senior science advisor at the State Department, from failures where they have occurred, and from analyzing whether agencies with security missions have functioned differently when policymakers with science or technical expertise served at the highest levels.

The likelihood that STH expertise can be successfully incorporated into the decision-making process at every level of the national biosecurity policy process depends not only on institutional structures, but on continued outreach among the bioscience research, science policy, security, law enforcement, and intelligence communities to develop a shared vocabulary, increase mutual understanding, and identify the problems that STH expertise can and cannot solve.

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

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[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.

Chapter 2

Biological Security in the Policy Landscape

Any attempts to understand the use of STH expertise in biological security policy must take place against the background of broader issues in science policy and politics. The "gulf of mutual incomprehension" between intellectuals trained in the humanities and the sciences, lamented by C. P. Snow as the lack of shared vocabulary among those who make decisions on technology policy and those who understand the underlying technologies, has changed little in the last forty years.[1] Individual leaders in the executive and legislative branches have placed varying degrees of value on S&T policy advice as part of the political decision-making process, both reflecting and exacerbating occasional tensions between the political, science policy, and science communities.[2]

As noted in 1988 by the Carnegie Commission on Science, Technology, and Government, "(s)cience and technology, effectively mobilized, can help the President achieve his Administration's goals. That mobilization can best be accomplished by bringing science and technology (S&T) into the highest levels of government."[3] Although all presidents since Truman have maintained some form of structured science advisory capacity, the influence and status of S&T advisors have depended upon each administration's distinct priorities. The President's Science Advisory Committee (PSAC), led by the Special Assistant to the President for Science and Technology, grew from demands for high-level technical advice during the Eisenhower presidency following the launch of Sputnik.[4] For its first few years, the committee thrived as a politically neutral liaison between the White House and the technical community, although its influence began to wane by the end of the Kennedy administration. President

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[1] C. P. Snow, *The Two Cultures*, (Cambridge, U.K.: Cambridge University Press, 1998 ed. [first published 1959]).

[2] The relationship between the current administration and the broad scientific community has appeared strained at times. Recent allegations that regulatory agencies have manipulated reports to remove or de-emphasize politically unpalatable data, and the replacements of appointees to federal technical advisory committees with experts who appear to have more politically sympathetic views, have drawn outcries not only from partisan opponents but an unusually public statement on "Restoring Scientific Integrity in Policymaking" whose signatories include 48 Nobel laureates. The statement, list of signatories, and a companion report by the Union of Concerned Scientists can be found at http://www.ucsusa.org/global_environment/rsi/index.cfm. The equally vehement rebuttal by OSTP Director John H. Marburger III on "Scientific Integrity in the Bush Administration," (2 April 2004) can be found at http://www.ostp.gov/html/ucs/ResponsetoCongressonUCSDocumentApril2004.pdf (accessed August 2004).

[3] *Science and Technology and the President* (New York: Carnegie Commission on Science, Technology, and Government, 1988), available at http://www.carnegie.org/sub/pubs/ccstfrep.htm (accessed August 2004).

[4] Bruce A. Bimber, *The Politics of Expertise in Congress: The Rise and Fall of the Office of Technology Assessment* (Albany, New York: State University of New York Press, 1996), 18-20.

Nixon, already at odds with the university research community over its opposition to his Vietnam policies, grew increasingly frustrated with what he perceived as PSAC's insufficient political loyalty, marked by its members' objections to administration priorities such as anti-ballistic missile defense and supersonic transport. He eliminated the committee and the special assistant's office in 1973, allowing the director of the National Science Foundation to fill the role of science advisor when necesssary.[5],[6]

President Ford began restoring science policy advisory offices and structures upon taking office, and these have continued to evolve during subsequent administrations. The Office of Science and Technology Policy (OSTP), statutorily created in 1976 to advise the president on S&T issues,[7] succeeded the individual science advisors who served Presidents Truman and Eisenhower, the Office of Science and Technology initiated by Eisenhower and eliminated by President Nixon, and the successor program established by President Ford. During the George H.W. Bush and Clinton administrations, the Director of OSTP also held the title of Assistant to the President for Science and Technology, a special status not granted to the current OSTP director.[8] The current organizational structure for S&T advice to the White House includes the President's Committee of Advisors on Science and Technology (PCAST), a group of outside experts who issue reports and recommendations on a range of S&T issues, and the National Science and Technology Council (NSTC), a Cabinet-level council chaired by the president, started in 1993 to coordinate S&T policy development and implementation across all Federal agencies.

The Office of Technology Assessment (OTA), the former internal S&T advisory organization to the US Congress, also met a grim fate. Congress launched OTA in 1972 to fill the need for nonpartisan, unbiased S&T policy analyses on the range of increasingly complex technical issues facing legislators, derived from a source independent of the executive branch.[9] A strictly bipartisan Technology Assessment Board comprised of members of Congress reviewed OTA reports to ensure lack of bias and oversaw the staff of about 200 OTA analysts, most of whom held advanced degrees in a scientific discipline.[10] As described by a roundtable participant who served within OTA, the organization existed to provide Congress with policy analysis on issues where a basic understanding of the underlying science and

[5] Ibid.

[6] The National Science Board, "A History in Highlights: 1950-2000," accessible at http://www.nsf.gov/nsb/documents/2000/nsb00215/nsb50/1970/supp_dir.html (accessed August 2004).

[7] National Science and Technology Policy, Organization, and Priorities Act of 1976, Public Law 94-282 (11 May 1976).

[8] Brendan A. Maher, "John H. Marburger III: Science Advisor to the President," *The Scientist* No. 16(4) (18 February 2002), 60.

[9] The Technology Assessment Act of 1972, Public Law 92-484 (13 October 1972).

[10] Ted Agres. "Informing Congress: A Return of the OTA?" *The Scientist* No. 15[19] (1 October 2001), 8.

technology contributed dramatically to understanding the implications of policy decisions. OTA staff conducted the analyses and wrote reports, with the assistance of advisory panels of "technical and substantive experts," in response to bipartisan requests from Congressional committees. OTA conducted fairly long-term studies, rather than answering quick technical questions about scientific facts (the purview of CRS), although the staff could provide studies ranging from broad assessments that might take a year or more to shorter-term projects, such as workshops on specific topics. Technical memos and background papers contained factual material, while assessments presented policy options, rather than recommendations.

> They were always on controversial areas – Congress doesn't care about things that don't come to its attention – and they typically got wider interest because the communities that really cared about those areas would both be working with us as we did the study, and they'd be usually waiting to see it as it came out.…In many ways, I think we wrote for the public constituency, because that's one way to get the message back to Congress.[11]

After 23 years and hundreds of comprehensive reports spanning the life sciences, environmental and energy issues, transportation technologies, and military and security analyses, the 104th Congress voted to withdraw funding. OTA closed in September 1995, a victim largely of budget politics.[12] Efforts to revive OTA in the recent years through legislation have not succeeded despite support from the science policy community.

What do these ups and downs in formal science advisory bodies portend for providing STH expertise in the national biological security policy process? Roundtable participants, especially those in the session that drew heavily from the "professional" science advisory community, discussed extensively how these legacies and the current science policy climate affect decision-makers' openness and access to science policy advice. Although both PSAC and later OTA enjoyed high levels of credibility among technical experts and receptive policymakers, their well-merited reputations for offering politically neutral and competent S&T advice did not prove sufficient to save them during times of budget, organizational, and political turmoil. The executive branch in particular, with its more uniform set of political objectives, may be less open to influence by outside S&T advice that appears insensitive toward an administration's goals, or by a science community viewed as openly partisan. Although it would be an exaggeration to say that levels of trust between the current administration and academic researchers have disintegrated to those of the early 1970's, several participants pointed out that recent heated exchanges

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[11] Roundtable discussion, Session 1.

[12] Bruce Bimber, *The Politics of Expertise in Congress.* Following the "Republication Revolution" of 1994, the Republican Conference passed a resolution on Congressional reform that included cutting legislative branch budgets; abolishing OTA's relatively small $20 million budget offered symbolic savings with little short-term impact on legislators' constituent interests and services.

between groups of scientists or science advocates and the administration played out in the media,[13],[14] do affect the climate for S&T policy advice, particularly the receptivity of executive branch decision-makers to analyses that might be critical. While the scientists themselves may distinguish between objectively derived technical advice and their own political views and opinions, policymakers may not make such a clean distinction between the views of *science* and individual *scientists*.

Second, the demise of OTA left a vacuum that can be detected not only in uneven access to S&T analysis among members of Congress, but in the changing demands on remaining governmental and non-governmental policy analysis organizations. The role of non-governmental organizations (NGOs) that provide S&T advice, defined by the Carnegie Commission as the universe of institutions ranging "from broad-spectrum general-purpose scientific and technical groups, such as the American Association for the Advancement of Science, to elite academies, such as the National Academy of Sciences and its affiliated National Research Council, from there to an extensive array of discipline-specific societies, such as the American Physical Society, through think tanks dedicated to government work, such as the RAND Corporation, and on to policy advocacy groups," [15] continues to grow. The National Academies have taken on more of the burden for long-term studies. Legislators and their staffs who might have once turned to OTA for S&T policy or technical questions can depend on the remaining two Congressional analytical support agencies.[16] In addition, they also depend increasingly on S&T experts within the NGO community, who may have different backgrounds, different sources of information, and possibly different organizational stakes in various issues. Participants pointed out that these consulting relationships between Congressional staff and S&T policy analysts arise from no particular standard institutions; affiliations may grow from past working relationships, meetings at seminars or other formal S&T policy events, word of mouth, or informal professional/social networking.

The population of professionals who are "bilingual" in the vocabularies of research culture and government policy continues to evolve as well. Although no census has captured the numbers of technically trained scientists and engineers with advanced degrees working in government and policy analysis past and present, the variety of fellowship opportunities and academic programs aimed

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[13] Rick Weiss, "Science Not Being Distorted, White House Aide Says," *Washington Post* (3 April 2004).

[14] Geoff Brumfiel, "US Science Policy: Mission Impossible?" *Nature* No. 428 (18 March 2004), 250.

[15] *Facing Toward Governments: Nongovernmental Organizations and Scientific and Technical Advice* (New York: Carnegie Commission on Science, Technology, and Government, January 1993), available at http://www.carnegie.org/sub/pubs/ccstfrep.htm (accessed August 2004).

[16] Ted Agres, "Informing Congress."

specifically at cultivating such individuals has increased dramatically in the last twenty years.[17] The American Association for the Advancement of Science (AAAS) S&T Fellowship programs (described below) alone now counts about 1700 alumnae, with larger classes of fellows entering the program each year. Approximately one-third of each year's AAAS fellowship class elects to remain within the policymaking and policy analysis communities. This pool of "fellow fellows," jokingly referred to by some roundtable participants as the "Policy Mafia," has created an informal but robust network for the exchange of information and expertise. In addition to the AAAS programs, a number of new fellowship programs for technically trained professionals sponsored by technical societies, academic institutions, and foundations have been established in the past decade. Participants agreed that the presence of these fellows, former fellows, and other scientists seeking what are often labeled "alternative careers" in policy have changed the baseline level of technical sophistication in the policymaking and policy analysis communities, and not just in the executive branch agencies with R&D missions.

> …Going back to the fifties, the first Presidential Science Advisory Committee, the scientists were in a wasteland. There was nobody in town who had any clue about that, so those individuals who did were extremely powerful because they were the only ones who knew anything. Certainly by the seventies, certainly today, my impression is you really can't make that case any more….It's a little bit institutionalized. There are a lot of people with technical degrees.[18]

Former science and technology fellows sponsored by AAAS and other programs who return to academia may also help enhance the image of science policy as a desirable science career. Despite increased training opportunities and obvious interest, roundtable participants cautioned that scientists willing to leave the laboratory bench for policy work still remain the exception rather than the norm, and many of the academic researchers overseeing graduate and post-graduate education still regard such "alternative career" choices somewhat dubiously. Many participants with technical backgrounds in biology had experienced tacit or explicit disapproval from leaders in their academic institutions at expressing an interest to work in any government capacity other than within a national laboratory. Although scientists can test the waters with a short fellowship without permanently "leaving the bench," or participate in policymaking through short-term commitments to technical studies such as those carried

[17] Even partial lists of such science and technology policy fellowships show an enormous range of opportunities for scientists, engineers, and physicians at various career stages. A list of fellowships administered by the National Academies can be found at http://www.nationalacademies.org/grantprograms.html and the AAAS S&T Fellowship descriptions can be viewed at http://fellowships.aaas.org/. Several academic institutions offer one-year fellowships, and the impact of the Homeland Security Fellowship program will be seen in upcoming years. The MacArthur Foundation's Science, Technology, and Security Initiative seeks specifically to create science and security analysts (http://www.macfdn.org/issues/issue_1/story_1.htm). (All websites accessed August 2004).

[18] Roundtable discussion, Session 1.

out by the National Academies or standing advisory boards, most who stay in the policy community for more than a year find themselves too far out of the academic life cycle – or perceived as such by more traditional academic researchers – to return to the laboratory. Most participants agreed from personal experience that they had few regrets about "leaving the fold," as many termed the process of electing a science policy career over a science research career, as they had discovered during graduate training or post-graduate research that their interests encompassed more than science. However, the lack of professional rewards for public service in even more limited capacities worried many participants. Although, for example, the National Academies regularly recruit very distinguished scientists for study committees, such service does take scientists away from the laboratory and writing, with little or no professional recognition. Although a relatively minor burden for tenured or otherwise senior researchers, the lack of career incentives may discourage researchers earlier in their careers from volunteering to serve as technical experts. As giants who have offered decades of public service to infectious diseases and biological security research and policy (participants specifically mentioned Drs. Joshua Lederberg, Philip Russell, and D.A. Henderson) approach retirement, roundtable participants worried about who might take their places.

Participants in all sessions agreed that the generally low level of science literacy in the US presents a serious problem in communicating science and technology issues to policymakers and the public. The discussions touched on the ongoing need to improve science education at the primary and secondary education levels. Several participants pointed out that the traditional science training "pyramid," designed to weed out an increasing number of students at each level of education, contributes little to cross-disciplinary scientific understanding. As one participant mentioned, leaders in the legal field seeking science advice frequently joke that they became lawyers specifically because they did not understand science – a problem shaped by didactic methods rather than intellectual ability. Due to the vast number of existing reports and editorials on the subject of scientific literacy and science education, the roundtable discussions referred to the issues repeatedly but did not explore them in depth.

WHAT DOES STH EXPERTISE LOOK LIKE?

In order to proceed with a discussion on the adequacy or deficiency of certain types of STH expertise in the biological security process, one must first define them. In the course of the discussions, participants identified several forms that scientific expertise can take; all fulfill the general task of providing an interface between the scientific community and decision-makers. These currently accepted forms for providing STH expertise in the national biological security policy process strongly influence when and how science policy information can be supplied, particularly for agencies or bodies that rely strongly or exclusively on particular mechanisms. Definitions below are based on descriptions offered during roundtable sessions unless noted otherwise.

Standing advisory bodies to Congress

With the demise of OTA, the other two standing bodies that provide in-house analytical expertise to Congress have taken on an increasing number of technology-based studies. The Government Accountability Office (GAO, formerly the General Accounting Office) and the Congressional Research Service (CRS) offer different resources to members of Congress and their staffs. GAO carries out investigations at the request of members of Congress, evaluating how well federal programs meet their objectives and use funds, or issuing legal opinions on programs. GAO's reports are generally reviewed by the federal programs involved to allow comment; they are published for Congress, but made available to the public. GAO reports on S&T issues generally address processes (such as budgets or compliance with statutes) rather than technical matters. CRS responds to a large number of short-term direct requests from Congressional staff, including technical questions, but its analysts can also produce longer studies by request or in anticipation of requests (based on staff judgments). In recent years, CRS has made a concerted effort to hire senior analysts with S&T expertise, especially in the area of homeland security, and has established a small (8-person) technology assessment staff. CRS studies undergo internal review only, and are published as in-house documents exclusively for the use of Congress.

Standing advisory bodies to security and regulatory agencies

In addition to presidential advisory bodies such as PCAST, which formed its own subcommittee on S&T to combat terrorism in 2002, several standing federal advisory committees provide S&T expertise on security issues to Executive branch agencies. The most well-established of these, the Defense Advisory Board, provides S&T advice on issues of military importance to the Secretary of Defense. Board members chosen for relevant S&T expertise serve on internal task forces (with outside consultants added when necessary) to address specific technical or science policy questions, and subsequently submit reports outlining their recommendations, some of which can be accessed by the public.[19] Although the Board largely considers military technologies, recent task forces have focused on force health protection against biological weapons as well the SARS epidemic. The Army, Navy, and Air Force maintain their own similarly structured science boards as well. In February 2003, the FBI launched its Science and Technology Advisory Board, modeled upon the Defense Science Board, to report to the Director on S&T applications and strategies for FBI priorities, including preventing terrorist attacks. Independent S&T

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[19] Previously published reports can be found at http://www.acq.osd.mil/dsb/reports.htm (accessed August 2004).

planning advice offered by the new Homeland Security Science and Technology Advisory Committee will be directed to the Under Secretary for Science and Technology of the Department of Homeland Security (DHS). The intelligence community maintains standing committees of experts to provide insight into emerging S&T, economic, and defense topics. Standing advisory boards provide two major advantages: the abilities to mix "new" experts with those more versed in the policy environment through staggered rotations, and to build trust with decision-makers.

Issue-specific or ad hoc advisory bodies to security and regulatory agencies

Many agencies make use of advisory bodies of technical experts convened regularly or on an ad-hoc basis to consider specific technical areas rather than general S&T issues. These may be statutorily required by Congress, such as the Secretary's Council on Public Health Preparedness at the Department of Health and Human Services (HHS), or convened by the agencies themselves to gather information on a specific topic quickly. For example, the FBI has created an advisory group on microbial forensics to provide technical advice on building a more robust national capacity for tracking biological weapons to their source through molecular signatures.[20] Such advisory groups can provide input ranging from assessment of technical arcana to evaluating long-term policy strategies, allowing agencies to compensate quickly for a lack of internal expertise in this field or reassuring Congress and the public about policy objectivity. These structures also provide an avenue for allowing S&T experts from academia or industry to participate directly in providing science policy advice to federal decision-makers.

Such limited-subject committees may also include groups of S&T experts convened by the intelligence, defense, and security communities to brainstorm or "red-team" technology scenarios. Some projects to bring together changing multi-disciplinary teams of technical experts in various research fields in order to approach security questions from a fresh perspective have endured for more than a decade. Public access to information about committee membership and meetings varies; the intelligence community approaches some S&T experts through consulting mechanisms that include public disclosure, while others disclose neither member participation nor the project descriptions in official publications.

Professional societies

Professional societies, representing those who share specific technical training or working areas, have become a growing source of information on biodefense and biosecurity issues in the past three years. Speakers from societies representing public health workers and laboratories, health care providers and

[20] Bruce Budowle et al., "Building microbial forensics as a response to bioterrorism," *Science* No. 301 (26 September 2003), 1852.

hospitals, and state and local health officials have testified frequently before Congress about readiness for potential biological attacks. Professional societies representing biological and biomedical researchers have provided technical information and science policy advice on biological security measures, as well as a larger forum for engaging the researchers most directly engaged in biodefense research. These organizations bring their members into contact with policymakers, allowing them to share their technical expertise as well as their views of the "real-world" environment affected by government decisions, with an understandable commitment to advocacy on behalf of their members in addition to S&T advice.

Non-profit, non-governmental policy organizations

In the last decade, many defense and security policy analysis organizations have cultivated increased technical expertise in biological security issues.[21] Some groups that once concentrated primarily on weapons proliferation issues have added biodefense and biosecurity to their portfolios; others, such as the UPMC Center for Biosecurity, were founded to address emerging biological threats and countermeasures specifically. All of these organizations produce reports and host meetings, symposia, or workshops, providing expertise to decision-makers through publications, briefings, and testimony, as well as through personal relationships with policymakers and their staffs (what the Carnegie Commission called "individuals as vectors" in its 1993 report on NGOs[22]). Participants in the first and third roundtable discussions acknowledged the impact of major funding organizations on the analyses conducted by policy organizations, with foundations' strategic areas of focus and funding decisions driving the direction of collective grant-making and subsequent studies.

The range of non-profit, non-governmental organizations offering independent technical and policy analysis includes federally funded research and development centers (FFRDCs). FFRDCs conduct studies by direct contract to regulatory or security agencies. The Department of Defense (DOD) employs several non-profit FFRDCs to conduct S&T studies, as does each service branch. Defense FFRDCs such as the Institute for Defense Analysis retain experts in a range of S&T disciplines, with areas of focus that include biological security. (DOD also contracts for scientific studies with for-profit FFRDCs operated

[21] An illustrative but non-comprehensive list includes the Council on Foreign Relations, the Center for Strategic and International Studies, the Carnegie Endowment for International Peace, the Stimson Center, the Center for Nonproliferation Studies at the Monterey Institute for International Studies, the Nuclear Threat Initiative (NTI), the Chemical and Biological Arms Control Institute, the Center for Arms Control and Non-Proliferation, and the Federation of American Scientists.

[22] *Facing Toward Governments*, 1993.

by corporations and consulting groups such as JASON.) In April 2004, DHS established its first FFRDC, the Homeland Security Institute, at ANSER.[23]

AAAS, which serves more than 10 million direct or affiliated members and produces the journal *Science* for an estimated readership of about one million, fills a policy role as the largest general science membership organization. AAAS influences S&T policy in the legislative and executive branches through position statements, policy programs and national meetings, briefings and conferences for policymakers, and its annual policy yearbook and R&D budget analysis. Its analyses tend to focus on issues of interest to the scientific community in general, and include substantial work on the impact of post-9/11 security measures on research and researchers. As foreshadowed by a 1993 Carnegie Commission report,[24] AAAS has reached out to the judicial branch with a program that helps federal judges locate qualified scientists to serve as court-appointed independent technical experts. Recently, AAAS launched the MacArthur Foundation-supported Center for Science, Technology and Security Policy, intended to serve as a clearinghouse to connect policymakers to sources of technical expertise on national security issues, particularly science and security experts from the MacArthur Initiative Centers.[25] AAAS also exerts an immediate impact on policymakers through its Science and Technology Policy Fellowship program.

Fellowship programs

Fellowship programs provide one established method of introducing technical expertise directly into Congressional or Executive agency offices, simultaneously providing fellows with hands-on public policy experiences and government offices with resident scientists. The AAAS Science and Technology Fellowship program began in 1973, at about the same time as OTA, with seven Congressional fellows. The program spans the academic year, rather than a Congressional session, in order to allow faculty to participate during sabbaticals. Fellows are chosen through a rigorous selection process intended to screen for a solid technical background and the analytical and communications skills critical to success in a policy environment. Over the last 30 years, AAAS expanded its program to act as an umbrella organization for fellows sponsored by other scientific and engineering societies, and to begin fellowship programs for the Department of State, the US Agency for International Development (USAID), the Department of Defense (DOD), the Environmental Protection Agency, the National Institutes of Health,

[23] A press release from the Department of Homeland Security (April 2004) can be found at http://www.dhs.gov/dhspublic/display?theme=27&content=3535 (accessed August 2004)

[24] *Facing Toward Governments, 1993.*

[25] Information on AAAS membership, programs, publications, and the Center for Science, Technology and Security Policy can be located through http://www.aaas.org (accessed August 2004).

the National Science Foundation, the US Department of Agriculture (USDA), the Food and Drug Administration, and other federal offices. The most recently added AAAS science and technology fellowships include two Homeland Security Fellows to be placed within the DHS Directorate for Science and Technology, and an NTI/Global Security Fellow who can work in Congress or the Executive branch but must focus on biological threats. The demand for fellows has increased in the past few years, from 95-100 fellows annually in the past to more than 115 in 2004; the number of Defense fellows alone climbed from 2-3 per year to more than ten.

Science and technology fellowship opportunities at the State Department have also expanded beyond the AAAS Diplomacy Fellows program. The American Institute of Physics (AIP) and the Institute of Electrical and Electronics Engineers now sponsor fellows under the Professional Science and Engineering Society Fellows Program. (The first AIP Fellow, George Atkinson, became the second Science and Technology Advisor to the Secretary of State.) The Carnegie Corporation and MacArthur Foundations, in partnership with the State Department, have started the pilot Jefferson Science Fellows program, selecting five tenured faculty members from academic institutions for a one-year fellowship followed by a five-year period in which the fellows will remain available to the department as consultants.[26] Unlike the AAAS fellowships, which are open to scientists at any post-graduate career stage and frequently offer a career-changing experience, the Jefferson program aims specifically to recruit mid-career scientists who plan to return to their academic institutions.

The degree to which offices successfully integrate individual fellows into the decision-making process depends to a large degree not only on hierarchical structure, but whether the office has enough in-house STH expertise or repeated experiences with S&T fellows to make the best use of their skill sets. The effect of such science fellowships on the policy environment goes beyond the immediate impact of each fellow's projects, although many have played key roles in fashioning pieces of significant legislation, or developing and implementing agency policies. If the trend of approximately one-third of AAAS fellows electing careers as science policy professionals continues to hold, the number of science-policy "bilingual" experts available to provide STH expertise to the government will obviously grow.

The National Academies

The four organizations that compose the National Academies, chartered during the presidency of Abraham Lincoln to advise the government on science and technology issues, continue to carry out that

[26] Technical information on Jefferson Science Fellowships can be found at http://www7.nationalacademies.org/fellowships/Jefferson_Science_Fellows.html (accessed August 2004).

mission today at a much greater scope. The National Research Council (NRC) serves as the working arm for the National Academy of Sciences and the National Academy of Engineering, and with the Institute of Medicine coordinates the logistics of bringing together about 1000 study committees composed of around 10,000 volunteer technical specialists each year.[27] In addition to carrying out studies, the National Academies also convene workshops, administer fellowship programs, and conduct educational outreach.

About 80% of National Academies study requests come from federal agencies, many by statutory requirement, and receive support through contracts and grants. The remainder includes self-funded studies as well as those conducted with the support of private foundations, industry, or state governments. Examples of such studies include the self-funded investigation into potential roles for S&T in countering terrorism initiated after the terrorist events of fall 2001,[28] and the privately funded "Fink Report" on dual-use biotechnologies.[29] The latter, supported by the Sloan Foundation and NTI and initiated before the anthrax assaults, became an eagerly awaited template for federal decision-makers considering oversight regimes for inherently dual-use biological research.

The NRC process begins with the review and approval of study requests. After the project has been defined and approved, the assigned NRC project staff sets about recruiting unpaid subject matter experts to sit on a study committee capable of addressing the issues. National Academies studies generally draw the nation's pre-eminent scientists and technology experts. After the committee meets and considers the project, sometimes soliciting additional insights from stakeholders, its members develop consensus on the content of the final report. An external NRC committee reviews this document to verify that the committee remained within its charge, and to ensure that the results appear free of bias and conflict. The National Academies remain the nation's premier source of independent S&T analyses, and the Academies' experience with classified information and national security issues dates to World War II. Currently, every major unit of the National Academies is conducting at least one project related to biological security or defense.

All roundtable discussants expressed great familiarity with National Academies studies, many as "consumers" using such studies in advising senior policy makers during decision-making processes, and some as both users and NRC study committee veterans. All agreed on the critical role that NRC studies play in government decision-making; some expressed frustration with the amount of time and resources

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[27] Information on the history and organization of the National Academies can be found at http://www.nationalacademies.org/about/faq.html (accessed August 2004).

[28] *Making the Nation Safer,* 2002.

[29] *Biotechnology Research in an Age of Terrorism,* 2003.

necessary to produce an NRC report, due to the format and the review process, and a few with purely academic experts on study committees who lack deep familiarity with the relevant policy environment. Finally, some cautioned that, while the National Academies policy requiring all reports to present consensus views ensures that decision-makers do not have to weigh warring S&T advice on a single issue, the need to eliminate dissension can lead to rather conservatively drawn conclusions. As remarked by one participant, "if you want a National Academy study you have the gold standard imprimatur of neutral science experts who can say it is truly non-partisan, politically neutral. But the problem is, there you do have to achieve consensus."

Science advisors and in-house expertise

The ranks of science advisors and in-house experts include both those with official titles designating them as such, and technically trained professionals within Congressional offices and regulatory or security agencies whose roles includes providing S&T policy advice as part of a more complex job description. The latter may be employed as the "lone scientist" in an office or program and fill the role of informal science advisor to decision-makers on a range of S&T issues, or may serve in an environment rich with other technically trained professionals. Examples of the "lone scientist" include the growing numbers of science-trained professionals working in Congressional offices as staff, or the scientist who heads a research or analytical program for an agency focused mostly on operational missions in security or law enforcement. Agencies rich with in-house S&T expertise include those with a strong research and development mission, such as HHS with its resources in the CDC and the National Institutes of Health, DHS with its Science and Technology Directorate, or even the Central Intelligence Agency (CIA) with its S&T development programs. Merely having in-house expertise does not guarantee that such resources will be brought into the policymaking process. As a participant with decades of experience as the "lone scientist," pointed out, many decision-makers in the law enforcement and the intelligence communities think immediately of turning to S&T experts to provide useful new gadgets and technical analysis, but reminding them that scientists can also inform the policy process at other levels requires constant outreach.

The most visible new example of a high-level, active science advisor comes from the Department of State. A 1999 NRC study on the increasingly important role of science and technology in foreign policy, funded by the Carnegie Corporation of New York and the Golden Family Foundation, emphasized the need for senior leadership within the State Department to keep STH issues appropriately on the decision-making agenda and to develop core STH competencies throughout the department.[30] Following one of the study's recommendations, and with statutory authority conferred by Congress, former Secretary of State Madeleine Albright appointed Dr. Norman Neureiter to serve as the first Science and Technology Advisor to the Secretary of State (STAS) in 2000. As noted above, he was succeeded at the conclusion of this three-year term by Dr. George Atkinson. The STAS under Secretary Colin Powell continues to lead a department-wide initiative – based substantially upon other recommendations in the NRC study – to reinvigorate science in the State Department. Despite a relatively small staff, the two advisors so far have embarked upon an outreach program to other agencies with S&T expertise, increased the number of science and technology fellows from all programs working at State (about 40 in 2003, distributed among 18 offices), increased the number of scientist detailees from other government agencies at both State and US embassies, and pursued a few bilateral initiatives designed to build S&T cooperation.[31] However, as with in-house expertise, merely having a science advisor is not enough to guarantee incorporation of STH expertise into the decision-making process. Support from the highest administrative levels in the department must exist to grant the science advisor adequate authority, access to departmental leadership, and resources.

[30] Committee on Science, Technology, and Health Aspects of the Foreign Policy Agenda of the United States, *The Pervasive Role of Science,Technology, and Health in Foreign Policy: Imperatives for the Department of State*, (Washington, DC: National Academies Press, 1999), 27-29.

[31] Norman P. Neureiter, "Science and technology in the Department of State," *Technology in Society* No. 26 (2004), 303.

Chapter 3

The Distinctive Challenges of Biosecurity

The challenges of integrating appropriate STH expertise into the national biological security policy process surpass the struggles to identify enduring channels for effective communication that permeate the whole intersection of science and policy. One of the first obstacles lies in the simple novelty of national security issues to many central stakeholders in the burgeoning fields of biodefense and biosecurity.[1] One roundtable participant pointed out that some researchers with expertise in the biology of *Bacillus anthracis* and other potential weapons agents encountered security issues for the first time in the wake of the 2001 anthrax assaults, when they found themselves in the novel position of being both experts and suspects to the same government agencies. With increased scrutiny on and funding for bioterrorism prevention in the US, the number of individuals newly immersed in related preparedness and research efforts has ballooned concomitantly. Biodefense and biosecurity mandates command an increasing amount of time, attention, and resources from professionals in fields where such issues until recently remained peripheral, including:

- health care providers, ranging from the caregivers themselves to the entire infrastructure of healthcare administration;
- public health professionals, encompassing epidemiologists, laboratory technicians, microbiologists, and many other specialists who work together in an interdependent network (including public and private clinical laboratories) at the local, state, and national levels to detect and control communicable diseases;
- biological and biomedical researchers, especially in the field of infectious diseases; and
- agricultural and food safety researchers and inspection/enforcement officers.

While broad priorities for biodefense research and response programs have been set at the Federal level, inherent reliance on a public health infrastructure composed largely of state and local assets (and Congressional mandates to allocate laboratory and hospital preparedness funding directly to states) have necessitated STH expertise at every level of government. This involvement has engaged organizations that represent health professionals at the state and local level, such as the Association of Public Health

[1] In the context of the roundtable discussions and this report, the term "biodefense" refers to all strategies designed to prevent the effective use of biological weapons, including technologies and public health, veterinary, and agricultural practices to protect human, animal, and plant health and safety. "Biosecurity," a broader and still evolving term, encompasses strategies to prevent the deliberate or natural introduction of pathogens into a community or ecosystem, and includes efforts to prevent malicious use of biological agents, skills, tools, and knowledge.

Laboratories, the Association of State and Territorial Health Officials, the National Association of City and County Health Officials, and the American Public Health Association. These have become not only vocal stakeholders in biodefense and biosecurity issues on behalf of their constituencies, but have served as conduits to convey STH expertise and policy guidance from the local and state levels to the federal level, and vice versa. Universities have received research funding from both DHS and NIAID through grants to individual researchers or consortia of laboratories, as well as larger awards to create regional homeland security and biodefense "centers of excellence," high-level biological containment laboratories, and physical or virtual centers to study specific questions or produce biodefense research resources.[2],[3] Organizations representing the academic community have thus become engaged in biosecurity and biodefense issues, as have professional societies, such as the American Society for Microbiology, that both represent researchers' interests and provide forums for the propagation of technical information through meetings and publications.

The roles of the various Federal agencies charged with aspects of biodefense and biosecurity have also evolved since 2001 as a result of both major legislation (including the Bioterrorism Prevention Act) and a series of executive directives and agreements. In fact, successive laws and agreements have moved the responsibilities for specific biodefense programs between agencies more than once within a span of years. For some executive branch agencies, the biodefense mission has changed little; DOD continues to focus mostly on military needs and force health protection. The State Department's overall biological weapons non-proliferation mission has remained fairly constant, complemented by increased attention on biosecurity issues within the Office of Counterterrorism. For agencies such as HHS (including budgets within CDC, HRSA, NIH, the Food and Drug Administration, and the office of the Secretary), increased funding has translated to a dramatic expansion of programs and offices created prior to the fall 2001 terrorist attacks as well as new responsibilities. CDC and HRSA now administer millions of dollars annually in state preparedness agreements, and NIAID's budget for biodefense research leapt from $53 million in FY 2001 to more than $1.4 billion in FY 2004.[4] USDA's biodefense responsibilities have expanded to include new research responsibilities, as well as several new food safety and biosecurity initiatives. The Environmental Protection Agency (EPA) has gained new responsibilities (with little budget accompaniment) for water security and decontamination of buildings, with its first foray into novel technologies for remediation of a structure following a biological attack demonstrated in the Senate

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[2] "NIAID Launches Biodefense Resources and Opportunities," Supplement to *NIAID Council News* (28 November 2003), http://www.niaid.nih.gov/ncn/newsletters/nl112803/nl112803_n08.htm (accessed August 2004).

[3] "Fact Sheet: Partnering with the Nation's Universities," Press Release, Department of Homeland Security, (27 April 2004), http://www.dhs.gov/dhspublic/display?content=3517 (accessed August 2004).

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

Hart Building and other portions of the Capitol complex in 2001. The largest change of all, of course, came in 2002 with the creation of the new agency, DHS, charged with leading national homeland security efforts. DHS oversees operational, research and development, and policy missions related to biodefense and biosecurity within its Emergency Preparedness and its Science and Technology Directorates. Four major offices within the latter (Programs, Plans, and Budgets; the Office of Research and Development [ORD]; the Homeland Security Advanced Research Projects Agency [HSARPA]; and Systems Engineering and Development) steer programs intended to assess biological threats, foster development of countermeasures, and encourage specific biodefense research strategies in the national laboratories, universities, and industry.

In this rapidly changing landscape, technical experts in bioscience, public health, and medicine and their counterparts in intelligence, security, and law enforcement have been forced to seek a shared vocabulary quickly, while struggling with new missions and the sudden realization of a biological threat. Roundtable participants related several anecdotes illustrating how a lack of basic mutual understanding can lead to poor communication and confusion. As an example, the term "surveillance" evokes very different images for specialists from different communities; the term may conjure disease detection and tracking systems for an epidemiologist, aerial photography for an intelligence analyst, and wire-tapping for a law enforcement expert, with each envisioning a different set of resources, tasks, and responses. Without progress on shared frames of reference, current enthusiasm for building stronger ties between these communities with vastly disparate missions may dissipate as a result of major or minor frictions.

THE SCHISM OF SECURITY AND THE LIFE SCIENCES

In the wake of World War II, the majority of scientists who became deeply engaged in science and security issues arrived from the field of physics, partly as a result of the sense of social responsibility instilled in the Manhattan Project generation, and partly because of the pressing technological issues of the Cold War and space race. As Vannevar Bush, Director of the Office of Scientific Research and Development that coordinated wartime scientific research for Presidents Roosevelt and Truman among many other roles in science policy, stated in a post-war article on the future of science:

> This has not been a scientist's war; it has been a war in which all have had a part. The scientists, burying their old professional competition in the demand of a common cause, have shared greatly and learned much. It has been exhilarating to work in effective partnership. Now, for many, this appears to be approaching an end. What are the scientists to do next?

> For the biologists, and particularly for the medical scientists, there can be little indecision, for their war work has hardly required them to leave the old paths. Many indeed have been able to carry on their war research in their familiar peacetime laboratories. Their objectives remain much the same.[5]

The legacies of heavily politicized nuclear threat issues and years of massive government-funded research projects fostered interaction between various groups of physicists, security policy analysts, and policymakers at every level. In contrast, many of the now-key players in biological security and defense have received a relatively recent introduction to the security concepts. Until quite recently, the community of biologists with any experience in studying biological weapons or defense against biological attacks, or who claimed strong ties to government policies in any way other than grant-making, remained fairly small. As summarized by a participant, there is a "profound difference in the level of experience and engagement of the life sciences community in security issues relevant to others, at least since the Biological Weapons Convention and the US got out of the offensive [biological weapons] business."

This historical schism between security issues, including those involving biological weapons, and the life sciences pervaded the policy analysis community as well, as described by participants familiar with various organizations. Although the National Academies continued to conduct studies on security topics that encompassed biological weapons issues (such as Cooperative Threat Reduction efforts) following the classified studies of the World War II era, most relied heavily on experts in security and defense rather than biology well into the 1980's and early 1990's. A major NRC report on the flow of science and technology information and national security, which heavily influenced the Reagan-era decision to refrain from classifying basic scientific research to the maximum extent possible, focused on the technology paradigm of energy research rather than the information-driven model of the life sciences.[6] Within OTA, the security program conducted studies of defense technology and arms control issues, encompassing nuclear threats, while biological and health issues fell into the separate division of life sciences. Not until the early 1990s did the security program turn to studying technologies underlying biological weapons;[7] the security staff relied largely on the advisory panels (rather than in-house life

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[5] Vannevar Bush, "As We May Think," *The Atlantic Monthly* (July 1945). Available at http://www.cs.sfu.ca/CC/365/mark/material/notes/Chap1/VBushArticle/ (accessed August 2004).

[6] Panel on Scientific Communication and National Security, *Scientific Communication and National Security*, (Washington, DC: National Academies Press, 1982). This report is frequently called "the Corson Report" after the study chair. In 1985, President Reagan adopted the central recommendations of the Corson Report in National Security Decision Directive-189, which specified that a) "to the maximum extent possible, the products of fundamental research remain unrestricted," and b) "the mechanism for control of information generated during federally-funded fundamental research in science, technology and engineering at colleges, universities and laboratories is classification ."

[7] US Congress, Office of Technology Assessment. *Technologies Underlying Weapons of Mass Destruction,* (Washington, DC: US Government Printing Office, 1993).

sciences specialists) to provide technical expertise in biology. Although many NGOs provided analysis on biological weapons non-proliferation regimes, the vast majority of these did not rely on technically trained bioscientists, and only a handful considered biodefense issues prior to the escalation in public awareness of the late 1990's. Analyses frequently paired biological and chemical weapons as an inseparable duo despite profound technical differences between the two classes of threats, and many enfolded the "Chem-Bio" chimera further into a combined "chemical-biological-radiological-nuclear" or "weapons of mass destruction (WMD)" whole.[8] This one-label approach may have contributed to an inaccurate impression among policymakers that a security paradigm developed for nuclear threats, the clearest-cut of the WMD non-proliferation strategies, would serve equally well for all WMD threats.

Finally, in addition to a lack of traditional ties to the national security policy process, many in the biological research community experienced an abrupt and somewhat discomforting introduction to security concepts during the development and implementation of policies formulated in response to the attacks of fall 2001. Like many scientists and engineers in the US, bioscientists have encountered the direct and indirect effects of new visa requirements for foreign scientists and graduate students on their institutions, their laboratories, and their professional societies. The presidents of the three branches of the National Academies summarized some of these concerns in a December 2002 open statement:

> The evidence we have collected from the US scientific community reveals that ongoing research collaborations have been hampered; that outstanding young scientists, engineers, and health researchers have been prevented from or delayed in entering this country; that important international conferences have been canceled or negatively impacted; and that such conferences will be moved out of the United States in the future if the situation is not corrected.[9]

Although recent indications suggest that new State Department actions have eased the visa backlogs that accumulated in late 2001 and 2002 as a result of new policies, many researchers fear that changed perceptions of US receptiveness to foreign students and visiting scientists may affect graduate education and research for years to come.[10]

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[8] The "Chem-Bio" label endures for convenience as well as program recognition reasons, even as experts in the fields of non-proliferation and security have begun to address the issues separately. Federal agencies, including the division still known as the Federal Emergency Management Agency within DHS, still produce informational materials combining advice on "Chem-Bio" preparedness and response.

[9] Bruce Alberts, Harold Fineburg, and William Wulf, "Statement on the Impact of Current US Visa Restrictions on Science and Engineering," December 13, 2002. Can be found at http://www4.nationalacademies.org/news.nsf/0a254cd9b53e0bc585256777004e74d3/e061a6d4c13ed9ec85256ca70072dce5?OpenDocument (accessed August 2004).

[10] Michael Arnone, "Security at Home Creates Insecurity Abroad," *The Chronicle of Higher Education* (12 March 2003).

In addition to sharing worries about visa issues with the rest of the US science community, the researchers most intimately connected with biodefense research have encountered specific security mandates in the form of the recently implemented select agent rules, as described briefly in the Introduction to this report. With the rapid development and implementation of regulations based on the Bioterrorism Prevention Act and Patriot Act, researchers who study pathogens now classed as select agents and their institutions experienced first uncertainty about the scope of the new rules, and then frustration with bureaucratic backlogs in processing registrations for laboratories and security risk assessments for individuals.[11],[12] The rules have imposed what some scientists have deemed an onerous paperwork burden, complicated by potential criminal penalties that can result from compliance failures. The well-publicized prosecutions of graduate student Tomas Foral under the Patriot Act for retaining two vials of anthrax-infected tissue in a university freezer, Dr. Thomas Butler (acquitted of lying to the FBI and smuggling plague samples but convicted of improperly shipping samples and 46 additional counts of fraud unrelated to the original charges), and art professor Steven Kurtz and genetics professor Robert Ferrell for mail and wire fraud after the FBI confirmed that the non-pathogenic agents procured by the latter for the former's performance art project did not fall under any bioterrorism laws, sent what many researchers have found to be a clear message about the Justice Department's zeal in prosecuting violations whether or not terrorist intent is suspected.[13],[14] Some institutions have destroyed pathogen collections, and some scientists discontinued select agent research projects, rather than risk an unintended breach of the new rules.[15]

Many select agent researchers also harbor concerns about self- or government-imposed controls on open publication in peer-reviewed journals of techniques that might prove useful in designing biological weapons, an extremely difficult set of criteria to define when almost all biological research falls into the inherently dual-use category. Although scientists involved in various disciplines of energy, computer sciences, and cryptography research have contended with information and technology control regimes for many years, most biological and biomedical researchers and the journals in which they publish their findings began truly wrestling with the issues only after 2001. Many journals have taken steps to screen submitted manuscripts for potentially worrisome data or techniques, but questions of how

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[11] Peg Brickley, "New Antiterrorism Tenets Trouble Scientists," *The Scientist* No. 16(21), (28 October 2002), p. 49.

[12] Ted Agres, "Researchers Bemoan Bioterror Bureacracy," *The Scientist* (24 September 2003).

[13] Jonathan B. Tucker, "Research on Biodefense Can Get Generous Funds, but With Strings Attached," *The Chronicle of Higher Education* No. 50(26), 5 March 2004.

[14] Jennifer Couzin, "US Prosecutes Professors for Shipping Microbes," *Science* No. 305 (9 July 2004), p. 159.

[15] Joanne Chan, "Issue Brief: Select Agent Rules (updated)."

to identify and censor such information without unduly inhibiting scientific progress or undermining the scientific process associated with peer review, and whether scientists and editors considering such data should work through classification and clearance processes, await resolution.[16] Despite reassurances that the 1982 National Security Decision Directive 189 (keeping basic research findings as open as possible and resorting to classification only if necessary) still stands, many bioscientists fear both heavy-handed use of classification and possible imposition of the poorly defined "sensitive but unclassified" label. [17] Few biological researchers have had experience with secrecy requirements apart from proprietary protections in the pharmaceutical and biotechnology industries, and many regard the security clearance and classification processes that are second-nature to the intelligence community with deep suspicion.[18]

New NIAID biodefense research grants continue to draw researchers to the field, countering warnings that the logistics of compliance would have a chilling effect on all biodefense research. As participants pointed out, this influx has created a wave of new experts with varying degrees of experience in handling different pathogens, as well as biosafety and security concerns borne of propagating new select agent research programs. Obviously, many bioscientists have decided to endure the requirements imposed by the new US biosecurity regime in order to carry out their work, but the degree to which US researchers have accepted the biological threat paradigm adopted by the intelligence and security communities still remains unclear. Whether or not philosophical differences on secrecy, the actual threat posed by domestic select agent research, and the effectiveness of current biosecurity regimes will affect the willingness of technical experts from the academic community to engage with the policy analysis and policymaking communities on biodefense and biosecurity strategies also remains to be seen.

STH ADVICE IN BIOLOGICAL SECURITY: THE CURRENT DEMAND

The demand for STH expertise in the biological security policy process has changed since the surge of interest in the late 1990's, and many times more since fall 2001. During the Clinton presidency, the National Security Council acquired its first special advisor on health and security matters with a medical background; now, most federal advisory councils and working groups on homeland security

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[16] Ronald M. Atlas, "Public Health: National Security and the Biological Research Community," *Science* No. 298, (25 October 2002), p. 753.

[17] Ryan Ricks, "Issue Brief: Sensitive but Unclassified Information (updated)."

[18] In one extreme example, a controversial initial announcement that the CIA intended to issue a classified report on an unclassified session on scientific openness, convened by the NRC to bring prominent microbiologists together with the CIA's strategic assessments group, drew subsequent public criticism and reprisals from some participants, ending with figuratively ruffled feathers on both sides and doing little to promote mutual trust between the two communities. See Peg Brickley, "CIA openness report to be classified?" *The Scientist* (7 April 2003).

issues boast at least one member, and frequently more, with life sciences training. Biological weapons are now recognized as threats technically distinct from chemical weapons, even if old labels remain. Nonetheless, as several participants highlighted, the understanding that biological weapons issues have attained a more prominent place in the security landscape does not translate into automatic inclusion of STH expertise in the early stages of decision-making processes. Nor, as all three discussions emphasized, do researchers trained in the biological sciences – or even pathogen research – necessarily have a full picture of the technologies and biological weapons capabilities upon which they may offer advice.

In attempting to capture the essence of the current demand for STH expertise in the national biological security policy process, participants in all three roundtable discussions identified basic characteristics of *experts* necessary to providing sound science and science policy advice. These experts can be classified in three general tiers, with myriad organizational models for connecting the advice that they provide to the decision-making process.

Technical Experts

Technical experts have scientific or professional training in a biological or biomedical discipline closely related to issues at hand, including reasonably recent experience in the laboratory, field, or clinic that grants acquaintance with cutting-edge research and real-world conditions. These subject matter experts can serve on advisory committees (such as the standing advisory boards, ad-hoc or issue-specific committees, or National Academies panels), or be recruited to address specific questions by government agencies or programs, but most likely serve as advisors briefly before returning to the research environment.

Technical Policy Advisors with Specific Expertise

These scientists have technical training as well as practical experience in a specific biological or biomedical field, but have chosen to forego a typical research career (temporarily or permanently) to work within a government agency or program. This group consists of mostly mid-career scientists who rely upon their research expertise and experience in providing guidance for operational and analytical missions, as well as intra- or inter-agency planning. For example, a technical science policy advisor might direct a program to meet national security objectives through funding particular lines of research and development, or to oversee the deployment of particular countermeasures. Participants agreed that these technical policy advisors (as well as the science policy professionals described below) sometimes have greater policy leverage as scientifically credible liaisons to interagency working groups than they do as available sources of expertise within home agencies, where they may be somewhat isolated by a stove-piped organizational structure.

Science Policy Professionals

The relatively small core of actively engaged science policy professionals have technical training and credentials which confer credibility among both researchers and government decision-makers, but focus on broader science and science policy issues. They may rarely (or never) rely upon their original areas of narrow technical expertise, but rather make use of their dual familiarity with researchers and research culture and the policy environment and its demands to connect decision-makers with the most appropriate types of STH expertise when needed, in an accessible and useable form. These professionals often serve as science policy advisors within legislative or executive branch organizations, or as policy analysts in government or non-government organizations.

Science policy professionals require a diverse set of skills and accomplishments that allow them to communicate productively and credibly as liaisons between the scientific community and decision-makers. As one participant explained, "There is a relatively small cadre of individuals that can fit the nexus between all of those domains, operational policy, analytical and scientific." Although S&T fellowship programs provide one avenue for grooming technically trained researchers for policy careers, participants emphasized that the career development of individuals with the right personality and skills cannot be taken for granted. "You need people like that, and there are a few folks around, but it's by accident that they develop that way as opposed to purposefully," explained one participant. Participants generally agreed that short-term training courses designed to give scientists a brief introduction to policy and security issues probably served well in helping researchers understand the implications of their work, but did not replace immersion in the policy-making/analysis communities as a training regimen for new science policy professionals. No participant agreed with the idea that graduate training programs in the biological and biomedical sciences should deliberately train students for careers unrelated to science or science policy (citing costs as well as the degree of commitment required to succeed in research), but most expressed support for mentoring programs to help scientists with an interest in public service understand the necessary skills and available options. The discussions proved less conclusive on the roles of graduates with degrees in hybrid fields, such as masters' degrees in science and security; some participants felt that these individuals lacked sufficient knowledge of and credibility with researchers to serve as effective policy liaisons, while others felt that the requisite communication skills, accompanied by some technical background, would meet the requirements of most policymakers.

Participants agreed that, for all three categories, scientists must establish and maintain credibility to have a positive impact. For a technical expert to serve as a "trusted skeptic," he or she must have not only impeccable research credentials, but enough distance from the government organizations soliciting advice to maintain an outsider's clear viewpoint and uninhibited ability to voice potentially unwelcome opinions. A participant with substantial security and research experience emphasized that identifying technical experts in biodefense often proves more difficult than simply seeking a distinguished publication record or academic reputation. A scientist may be a world expert on the natural history of a specific pathogen but have little or no knowledge of existing data on that pathogen's behavior in weaponized form (such as a deliberately released aerosol), information that may be limited to a small subset of mostly government biodefense researchers. "Expert exhaustion" can pose a problem, especially during a crisis or a period of intense policy debate, when the number of technical experts with reliable credentials and adequate free time can prove unequal to the demand. As one participant remarked, pointing out the number of individual technical experts who had served on multiple advisory panels, "If it is a fairly finite community, that group is going to be very heavily tapped, and given that most of them are stretched, because they are technical experts running laboratories…we're going to be limited to people who are semi-retired or older, very senior."

Although both technical experts and technical policy advisors should obviously have specific expertise in the programs that they guide, participants acknowledged that this is not always the case, and that the decision-makers who rely upon them may not distinguish between scientific disciplines at all. Due to the high ratio of physicists to biologists with policy experience, and the enfolding of biological weapons issues with nuclear issues, the "technical experts" in various biodefense and biosecurity policy programs have sometimes been physicists with informally acquired knowledge of biological weapons technologies. The degree to which this proves a problem depends largely on the circumstances. As one participant pointed out, the researchers who get into these positions are "smart and capable," and can function perfectly well as cross-disciplinary technical advisors by calling in specific expertise to complement their own knowledge. Another cautioned that those with a veneer of expertise in biological sciences laid atop a science background in another field could miss critical biosecurity details. "In particular, it makes a difference when you create programs in a climate of great suspicion, when it's very easy to make technical claims and charges and you don't have anybody on the inside saying, 'No, that isn't how it actually works. It isn't how it operates.'"

Above all, participants emphasized in all three roundtable sessions, science advisors of all sorts have to remember both their strengths and their limitations when speaking to issues outside of their technical training. Very few, if any, policy decisions depend on scientific evidence alone, and scientists new to serving as technical experts or policy advisors frequently become frustrated with the failure of policymakers to act upon what appears to be obvious evidence. Conversely, scientists who provide technical advice on issues with which they have little familiarity, or who offer value-driven opinions with the full weight of their credentials behind them, risk jeopardizing not only their own credibility but that of their colleagues. As one participant remarked, "Science professionals maintain their credibility if they stay in their lanes….You get physicists trying to do biology. But they go beyond that. You now get physicists telling people how to do intelligence. Their contributions to science are empirical, but you get over that and it becomes damaging."

Forms of science policy recommendations: describing reports

In addition to identifying the types of STH experts currently providing various forms of policy advice, participants discussed at length the various forms of reports or publications in which science and science policy advice can be presented. In doing so, they defined five broad categories for such reports, with each category divided into two opposing types, as described in the table below. Defining these categories allowed for a more fruitful discussion of criteria for forms of STH expertise found particularly useful. Any given policy report can fall into a pattern definable within all five areas. As an example, according to these criteria, the NAS report called *Making the Nation Safer* released in response to the 2001 terrorist attacks, described in Chapter 2, could be described as a self-driven, reactive, largely evidence-based open report on broad science policy issues.[19]

[19] *Making the Nation Safer*, 2002..

Table 1: Forms of STH Expertise

Specific technical analysis	**Broad science policy**
Draws on technical information and STH expertise to address a particular technical subject in detail that may range from a fairly broad review to a narrow assessment.	Draws on technical information and STH expertise to outline the implications of certain actions or policies, and may provide recommendations or options to guide decision-makers.
Open	**Closed**
Published for a general audience, with dissemination allowed or encouraged beyond the organization that requested the analysis.	Produced for use within a specific organization or program, with no intention of distribution outside of those circles. (Classified reports would represent one specialized subset of closed reports.)
Anticipatory	**Reactive**
Initiated by policy analysts and/or technical experts who foresee that an issue might become important in the future, and wish to consider that issue in depth before a crisis arises.	Initiated in response to a specific event or incident, or in response to an agency request driven by external influences or program needs.
Self-driven	**Solicited**
Conducted as a self-tasking by a policy analyst or analysis organization, in the absence of any specific external request or event, to study an issue based on interest, available expertise, or other opportunities. (Funding organizations, as well as internal interest, may shape such studies.)	Conducted in response to a specific request by a policymaker, program, or agency.
Evidence-based	**Estimate-based**
Relies upon the preponderance of existing data and STH expertise to determine the most probable correct answers to science or science policy questions, in order to aid in selecting between possible courses of action.	Relies upon available evidence and past experiences of STH experts to extrapolate the most probable answers when existing data is incomplete or nonexistent, in order to provide "best guesses."

INCORPORATING STH EXPERTISE INTO THE DECISION-MAKING PROCESS

In all three roundtable sessions, participants dedicated considerable time to discussing the integration of STH expertise in government decision-making, and factors that had – in their experiences – improved the odds that science policy advice would be weighed in the biological security policy process. First, participants cautioned that such integration of STH expertise, in most agencies and organizations, often depends on informal personal networks rather than a systemized approach. The likelihood that STH expertise enters the process through a more formal mechanism may reflect the value that high-level administrators place on science policy advice, the history of advisory mechanisms within the organization, or a combination of both. As summarized by a participant,

> How do agencies or those interested identify, tap into the expertise that exists? Obviously, there are lots of different models. When I came from [a Federal agency], it really until recently didn't have a fixed model they would go to, rather it was an informal network that was set up usually by somebody's Rolodex; actually part of my Rolodex got it started. But then you have standing bodies like the [Defense] Science Board that have a fixed population with identified government advisors that come in and work on problems….Ultimately, if you look at an agency that's very operational and like the one I came from, part of this dimension of seeking out, tasking and then identifying and accessing [STH expertise] has to do with trust building. 'I'm going to give you something I can understand, use, and has value to me.'[20]

Based on these and similar observations, participants discussed various agencies' and programs' successes and failures in setting up formal channels for ensuring access to STH expertise at various stages in the decision-making process. As several participants pointed out, the Manhattan project, subsequent nuclear arms development, and the space race endowed DOD with a legacy of relying on scientific expertise that has endured for more than 60 years. In that time, the department has established well-defined channels for soliciting S&T advice through its standing advisory boards and FFRDCs, and its leaders have shown an appreciation for the contribution of STH expertise in guiding research and development strategies, acquisitions plans, and red-teaming. Although more attention has been paid to energy and conventional weapons than biosecurity and biodefense issues, policymakers within DOD remain receptive to seeking S&T advice when necessary, a trait that stems largely from an appreciation of the very tangible advantage that S&T advances give to forces. Participants pointed out that this receptiveness often allows S&T advice to influence budget decisions, and therefore to influence policy decisions indirectly or directly. In addition, DOD – working through a program commissioned by the

[20] The name of the Federal agency in question has been omitted to preserve confidentiality of participants, as agreed upon in the conditions of the roundtable sessions.

Defense Advanced Research Projects Agency (DARPA) and administered by the Institute for Defense Analyses, an FFRDC – has sought to cultivate the interest of emerging academic researchers in science and technology through its Defense Science Study Group. These researchers spend 22 days over two academic years learning about issues and policies related to national security.[21] As described by a participant, this investment in teaching researchers about S&T applications and security policies in real-world settings can foster a new generation of potential S&T policy advisors, or simply increase researchers' interests in DOD-funded science and engineering projects; the ongoing involvement of program alumnae in various capacities indicates some degree of success. Another participant cautioned that this program, although successful for DOD, may have less allure for other agencies. The success of the Defense Science Study Group depends to a great extent on the "glamour" of, and the lure of grants to study, new technologies. Despite these caveats, some participants felt that specific aspects of this program, particularly its emphasis on introducing scientists to the operational contexts for S&T developments and policy recommendations and its sensitivities to the academic life cycle, provide a template for engaging research professionals in biosecurity or biodefense programs within other agencies.

With tremendous in-house biological and biomedical expertise in the CDC, NIH, and its other programs, HHS can depend largely on internal science advisors with the assistance of its issue-specific advisory committees. Other agencies involved in the national biological security policy process have much shorter records in incorporating STH expertise. The State Department has no external S&T advisory panels, although its resources include the Senior S&T Advisor and a cadre of S&T fellows to supplement its finite in-house expertise. The senior scientific leadership at DHS, given the opportunity to start "from scratch," appears to have found at least initial success in creating a strong Science and Technology Directorate with a system for cultivating coordination between S&T portfolio managers and decision-makers in the other directorates. The S&T Directorate now boasts a strong in-house expertise (including an increasing number of biologists to supplement the initial core of physicists), and an S&T fellowship program and an external S&T advisory committee that arose nearly simultaneously with the department itself. Despite this promising start, most participants agreed that the agency itself remains too new to draw many lessons-learned, or conclusions about whether S&T policy advice channels have surpassed individual personalities to remain systemized in the long-term.

In-house S&T expertise does exist in intelligence and federal law enforcement agencies, but the organizational components of the programs with a technical or research and development focus tend to be segregated from the offices that make decisions on broader policy issues. As described by one

[21] Information on the program can be found at http://dssg.ida.org/ (accessed August 2004).

participant, the various programs tend to be "neighboring tribes, at best." In addition, the intelligence and law enforcement communities have less experience incorporating STH expertise as a driver of policy decisions than in turning to S&T programs as a source of "unique tools of the trade…the gizmos that nobody else has that help us collect intelligence."

The FBI has just launched new efforts to include STH expertise in the biological security policy process; the agency's small size and fairly flexible organizational structure can lend themselves to relatively quick change, given sufficient support from high-level leadership. The opportunity does exist for more management cohesiveness in science issues within the Department of Justice (DOJ) as a whole. DOJ has a senior science advisor to the Director, although at the time of the roundtable sessions, participants cautioned that this position remains mostly symbolic in the absence of sufficient resources or authority. Several participants cautioned that the many reform initiatives being considered by and for the intelligence community will create an upheaval that may create new opportunities for incorporating STH expertise into decision-making processes in the long run, but will probably not be hospitable to new institutions in the near term. Various parts of the intelligence community have successfully gleaned STH expertise from issue-specific committees, consultants, and "red-teaming" groups, and the Central Intelligence Agency has increased its efforts to engage bioscientists through National Academies-facilitated workshops and studies with some success.

An issue that affects the ability to communicate STH expertise to policymakers in general, but one that particularly affects the intelligence community, is that reports to policymakers may be derived from many months of in-depth analysis under the aegis of various entities. As one participant pointed out, what started out as a six-month long, highly technical study may be boiled down into one paragraph for the report that actually goes to decision-makers.

> I think we do a lot of taking the 50-page papers and turning them into a paragraph. A paragraph would be generous. A memo to the Secretary of State is one page maximum, that is it. One page. So we're taking a lot of disparate data and distilling it for the policymaker's recommendations. I don't know if it's underrepresented or that they'd say oh, this must have been done in 20 minutes because it's only one page. They are not aware that there is this back story, if you will.

The first step to incorporating STH expertise successfully and consistently, participants agreed, lies in getting scientists "out of the ghetto and into the main office." Even agencies that house significant in-house STH expertise are unlikely to integrate those experts into decision-making beyond their specific technical realms if they remain lodged within organizational structures that promote the "neighboring tribes" mentality. Participants suggested that lessons can be learned from some successes at DOD and

State, as well as less-than-sterling attempts to encourage incorporation of STH expertise, about changing an agency's or program's culture so that policymakers become accustomed to considering STH advice throughout all stages of decision-making relies. Keys to success include:

- Placing a small core of science policy professionals, with appropriate cross-disciplinary skills to contribute to non-technical as well as S&T issues, at multiple levels throughout the organization, rather than just within programs or offices that concentrate on technical or research issues;
- Ensuring that at least some of these science policy professionals are integrated into the staff that fulfills policy and planning functions in a systemized way;
- Creating credible scientific leadership within the agency, such as a senior S&T advisor, with adequate resources and authority supported directly and visibly by the head of the program or organization; and
- Educating senior decision-makers to promote recognition of the relevance and value of STH expertise incorporated early in the decision-making process through both internal and external outreach.

Once adequate scientific leadership has been established, the agencies can find themselves in far better position to make use of both STH expertise (in the form of technical reports and science policy recommendations) and experts (such as fellows, outside technical advisors, and technical policy advisors). Another step that increases the likelihood that STH advice will be incorporated into the decision-making process, participants with experience in security and federal law enforcement emphasized, is the inclusion of operational suggestions or at least concrete policy recommendations in the reports produced by policy analysis organizations. Whether or not reports on S&T issues find use within various agencies and programs frequently relies upon the actions of science policy professionals who can act as "translators" to link technical findings into potential actions for policy-makers. If such science policy professionals have not yet been firmly established within an agency, even excellent recommendations may go ignored by decision-makers in the target audience.

As an example of a successful model for incorporating policy recommendations made by STH experts into the national biological security policy process, these participants emphasized the value of the founding of the National Science Advisory Board for Biosecurity (NSABB) as a case study. As described previously in this report, the National Academies initiated a study on Biotechnology Research in an Age of Terrorism (also known as the "Fink Report" after its chair, Dr. Gerald Fink), a self-driven, anticipatory, largely evidence-based open report on broad science policy issues, prior to the anthrax assaults of fall 2001 with the support of the Sloan Foundation and NTI. The study committee consisted of experts in a range of biological and biomedical disciplines, as well as international law and defense security issues, who set about assessing the "capacity of advanced biological research activities to cause disruption or harm, potentially on a catastrophic scale," through either the theft or diversion of pathogens or the creation of novel threat agents.[22] During the course of this study, the biosecurity regulatory regime in the US changed profoundly, and the committee considered the impact and adequacy of the new regulations among its other charges. In its report, published in fall 2003, the Committee outlined a new system for overseeing inherently dual-use biotechnology research (which might result in knowledge or tools that could be applied equally to legitimate research and development or the production of biological weapons). Recommendations included systems for educating scientists, categorizing and reviewing "Experiments of Concern" and unexpected results at several levels, sustaining communication between the life sciences and security communities, improving biosafety, promoting international harmonization of biosecurity regulations, and creating the NSABB. In March 2004, the Secretary of HHS announced the charter of the NSABB, a board designed to advise all federal agencies that support life sciences research on overseeing such dual-use biological research, "taking into consideration both national security concerns and the needs of the research community."[23]

The charter states that the NSABB will be composed of outside experts in a variety of relevant biological, biomedical, health, legal, and security fields, plus ex officio members from the represented Federal agencies, and HHS has already set about hiring S&T experts to head the committee staff. Although decision-makers did not adopt every recommendation of the Fink report, they did charge the NSABB specifically with addressing most of its recommendations. Thus, a comprehensive anticipatory report's operational recommendations on science policy have been translated into a structure intended to ensure that appropriate STH expertise goes into development of particular regulatory and oversight structures, providing an amalgam of community expertise and top-down authority. Although participants emphasized that this model had not achieved perfection (given the initial two-year lifespan of the Board, some confusion about the authorities of the various agencies involved, what seems like an overwhelming workload for a Board scheduled to meet four time per year, and the obvious omission of classified and industry research from the Board's scope), they did suggest that it provided a relatively satisfactory solution to a biosecurity dilemma that could have resulted in stringent, top-down, and possibly counter-productive regulation of biological and biomedical research. The keys to this success, they believed, lay

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[22] *Biotechnology Research in an Age of Terrorism,* 2003.

[23] Charter, National Science Advisory Board for Biosecurity (4 March 2004), available at http://www.biosecurityboard.gov/SIGNED%20NSABB%20Charter.pdf (accessed August 2004).

in the strengths of the science policy report and recommendations, which offered a mix of comprehensive, comprehensible background information and a set of policy recommendations that outlined specific courses of action.

Chapter 4
Surmounting the Barriers

The need to incorporate STH expertise into realms once reserved for "hard" security issues has become an accepted fact for most policymakers since the anthrax assaults of 2001. Slowly, with the weight of numerous reports, briefings, workshops, symposia, hearings, and media articles, many decision-makers with little or no familiarity with the life sciences before fall 2001 have come to understand that biological organisms reproduce, can be found in nature (with the exception of smallpox), and that the basic tools of health-enhancing research cannot be distinguished on a purely technical basis from the building blocks of biological weapons production. For the most part, initial reflexive urges to impose a nuclear threat-control paradigm upon biological agents have dissipated with increased sophistication among the relevant stakeholders. Nonetheless, the fields of biological and biomedical research continue to advance rapidly, and policy mechanisms designed to counter known biological threats identified three years ago may already be obsolete. A constant influx of fresh perspectives, born of active communication between technical experts, science policy professionals, and experts in security and law enforcement issues will be required to prevent the first reactions to a domestic biological attack from becoming entrenched and unyielding dogma.

Although some decision-makers, STH technical policy advisors, and science policy professionals have developed personal networks to exchange STH information, whether many of these fairly new S&T advisory mechanisms for biodefense and biosecurity issues will prove robust enough to survive the comings and goings of individual personalities remains unclear in a still-evolving policy environment. In order to secure a new supply of qualified S&T experts capable of sustaining these networks, and the goodwill of the bioscience and public health communities – critical to providing both technical expertise and fostering mutually beneficial education and outreach efforts – obstacles to strong communication between security and life sciences professionals must be identified and removed. In some cases, conceptual barriers may result from cultural conflicts between the bioscience, public health, and security paradigms. Practical barriers include customs or deficiencies that hinder the development or participation of qualified S&T professionals, bureaucratic obstacles to intra- or interagency communication, inadequate support for S&T advice process from high-level authorities, and insufficient resources to carry out potentially helpful research projects. In considering both the conceptual and practical barriers to achieving consistent incorporation of life science expertise at every stage of this process, roundtable participants attempted to look beyond transient political attitudes to address systemic issues.

CLASSIFICATION AND SECRECY ISSUES

A barrier with both practical and conceptual aspects facing the S&T policy community lies in access to classified materials, stemming from a relatively small population of bioscientists accustomed to secrecy issues and cultural differences between the bioscience and intelligence and law enforcement communities on the desirability of open information. The National Academies have a record in dealing with classified security analyses when necessary that extends back to World War II, and OTA decided that – as its main consumers had access to classified materials – those should be included as source materials. On the other hand, most NGOs, and some governmental advisory organizations such as CRS, rarely work with classified materials; for organizations that attempt to inform policy decisions by reaching a broad audience, or that disseminate their recommendations through electronic means, relying upon such materials makes little sense. Although some real frictions have manifested over classification or suggested classification of science policy recommendations generated from open meetings or based solely upon open sources,[1] participants agreed that, in many cases, researchers' concerns reflect "not as much of a tension as a perceived tension." Participants familiar with classified studies agreed that many researchers new to classified study environments regard the process as somewhat shrouded in mystery, and may be reluctant to participate in studies that require clearances because of misapprehensions about what they might be allowed to address. As one participant described the response of a scientist who had somewhat dubiously applied for the clearance necessary to participate in a classified biosecurity discussion, "I can remember him saying with absolute amazement, 'You know, those were good discussions. They were open. We were exchanging ideas. People weren't inhibited. They weren't prevented.'….[It's important for a scientist] to hear that, in the right circumstances, a classified environment is an enabling environment because it simply lets you put all issues on the table."

In addition to simple unfamiliarity with classification issues, many researchers – especially those conducting biodefense studies with pathogens categorized as select agents – fear that classification of and imposition of the vague "sensitive but unclassified" label on basic research publications in well-intentioned efforts to prevent biological weapons proliferation could actually hinder the development of critical defenses against disease. Profound philosophical differences toward information control can be

[1] As described in Chapter 3, the CIA's initial intention to release only a classified report on an unclassified workshop on scientific openness spurred acrimonious public debate. Another controversial, if less bitterly debated, decision involved the classification of portions of an NRC study committee's report on agricultural threats, which derived information that could have provided insights into US vulnerabilities solely from open-source materials.

characterized by a fierce loyalty toward open publication, a mainstay of validating peer-reviewed research, on the part of the scientific community, and what one participant described as a tendency in the intelligence community to stamp "classified" over any information collected, even if it can be found in open sources. Participants with extensive experience in law enforcement and intelligence agreed that classification powers are often wielded overzealously for a combination of cultural and psychological reasons: first, if we have the information, it should naturally be secret, and second, classified information may get more attention from high-level decision-makers.

Participants agreed that this cultural divide on classification issues can be surmounted to build trust between the two communities through concentrated outreach on both parts. A relatively easily accomplished task involves increasing accurate perceptions of the nature of classification and secrecy in science and science policy analyses within the community of potential biodefense experts. Some progress toward fulfilling this need should evolve from the actions of the NSABB, whose members will all receive secret clearances themselves, as a natural part of its educational mission. Because the concepts of not divulging details for national security purposes strongly resemble those adopted to protect proprietary pharmaceutical information, the parallel mechanisms should be obvious to most biological and biomedical researchers when the case for protecting such information appears justified.

The converse action recommended by participants, a concerted effort by STH experts to help the intelligence community understand and accommodate concerns about classification of research issues, may prove more challenging. One participant with extensive security experience admitted being puzzled by the lack of "pushback" from the bioscience policy community on reflexive, and not always informed, wielding of the classification stamp. One avenue for achieving such pushback, in addition to continued education on biosecurity and biodefense issues by governmental and non-governmental organizations and more stringent Congressional and internal oversight, might be found in the S&T advisory councils to the FBI, DHS, the HHS Office of Public Health Preparedness, and other agencies where they exist, as part of their technical missions. Accomplishing this task would require outreach within the S&T community as well as to the intelligence and law enforcement agencies to establish a clear message on when classification of biodefense and biosecurity information might prove counter-productive, and to provide willing expertise where possible to help make informed decisions on restricting information.

As one aspect of the latter, some participants described a need to create formal channels for continuing feedback between scientists and policy or intelligence analysts after workshops or studies have been concluded, rather than relying on groups of academic experts who "operate in a vacuum, present ideas, and then go away." This would require identification of resources and an operating base for the science policy professionals who would be needed to serve as liaisons between the two communities for the duration of the relationship. If accomplished, such efforts could create a trusted group of experts “on retainer” to various decision-makers for a pre-determined period of time.

DEEPENING THE POOL OF EXPERTS

Participants discussed at length the barriers that, in practice, can limit the pool of technically trained science professionals both interested and willing to participate in the national biological security policy process to either quite senior scientists or those who have given up professional recognition within their disciplines for the less tangible rewards of a science policy career. These obstacles include a lack of encouragement or mentoring for those interested in science policy options, especially for professionals considering a policy career but not yet ready to “leave the fold,” and the nature of tenure demands for those scientists who would like to contribute time to public service (as experts on National Academies panels, etc.) without leaving their laboratories for a prolonged period.

Many participants encouraged further investigation into the demand for career development programs for scientists with an interest in public service and science policy who might not be ready for or interested in a year-long fellowship commitment. The AAAS and other S&T fellowship programs offer one means for learning more about science policy within the confines of an academic year, but most participants felt that – with a few exceptions, including applicants to the pilot Jefferson S&T Fellowship program – scientists willing to sacrifice that much time to interests other than research had probably already pondered a career transition. Few fully supported the idea of presenting such an introduction to policy issues in very short “policy boot camps” for purposes other than helping researchers understand the security implications of their work, fearing that an education in biodefense and biosecurity concepts designed to conclude within a week or two might result in a cadre of scientists with a little knowledge, and credentials that might appear impressive to decision-makers, but no real world experience. Again, some participants emphasized that lessons could be learned from the Defense Science Study Group and its successes in recruiting rising academic stars, and how the program has maintained strong relations with not only the individuals who participate but their institutions.

Another question, even less amenable to easy answers, lies in seeking methods to make short-term commitments to public service a “career builder” for academic researchers, rather than a potential obstacle to earning tenure. The MacArthur Foundation-funded academic Science and Security Centers do promote changes in the tenure environment for their faculty, especially at land-grant schools with a strong tradition of service, but finding ways to extend academic rewards for science policy service beyond jointly appointed faculty in those centers may be difficult.

A potential method for introducing researchers interested in public service (for example, as technical experts), but not necessarily eager to leave the laboratory entirely, to policy concepts could come in the form of a curriculum to develop non-technical communications skills. As explained by a participant with both science training and security experience,

> One of the reasons that scientists have difficulty interfacing with policy community is because the way they're accustomed to presenting the information. It's a very difficult process to get people to move from the scientific abstract to the executive summary….You don't deal with the materials, the methods, the results, the conclusions. That's not there. You have to include the players, the context, the reason and the recommendations and the conclusions may be irrelevant.

Such a curriculum could be conducted in short classes over a long period without interfering unduly in research obligations, be open to scientists at every career level, and encompass an introduction to the history of science policy as well as technical skills in composition and presentation. Although not calculated to appeal to every researcher, a communications education program could benefit the policy analysis community by preparing researchers interested in serving as technical experts to do so more productively, and the individual researchers by augmenting an often-neglected part of science training.

Finally, although science policy careers are not and should not be the norm for graduates of biological and biomedical research programs, neither should a young researcher's decision to pursue such a career penalize his or her training institution and provide a concrete reason for a department's educational leadership to discourage such choices. Participants suggested that attention should be paid to ongoing discussions at the NIH, the main funding source for bioscience training, regarding the categories of post-training career choices deemed as indicators of successful service for former recipients of federal pre-doctoral or post-doctoral training grants. Including policy analysis or policy advisory positions along with research appointments as worthy outcomes of federally funded scientific training could cultivate a more positive environment for young scientists interested in policy issues, or at least ensure that academic institutions do not "lose points" for their graduates who go on to serve the nation's science needs as policy professionals rather than laboratory researchers. In addition, some participants noted with irony that many professional societies that provide S&T policy advisory and advocacy functions to policymakers on behalf of their members fail to include options common to S&T policy careers when conducting salary or employment surveys, making evaluating the growth of this population difficult other than as some percentage of the nebulously classified "other." Organizations that benefit from science policy professionals or promote their development should encourage membership organizations, professional societies, and funding organizations such as NIH to edit their regular surveys as necessary to allow an accurate census of the population of S&T policy professionals in the context of planned studies to examine career choices within the larger community of S&T research professionals.

RELIANCE ON INTERAGENCY EXPERTISE

One aspect of providing STH expertise articulated by some participants reflected a bias that might not be intuitive to policy analysts in the NGO community: a tendency for government decision-makers to seek technical information, when necessary, from other government sources.

> ….Within the [executive branch agency] I've found that 95%, 99% of the time is involved in talking to other people in the government, in the US government or other governments. It is very, very rare when I'm interacting with people outside of government. I'm actually familiar with the UPMC Center somewhat, and there is a handful of people in my head that I can say okay, I have an issue or question, that I can call on. But more often, if I or a colleague is wrestling with a scientific or technical question, I'm probably going to call someone in another government agency.[2]

Several participants illustrated examples of successful intra- and interagency exchange of STH expertise, sometimes as a result of formal mechanisms for consulting on particular issues, and sometimes as a result of the "Rolodex Effect," in which science policy professionals or technical science advisors deliberately cultivate relationships with decision-makers in order to provide an obvious source of STH expertise when necessary. Although some agencies collaborate well on issues of overlapping jurisdiction (participants, for example, discussed how responsible offices at HHS and the State Department consider the technical aspects of international biosecurity issues to coordinate public health and security concerns), participants also acknowledged that interagency relationships cannot always surmount the "neighboring tribes" mentality that can segregate programs with technical missions from their more broadly charged counterparts within a single agency. As a participant representing a science-based program explained,

> It's not as interagency as we would like it to be. For example, when I contact State I like to contact State INR [Bureau of Intelligence and Research]. When I contact the Agency, I would like to contact not just the S&T people, but the CI people, the Intel people. The same thing with the NSC. I can talk to all the health experts, that's fine. But what are the national security implications?

[2] The name of the Federal agency in question has been omitted to preserve confidentiality of participants, as agreed upon in the conditions of the roundtable sessions.

When building strategies to ensure the availability of appropriate STH expertise throughout the national biological security policy process, it is necessary to recognize that the majority of government decision-makers – with the possible exception of members of Congress and their staffs – are most likely to turn first to other government experts for necessary information. Participants emphasized that this results not only from convenience, but from trust in the motives of the organization providing the expertise. Obviously, this requires not only that government organizations hire an adequate number of science policy professionals and technical policy advisors, but that these communicate with each other when necessary. Building a strong core of internal STH expertise depends, in part, upon the availability of professionals with the appropriate skills and knowledge, and the commitment of the organization's leadership to fostering integration of S&T professionals into the decision-making process. Lessons in determining the most effective methods of encouraging interagency sharing of appropriate STH expertise may be drawn from the examples of interagency working groups, temporary assignments of employees from one agency to another, and "virtual committees" of experts representing different programs and agencies that have been favored by the intelligence community. OSTP remains in the best position to assess and guide appropriate interagency exchange of STH expertise if connections between individuals or offices do not arise naturally.

A growing body of STH expertise on biodefense and biosecurity issues now resides in the NGO community; for it to be accessed, such organizations must build trust with government decision-makers. Such relationships may be easier to build with members of Congress and their staffs, who have diverse agendas and levels of interest in technical advice, than with the more politically uniform executive branch agencies. Some NGOs have achieved such trust by building a large portfolio of work, while others do so by couching their goals unambiguously. For example, the National Academies enjoy a long-standing reputation for politically neutral, unbiased, scientifically credible STH policy advice; FFRDCs function as quasi-governmental organizations, establishing trust because they produce advice and analyses specifically at the request of government agencies. Such a process of building credibility could be the work of years or decades, especially when decision-makers may have neither the time nor the technical knowledge to evaluate the objectivity of specific STH advice. Adopting a reliable system for quality assurance in technical reports, as recommended by the Carnegie Commission on Science, Technology, and Government more than a decade ago,[3] might provide one mechanism to allow NGOs to validate STH findings or recommendations, as can the more academically oriented peer-reviewed publication process.

[3] Carnegie Commission on Science, Technology, and Government, *Facing Towards Governments* (1993).

BUILDING A BETTER STUDY

As described in the previous chapter, many types of reports can convey STH expertise, and all meet different needs. However, some participants felt strongly that adopting specific approaches while developing such reports could help ensure that decision-makers make the best use of specific S&T recommendations. Participants with extensive experience in security fields, rather than science-based agencies, emphasized the need for reports that include operational recommendations when possible, to help those organizations that lack a substantial science policy professional core to translate less-specific observations into recommendations. The second roundtable session in particular also focused on the need to complement core expertise in biodefense and biosecurity studies – those who study pathogens, infectious diseases, and potential countermeasures – with a broader community of relevant experts who can help decision-makers consider policy recommendations in a richer context. Participants suggested that lessons could be learned from examining successful cross-disciplinary working groups and advisory committees to build a "template" for a typical biodefense study group that includes experts in sociology, anthropology, political science, and other social sciences in addition to biology and security.

Some participants felt that the demise of OTA had left significant gaps in two specific areas: reports designed to provide insights on (sometimes politically controversial) technical issues for a public constituency, and anticipatory reports allowed the luxury of taking the long view. Although National Academies reports are made available to the public, many participants felt that the generally low levels of scientific literacy mean that these reports may be accessible to the public only through the prism of media interpretation, which may or may not capture nuances accurately. Part of the responsibility, participants agreed, rested with science experts' frequently inadequate efforts to communicate scientific uncertainty and risk issues to policymakers or the public, especially if the analysis will eventually be reduced to a short news clip or a single line in a short memo. Potential solutions posed included suggestions that risk communication strategies be emphasized more strongly in scientific training, especially if made part of a curriculum aimed at developing scientists' non-technical communication skills. A participant also emphasized that guidelines exist within the intelligence community to attempt to quantify certainty for policymakers using a set of pre-determined criteria; although these may not apply directly to STH policy advice, such a rubric could provide some basis for helping technical experts find ways of expressing degrees of certainty or agreement within programs that rely upon consensus.

Among its many studies, OTA's relative institutional flexibility provided the opportunity for self-driven, anticipatory investigations – as long as they captured the interest of members of Congress and their staffs – inspired by working groups of experts invited to brainstorm about possible looming policy issues. With the demise of OTA, CRS acquired more technical experts who can also prepare anticipatory reports that staff predict might be useful for the closed audience of Congressional staffs. The previously cited Fink Report on dual-use biotechnologies provides one example of an anticipatory study conducted by the National Academies with the support of non-government funding; only about 20% of the projects conducted through the National Academies receive funding from a non-federal source. Participants agreed on the need for studies that can anticipate, rather than merely respond to, serious biodefense and biosecurity policy issues before political pressures or events demand immediate actions. Participants in the second session cited the decision to create multiple Biosafety Level 4 (high-level biocontainment) laboratories at several academic centers within the US as an example of a biodefense issue that, with hindsight, would have benefited from an anticipatory study to estimate typical and emergency capacity needs, long-term costs to the government and the host institutions, and community concerns. Although several participants cautioned that high-level policymakers would be extraordinarily unlikely to peruse purely speculative reports, a need remains for studies that anticipate issues on the horizon. In order to achieve this, policy analysis organizations, including the National Academies, require the necessary financial resources to develop anticipatory, self-driven, open broad policy analyses that focus on issues identified by technical experts as of imminent but not current concern.

Some participants suggested that further research might find suggestions to address how to focus whatever resources might be available for anticipatory studies, which – with the exception of national securities studies on emerging technologies – would not be expected to draw wide support from government agencies. Anticipatory reports produced in the past by OTA, the National Academies, and other organizations met a mix of fates, with some destined directly for the bookshelf, some stirring the opinions of policymakers and the public, and some becoming "technical bibles" relied upon by science policy professionals for years. As an example, many participants cited the two-volume reference on *Technologies Underlying Weapons of Mass Destruction* published by OTA in 1993, which remains a useful source more than a decade later. Although timing certainly plays a role in whether anticipatory reports fill a suddenly apparent need (as illustrated vividly by the Fink Report), some participants believed that most cases would prove more complex:

> I suspect …that if you could find truly successful studies you would find that they all share something. That the failures are diverse, that the recommendations were fuzzy or difficult, that they were so broad, that the expert committee took their charge into such a broad light it was impossible to boil it down. The timing was bad. Whatever was recommended was technically feasible but not politically feasible.

Although not all participants agreed, an enthusiastic minority advocated an analysis of successful and unsuccessful anticipatory studies, interviewing contributors and consumers to determine whether certain characteristics could be used to predict the usefulness of proposed anticipatory studies.

CEMENTING SCIENTIFIC LEADERSHIP

Participants agreed strongly that developing and supporting scientific leadership within government agencies and programs, ideally in the form of a senior science advisor, constitutes a critical step in securing both adequate in-house expertise and institutional receptivity to STH advice. Without authority, permanence, and sufficient resources, the science advisor can end up being “a cheerleader for science,” whose most effective possible role is “trying to connect disparate agencies and perspectives as opposed to being an advisor and influencing how science is driven.”

In addition to building upon lessons learned from the early successes in establishing a senior science advisor at the State Department and from failures where they have occurred, participants also suggested further study of how agencies with security missions have functioned when policymakers with science or technical expertise served at the highest levels. The tenures of former CIA Director John Deutsch and former Secretary of Defense William Perry provide case studies to examine whether institutional receptiveness to S&T advice, or formal mechanisms for incorporating STH expertise into decision-making, increased when technically trained professionals helmed the programs.

RECOGNIZING THE LIMITS AND REACHING OUT

All three roundtable sessions reached the independent conclusion that no single form of STH expertise meets every need, and that no one expert has access to all of the necessary information, or all of the right contacts. Even in the course of the roundtable discussions on providing STH expertise to policymakers, the science policy professionals involved expressed differences of opinions on various technical issues, based on their own experiences and sources of information. Explaining the processes through which scientists resolve difference of opinion remains very difficult in the context of providing science advice to policymakers, especially if the contacts between decision-makers seeking expertise and STH experts result from informal networking rather than any formal mechanism. One participant outlined both the strength and the weaknesses of the ways in which STH policy experts representing NGOs establish personal networks for providing STH expertise to Congressional policymakers:

> I walked in the door and said, "Here is what we have. If you need information about public health, you call me. If you ever have a question, you call me," and established a relationship with the offices where I would tell them what we could find out, whether it suited our agenda or not….It was a good thing for the offices that called, but the problem with that is that it's not uniform. There will be offices that call me because we've got an established relationship and trust. Not all 535 and not all the committees. It's still very selective and those relationships that occur between members of Congress and the NGO's are all very spotty and happenstance and, you know, there may be this one little group that you really trust and you call them all the time, but is that really the most objective advice that you could get and do you know that? So, it's important that those resources are there, but I don't think it's the perfect system. And collectively maybe it is; collectively, each office is getting informed a little differently by a slightly different expert view and then when they come onto the floor and hash it out, you end up with a good product at the end. At least they all have access to expertise, even if the experts aren't necessarily giving them all the same information.

Many participants discussed, with varying degrees of optimism, the likelihood that OTA could be revived in a form based more or less upon the original organizational structure, to resume its place in conducting anticipatory as well as requested studies and providing members of Congress with more uniform access to STH expertise. Whether the new AAAS Center for Science, Technology and Security Policy can fulfill its ambitious goals of linking experts from the MacArthur Initiative Centers with scientists and policy analysts from the NGO community to provide policymakers with a clearinghouse for relevant STH expertise remains to be seen, but its success could conceivably provide a structure for improving both access to and evenness of STH policy advice on biosecurity issues.[4]

Whether or not a proposed OTA successor develops, policymakers considering biological security questions will continue to rely on a mix of in-house expertise, advice from trusted advisory committees, and reports from NGOs, with trust and accessibility determining the acceptability of S&T policy advice. The likelihood that STH expertise can be successfully incorporated into the decision-making process at every level of the national biosecurity policy process depends not only on institutional structures, but on continued outreach among the bioscience research community, science policy professionals, and the security, law enforcement, and intelligence communities to develop a shared vocabulary, increase mutual understanding, and identify the problems that STH expertise can and cannot solve. As one participant remarked, "I think we're following the comforting pattern of going to science and technology experts for science and technology fixes, to problems that are socio-political, much larger than the sciences themselves."

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[4] Information on the Center, launched in early 2004 with the support of the MacArthur Foundation, can be found at http://www.aaas.org/programs/science_policy/cstsp/about.shtml (accessed August 2004).

Chapter 5

Conclusions

In recent decades, policymakers around the world have struggled to keep pace with the changing roles of science and technology in societies, and with increased dependence on S&T policy advice in both domestic and international arenas. In areas such as biotechnology, the incredibly rapid pace of discoveries and technical advances – with just fifty years separating the description of the structure of DNA and the completed sequence of the human genome – continually present the public and its political representatives with new possibilities and new quandaries. Promising preliminary studies in embryonic stem cell therapies, for example, hint at possible cures for a range of diseases that cannot be treated successfully with current technologies, based on a first step (the destruction of an embryo) judged morally unacceptable by a percentage of the U.S. population. The receptiveness of individual policymakers to STH expertise in considering such complex issues relies on a mix of political and personal factors, but most certainly depends on their access to and interest in credible, relevant science policy advice.

The suddenly evident threats of both emerging infectious diseases (as demonstrated by the incremental spread of West Nile Virus across the U.S., the 2002 SARS epidemic, and the anomalous appearance of monkeypox in the Midwestern U.S. in 2003) and deliberate release of biological agents such as anthrax demand STH expertise to approach issues less ethically fraught, but no less technically complicated. In the United Kingdom and Canada, recent outbreaks of bovine spongiform encephalitis (BSE, or "mad cow disease"), foot and mouth disease in cattle, and the newly recognized SARS virus proved both politically and economically damaging, and prompted government officials to re-examine the use of life sciences research in policymaking.[1] In the wake of the 2001 anthrax assaults, U.S. policymakers scrambling for quick solutions to diminish national vulnerability to biological terrorism – or

[1] The British government responded to the BSE crisis with a set of guidelines for government departments in using science in policy-making, as well as a code of practice for scientific advisory committees released in 2001. The U.K. Parliamentary Office of Science and Technology (POST) built upon a series of analyses undertaken by various government agencies and academic researchers to formulate a series of recommendations for improving the use of science and policy in 2003, using lessons learned from the BSE and foot and mouth disease incidents and climate change issues. However, these analyses collectively did little to illuminate how policymakers actually use science advice in daily decision-making; establishing a metric for measuring the success of particular science advice strategies remains difficult. A summary and bibliography of these reports can be found in the POST publication "Science in Policy," Postnote No. 196 (June 2003), available at http://www.parliament.uk/post (accessed August 2004). In 2000, the Canadian government published a "Framework for Science and Technology Advice" for government decision-makers that suggested a code of conduct for science advisors and a framework for considering risk management and uncertainty, a set of guidelines for helping decision-makers seek and review information on issues likely to require science advice, and appointing a "science advice champion" in all science-based agencies and programs, responsible to the Deputy Prime Minister, to help coordinate and implement science advice programs. (Report available at http://strategis.gc.ca, accessed August 2004).

at least to reassure the public – discovered not only that a slow and comprehensive approach to develop prevention and response capabilities would be required, but that the majority of technical experts in bioscience, health, and security issues shared few common assumptions. During the first weeks following the anthrax assaults, technical information and hypotheses changed daily, and S&T policy advisors with any relevant subject matter expertise (as well as many whose expertise might be termed tangential at best) found themselves stretched to the limit.

Although OSTP can help coordinate the exchange of STH expertise among U.S. agencies and programs, most analysis on the use of science advice in decision-making has depended upon NGOs, including the reports issued by the Carnegie Commission on Science, Technology, and Government in the late 1980's and early 1990's, and by the National Academies through both self-driven and agency-requested reports. In some ways, such as the proliferation of NGOs offering STH expertise with few oversight or validations mechanisms and the need to better realize the potential of S&T advice at every level of decision-making, the policy environment has changed little since that time. In others, such as the demise of OTA as an advisory body to Congress, the establishment of a new senior science advisor to the Secretary of State based on an NRC study, and the creation of a new executive branch agency charged with overseeing all S&T issues related to homeland security, the S&T policy landscape has been radically transformed.

In order to characterize the roles of and demand for STH expertise in the national biological security policy process, this study convened three groups of science policy experts and decision-makers whose collective experience represented the policy analysis, public health, biological and biomedical research, law enforcement, intelligence, foreign policy, and security communities. Their discussions of the types and uses of STH expertise form the basis for this report and its conclusions. The general science policy climate can affect the receptiveness of policymakers to STH advice, just as it can affect the willingness of technical experts to participate in government education efforts. As one roundtable participant remarked, "At the moment, the government is sending very mixed signals to the life sciences community in terms of how much or how attractive it is to get engaged in these issues."

Participants did not suggest that novel forms of STH expertise would be required to inform the biological security policy process, but emphasized the importance of learning from successful and unsuccessful S&T policy initiatives to strengthen existing institutions for providing science advice. Myriad avenues for presenting STH expertise to policymakers have been explored by governmental and non-governmental organizations, and adopted successfully under various circumstances. Chapters 2 and 3 list classes of science advisory instruments capable of contributing to sound policy decisions if welcomed as an essential component of the decision-making process, a goal most likely to be achieved within organizations if supported by strong leadership and qualified science policy professionals integrated deeply into policy and planning infrastructures. Selecting science policy institutions likely to endure within particular organizations remains an uncertain venture, even if high-level leadership can be persuaded of their inherent value. As Dr. Norman Neureiter, the first Science and Technology Advisor to the Secretary of State, cautioned about the department's strong but young commitment to accommodating science policy advice,

> For all of the Fellows, the individual S&T initiatives, and the strong support from the top of the department, I still believe that S&T has only shallow roots in the Department of State as an institution, and there is much more that can be done. It behooves the outside S&T community, which has so strongly supported the NAS/NRC study and our efforts to turn its recommendations into reality, to continue its vigorous support and to remain involved. Eternal vigilance should remain the watchword in following future development in the fascinating interplay of S&T and foreign policy.[2]

The same can be said for efforts to incorporate STH expertise across all government agencies and programs, even those with research missions and significant in-house science resources. In order to secure access to and interest in STH expertise for decision-makers throughout the biological security policy process, the S&T community itself must remain involved regardless of fluctuations in the political climate or conflicts with its law enforcement, security, and intelligence counterparts.

For each agency or organization, a combination of types of STH expertise and experts will be required to provide policy input at every stage of decision-making, rather than merely as a part of brain-storming at the beginning, or to validate policies at the end of the development process. Participants suggested that successful S&T advisory systems depend upon a three-tiered system of science professionals, based upon the technical experts who maintain their research careers but provide insights into real-world conditions and cutting-edge technologies; followed by technical policy advisors with subject matter expertise who function as managers of and advisors to technical programs with operational or analytical missions; and finally a small core of science policy professionals who constitute the interface between technical experts and decision-makers, connecting those who make policy to appropriate and accessible STH information. Many successful examples of STH policy advisory institutions exist, ranging from long-lived standing advisory boards capable of providing external perspectives and technical knowledge – as well as unpalatable advice that might be difficult for an insider to offer without suffering repercussions – to ad hoc committees enriched for issue-specific expertise, to S&T fellows and

[2] Norman P. Neureiter, "Science and Technology in the Department of State," *Technology in Society* No. 26 (2004), p. 303.

other in-house experts, to NGOs specializing in STH policy advice that range from the gold standard of the National Academies to small advocacy organizations. An opportunity exists for the lessons learned from these to be incorporated in the relatively new S&T advisory structures being developed by DHS, with its influence over all domestic security S&T issues, and the FBI.

In the wake of the fall 2001 terrorist attacks, many scientific researchers, like other Americans, felt a strong need to do something to remedy the terrible destruction, and prevent future loss of life. For professionals in the bioscience research community, the subsequent anthrax assaults brought a communal loss of innocence as well, and the community continues to struggle with the legacies of the biological attacks. New intelligence and counter-intelligence concepts, concerns about top-down and self-imposed information control strategies, the clearance-like (but more poorly defined) security risk assessments required to prevent "restricted persons" from acquiring access to dangerous pathogens, new physical security mandates for laboratories studying select agents, and visa complications and other obstacles to international collaborations have followed thick and fast, one upon the other.

Further support, in the form of resources and attention from all stakeholders, will be required to maintain strong communication among the diverse communities of experts in biological and biomedical sciences, public health, security, law enforcement, and intelligence to maintain enthusiasm for building a shared vocabulary and sharpening each others' assumptions given inevitable frictions. Conflicts over classification and secrecy issues have endured in other fields for decades; bioscientists newly considering their own roles in preventing unintended propagation of potential weapons technologies without unreasonably hindering research freedom must look to the experiences of energy researchers, and develop a more coherent approach to "pushing back" against counter-productive classification programs when necessary. Research will be needed to establish new avenues for encouraging the career development of scientists interested in public service and policy careers or, at the least, eliminating disincentives where possible. Efforts must be made to strengthen the cadre of governmental S&T policy experts, and to make the best use of STH expertise in NGOs. Finally, resources will be needed to fill unmet demands for anticipatory studies that consider the biosecurity and biodefense policy issues on the near horizon before moments of crisis arise.